2025

Annual Report

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to

Commission File No. 001-38359

Adicet Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-3305277**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

131 Dartmouth Street, 3rd Floor
Boston, MA 02116
(650) 503-9095
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 $0.0001 per share	ACET	The Nasdaq Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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

As of June 30, 2025, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was approximately $50.5 million based on a closing price of $0.61 per share as quoted by The Nasdaq Global Market on June 30, 2025. In determining the market value of non-affiliate common stock, shares of the registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 10, 2026, there were 9,596,407 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2026 annual meeting of shareholders, scheduled to be held on June 17, 2026, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2025. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Summary of the Material and Other Risks Associated with Our Business

- We have a limited operating history and face significant challenges and expenses as we build our capabilities.
- Our business is highly dependent on the success of prula-cel (formerly ADI-001). If we are unable to obtain regulatory approval for prula-cel in one or more indications and effectively commercialize this product candidate for the treatment of patients in indications for which we receive approval (if any), our business would be significantly harmed.
- Our gamma delta T cell candidates represent a novel approach to the treatment of autoimmune diseases and cancer indications that creates significant challenges for us.
- Our product candidates are based on novel technologies, which makes it difficult to predict the likely success of such product candidates and the time and cost of product candidate development and obtaining regulatory approval.
- Our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.
- We may not be able to file Investigational New Drug (IND) applications, or comparable regulatory submissions, to commence additional clinical trials on the timelines we expect, and even if we are able to, the U.S. Food and Drug Administration (FDA) or analogous regulatory authorities may not permit us to proceed.
- We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.
- The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- We may not realize the anticipated benefits of our workforce reduction and strategic pipeline prioritization.
- Although we have commenced manufacturing operations at our manufacturing facility, we currently depend on the ability of our third-party suppliers and manufacturers with whom we contract to perform adequately, particularly with respect to the timely production and delivery of our product candidates, including prula-cel. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.
- The pharmaceutical industry in China is highly regulated and such regulations, including the Foreign Investment Law and the "negative list," are subject to change which may affect development, approval and commercialization of our product candidates.
- The uncertainties in the People's Republic of China's legal system regarding the Foreign Investment Law may subject our contractual arrangements to different interpretations or enforcement challenges, subject us to severe penalties or force us to relinquish our interests in our operations.
- Business disruptions, including armed conflicts, could substantially delay our clinical trials or seriously harm our future revenue and financial condition and increase our costs and expenses.
- A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business, including the potential impact of global conflicts on our supply or clinical trials.
- We have in the past failed and may in the future fail to achieve and maintain effective internal control over financial reporting, which could harm our business and negatively impact the value of our common stock.
- If our collaboration with Regeneron Pharmaceuticals, Inc. (Regeneron) is terminated, or if Regeneron materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed.
- Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- The trading price of our common stock is highly volatile, which could result in substantial losses for purchasers of our common stock. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the timing of and our ability to execute our clinical trials for prula-cel in autoimmune indications, including the ability to successfully complete our Phase 1 clinical trial in lupus nephritis (LN) and initiate Phase 1 clinical trials in lupus erythematosus (SLE), systemic sclerosis (SSc), antineutrophil cytoplasmic autoantibody associated vasculitis (AAV), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS) and rheumatoid arthritis (RA);
- the timing, costs and effects of our workforce reduction and strategic pipeline prioritization;
- our expectations regarding the preclinical development of ADI-212, and our ability to develop other product candidates in our research pipeline;
- our expectations regarding prula-cel, including site activation and enrollment for and the availability, timing and announcement of data from our Phase 1 clinical trials for prula-cel and timing and plans for a potential Phase 2 pivotal trial;
- our expectations regarding discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of a potential path to support Biologics License Applications (BLA) and Marketing Authorization Applications (MAA) for our product candidates;
- the anticipated timing of our submission of Investigational New Drug (IND) applications or equivalent regulatory filings and initiation of future clinical trials, including the timing of the anticipated results;
- our expectations regarding the impact of unstable market and economic conditions, including impacts of inflation, tariffs and adverse developments affecting the financial services industry, on our business, results of operations or financial conditions;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of acceptance and clinical utility of any products for which we receive regulatory approval;
- our expectations regarding the manufacturing of our product candidates and any products for which we receive regulatory approval by us or by our third-party suppliers;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any current and future collaboration;
- our research and development activities outside of the United States, including in China, and related contractual relationships;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;

- our financial performance;
- our expectations related to the use of cash, cash equivalents and short-term investments in treasury securities;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to maintain effective internal control over financial reporting;
- the impact of government laws and regulations; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Annual Report on Form 10-K, and we believe these industry publications and third-party research, surveys and studies are reliable.

BASIS OF PRESENTATION

In December 2025, we effected a 1-for-16 reverse stock split (the Reverse Stock Split) of our common stock, par value $0.0001 per share (common stock). As a result, every 16 shares of our common stock issued or outstanding were automatically reclassified into one validly issued, fully-paid and non-assessable new share of common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to receive fractional shares were automatically entitled to receive cash in lieu of such fractional share. Proportional adjustments were made to the number of shares of common stock awarded and available for issuance under our equity incentive plans, as well as the exercise price and the number of shares issuable upon the exercise or conversion of our outstanding stock options and other equity securities under our equity incentive plans. All outstanding warrants were also adjusted in accordance with their terms, which resulted, among other changes to the warrant terms, in proportionate adjustments being made to the number of shares issuable upon exercise of such warrants, as applicable. Accordingly, unless otherwise noted, all share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. The shares of our common stock retained a par value of $0.0001 per share.

PART I

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Adicet Bio," "Adicet," the "Company," "we," "us" and "our" refer to Adicet Bio, Inc. and its subsidiaries, as applicable.

Item 1. Business.

Overview

We are a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. We are advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients.

Our approach to activate, engineer and manufacture allogeneic gamma delta T cell product candidates derived from the peripheral blood cells of unrelated donors allows us to generate new product candidates in a rapid and cost-efficient manner. Our allogeneic "off-the-shelf" manufacturing process is designed to allow product from unrelated donors to be stored and sold on demand to treat patients without inducing a graft versus host immune response. This is in contrast to products based on alpha beta T cells, which either must be manufactured for each patient from his or her own T cells, or require significant gene editing to manufacture if the T cells are derived from donors that are unrelated to the patient.

Our lead product candidate, prulacabtagene leucel (prula-cel, formerly ADI-001), a first-in-class allogeneic gamma delta T cell therapy expressing a CAR targeting CD20, is being developed for the potential treatment of autoimmune diseases. We are also pursuing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen (PSMA). ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and to deliver multiple anti-tumor mechanisms of action to the tumor microenvironment. We aim to submit a new regulatory submission, such as an Investigational New Drug (IND) application or equivalent every 12-18 months.

Prulacabtagene leucel (prula-cel, formerly ADI-001)

In December 2023, the U.S. Food and Drug Administration (FDA) cleared our IND application for prula-cel in lupus nephritis (LN). In August 2024, we expanded our prula-cel autoimmune clinical development program to include systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and anti-neutrophil cytoplasmic autoantibody associated vasculitis (AAV). In September 2024, we activated sites for our Phase 1 clinical trial of prula-cel in autoimmune diseases and opened enrollment for patients with LN. In October 2024, we received clearance for our IND amendment to evaluate prula-cel in idiopathic inflammatory myopathies (IIM) and stiff person syndrome (SPS) as part of our Phase 1 clinical trial in autoimmune diseases. We believe the favorable safety profile, cellular kinetics and B cell depletion in peripheral blood and secondary lymphoid tissue demonstrated with prula-cel clinical experience to date is favorable for development in autoimmune diseases. We believe the potential market opportunity for prula-cel in B cell mediated autoimmune diseases is substantial based on the prevalence in the U.S., EU5, China and Japan of greater than 1.7 million patients with autoimmune diseases where CAR-T cell

therapy has demonstrated clinical proof-of-concept, including SLE (which includes LN), SSc, IIM and SPS. In June 2024, the FDA granted Fast Track Designation to prula-cel for the potential treatment of relapsed/refractory class III or class IV LN. In February 2025, the FDA granted Fast Track Designation to prula-cel for the potential treatment of adult patients with refractory SLE with extrarenal involvement and for SSc. In April 2025, we expanded enrollment to include patients with SLE for our Phase 1 clinical trial evaluating prula-cel in autoimmune diseases and in July 2025, we reported that the first SSc patient has been dosed in the second cohort of the Phase 1 clinical trial. In October 2025, we announced positive preliminary results from seven SLE and LN patients dosed in our ongoing Phase 1 trial of prula-cel in autoimmune diseases as of the August 31, 2025 data cut-off date. We plan to meet with the FDA in the second quarter of 2026 to inform potential pivotal trial design. Subject to regulatory clearance to proceed, we expect to initiate a potential pivotal study in LN or LN and SLE patients in the second half of 2026. In November 2025, we reached alignment with the FDA to allow LN and SLE patients to be dosed with prula-cel in the outpatient setting in ongoing and future clinical trials. Phase 1 enrollment is ongoing and we expect to provide a clinical update for this trial in LN, SLE and SSc patients in the first half of 2026, with a plan to provide an additional update in the second half of 2026. We also reported in October 2025 that the first patient was dosed in a Phase 1 clinical trial of prula-cel in patients with treatment-refractory rheumatoid arthritis (RA). The study will evaluate two conditioning regimens: cyclophosphamide alone and cyclophosphamide with fludarabine, to explore the potential to reduce the need for conditioning. The next clinical update on this trial is expected in the second half of 2026.

ADI-212

We are advancing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen. ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 (mbIL-12) armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and deliver multiple anti-tumor mechanisms of action within the tumor microenvironment. We expect to submit a regulatory filing for ADI-212 for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in the third quarter of 2026. Subject to regulatory clearance to proceed with a clinical trial, we expect to initiate patient enrollment in the fourth quarter of 2026. We believe the potential market opportunity for ADI-212 in mCRPC is significant based on the prevalence in the U.S., EU5, China and Japan of approximately 75,000 patients with second or third line advanced disease.

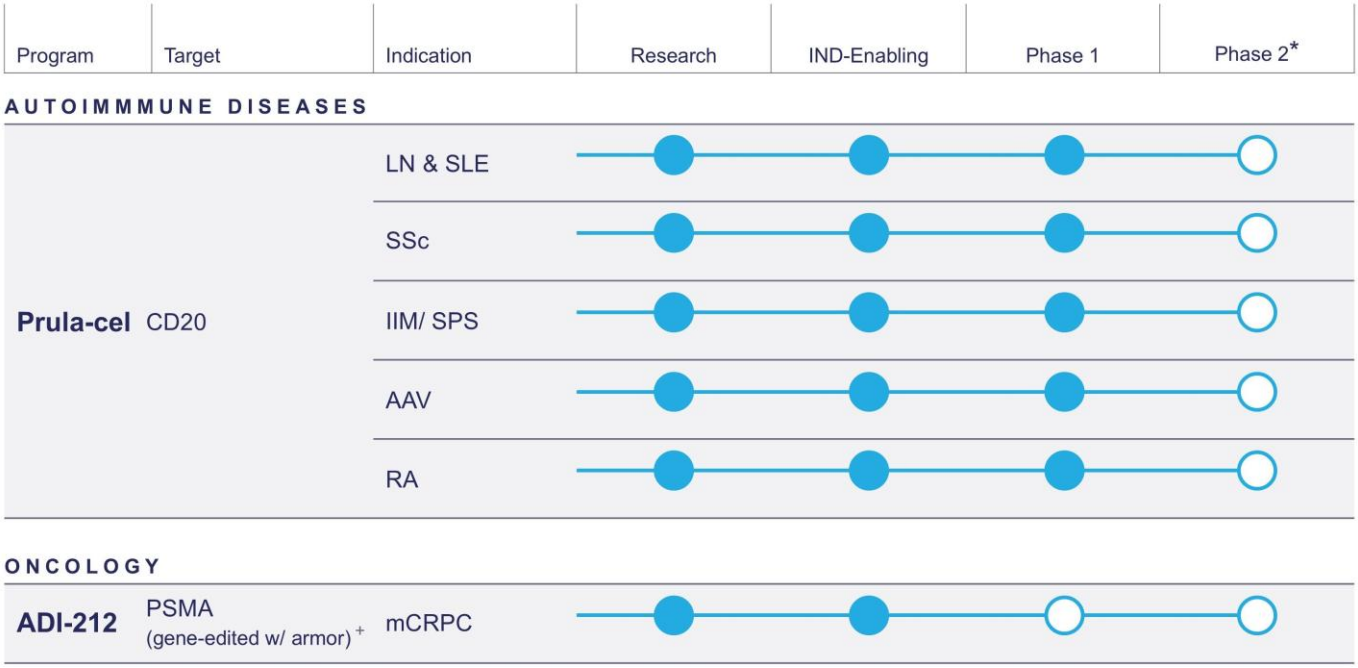
ADI-270

Due to the prioritization of prula-cel in autoimmune indications and ADI-212 in mCRPC, we have discontinued the development of ADI-270 and closed enrollment in the Phase 1 clinical trial in patients with metastatic/advanced clear renal cell carcinoma.

Our Pipeline

We are currently developing a pipeline of allogeneic “off-the-shelf” gamma delta T cell therapies, using either previously validated antigens or those that we identify and target using our CAR and other technology. Our most advanced product candidate in development, prula-cel, is in an ongoing Phase 1 clinical program across multiple autoimmune indications and we reported clinical data in LN and SLE patients from this trial in October 2025. We are also developing a pipeline to advance the research and development of allogeneic CAR T cell product candidates in autoimmune, hematological malignancies and solid tumor indications. We expect to continue to develop product candidates in autoimmune diseases and cancer based on our T cell platforms using ex vivo and in vivo CAR or other technologies.

Our pipeline is represented in the diagram below:



* Phase 3 may not be required if Phase 2 is registrational
+ License agreement with CRISPR for gene-editing technology. CRISPR has opt-in right to participate in a 50/50 cost and profit split.
RA is in a separate Phase 1 study of prula-cel.

Figure 1. Company Pipeline

Our Strategy

Our objective is to be the leading biotechnology company developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Key elements of our strategy include our plans to:

- **Continue to advance clinical development of prula-cel. Prula-cel**, our lead product candidate, is in Phase 1 clinical development across multiple autoimmune diseases. CD20 is a validated target for autoimmune diseases.
- **Advance preclinical and clinical development of ADI-212 in mCRPC.** Building on gamma delta 1 tissue tropism to solid tumors and three mechanisms of anti-tumor activity (CAR, innate and adaptive), CAR gamma delta 1 T cells may be well positioned to address solid tumors.
- **Continue to innovate and invest in the gamma delta T cell platform and pipeline**. We expect to continue to develop product candidates in autoimmune diseases and cancer based on the gamma delta T cell platform using either previously validated antigens or those that we identify and target. We also expect to continue to develop product candidates in autoimmune diseases and cancer based on our allogeneic gamma delta T cell platform using CAR and other technologies. We may utilize genetic engineering, editing technologies or other technologies with the goal of further improving the activity and tolerability profile of our product candidates. A key strength of our gamma delta T cell therapy platform lies in our ability to target antigens of both known and unknown potential and devote our clinical development resources to those antigens that show the most promise in preclinical in vivo analyses and early human trials.
- **Exploit the potential for outpatient administration**. While we expect that the initial subjects receiving our allogeneic gamma delta T cell-based therapies in clinical studies will be hospitalized for a minimum of 24-hours for observation after infusion, a favorable tolerability profile may allow administration of such investigational therapies in an outpatient setting. The FDA's recent decision to allow for outpatient dosing for LN and SLE patients in ongoing and future clinical studies further supports this directional approach. We believe this would represent a significant competitive advantage for our gamma delta T cell-based therapies as compared to existing approved CAR T-cell therapy or other therapies.
- **Drive innovation in new areas by exploring additional therapeutic modalities to expand and strengthen our long-term autoimmune pipeline portfolio.** Our strategy includes a broader research initiative encompassing

additional preclinical programs, including gene-edited CAR T, "armoring" technologies and in vivo CAR T programs targeting B cells with the potential for reducing or eliminating the need for conditioning. We will continue to evaluate and incorporate additional therapeutic modalities that may broaden our capabilities and support the long-term growth of our pipeline.

- **Expand and protect our intellectual property**. We will continue to aggressively protect the allogeneic gamma delta T cell production methodology we have developed as well as specific product candidates based on proprietary antigen-binding domains. For more information on our intellectual property, see "Business—Our Intellectual Property" section of this Annual Report on Form 10-K.

Background

Autoimmune Diseases

CAR T therapy, originally developed as a cancer treatment, has recently been the subject of increased interest for autoimmune diseases, due to its potential to remove disease causing immune cells with a single dose or treatment over a short period of time. Currently approved therapies for autoimmune indications treat only the symptoms with a chronic treatment regimen and are not considered curative. There are currently no FDA approved CAR T therapies for autoimmune indications. Initial support for and increased interest in the use of CAR T therapies for autoimmune indications was based on durable proof of concept data presented by Dr. Georg Schett at the American College of Rheumatology and the 2023 American Society of Hematology Meeting showing that CD19-targeted CAR T cells induced persistent, drug-free remission in three distinct autoantibody dependent autoimmune diseases with good tolerability.

Limitations of Autologous Cell Therapies

Autologous cell therapies, such as those developed by Kite Pharma and Novartis, have a number of limitations, including but not limited to the following:

- **Treatment delays imposed by individualized manufacturing**. Due to the individualized manufacturing process, patients must wait up to three to four weeks for the individualized products to be manufactured and administered. In the registrational trials for Yescarta® and Kymriah®, up to 31% of intended patients ultimately did not receive treatment primarily due to complications from the underlying disease that occurred during manufacturing or due to manufacturing failures.
- **Manufacturing variability and failure**. An article published by the American Society of Hematology in 2023 reported CAR T manufacturing failure rates between 1-13%. The article states that, in some cases, the manufacturing process fails to yield a product and, in others, results in one which does not meet pre-specified criteria for release and labelled an out of specification product
- **High costs limit patient access**. The high cost of therapy and payer policies can limit access to autologous CAR T-cell therapies. According to a 2019 article published in the journal *Managed Care*, treating physicians estimate that the costs of autologous CAR T-cell therapies combined with patient care services are approximately $1 million per patient, generating reluctance of payers to approve these therapies for patients before they have exhausted other options. These therapies are then relegated to the most heavily pretreated patients who may be unable to withstand the potential severe side effects.
- **Scalability**. Because each patient requires a custom manufacturing batch, the production of autologous CAR T cells at the scale needed to meet commercial demand and anticipated label and geographic expansions may be challenging.

Autologous cell therapies, such as CAR T cells derived from alpha beta T cells, have been successful in their initial use in hematological malignancies. However, manufacturing of these cells imposes some critical limitations that could be minimized if similar allogeneic cell therapies that can be given to any patient, regardless of the donor of cells, are developed. We believe that allogeneic cell therapies offer great promise for optimizing the access to therapy, overcoming manufacturing-related and cost-related limitations of autologous cell therapies.

Potential Advantages of Gamma Delta T Cell-Based Therapies

Immunotherapies developed using gamma delta T cells have a number of potential or anticipated advantages over other therapies developed using other cell types, including the following:

- **Consistent values observed.** Exposure, measured by Cmax, D28 persistence and area under curve with prula-cel, has been consistent with values reported for approved autologous CD19 CAR T therapies. This property differentiates our CAR gamma-delta1 allogeneic T cell therapies from other allogeneic therapies.
- **Potential for superior cytotoxic activity**. T cells from some patients, for example those with chronic lymphocytic leukemia, often display an exhausted, or otherwise dysfunctional, phenotype and CAR T cell products from these cells may perform poorly. Our allogeneic cell therapy is manufactured from unrelated donors whose T cells have been shown to generate highly active CAR T cells. Clinical B-cell depletion data from prula-cel in lymphoma, mirrors the B-cell depletion reported in academic studies by Shett et.al. of autologous CD19 CAR-T in lupus patients who experienced robust efficacy associated with an immune reset of the B cell compartment. Similarly, in lymphoma patients, prula-cel has demonstrated deep cytoreductive complete responses that surpassed the depth of response demonstrated by autologous CAR T therapy in the same patient.
- **Tissue and tumor localization**. In addition to being present in the circulation at low frequency, gamma delta T cells have an inherent propensity to home to tissues and tumors. Their ability to be activated in tissue environments less perfused with oxygen, such as those found in the tumor microenvironment, has the potential to increase the activity of gamma delta T cells in solid tumors and in tissues. Similarly, this tissue homing may be ideally suited to deplete B-cell nests located in peripheral tissues including secondary lymphoid organs and kidneys associated with autoimmune disease, which may better enable an effective reset of the immune system.
- **Major Histocompatibility Complex (MHC)-independent antigen recognition for tissue homeostasis and tumor targeting**. Gamma delta TCR can recognize antigens associated with dysfunctional cells, associated with tumorigenic or dysregulated functions, in a MHC-independent manner. This further facilitates the use of products derived from donors who are unrelated to patients which may avoid the need to match the human leukocyte antigen (HLA)-type of the donor to the patient.
- **Limited ability for antigen escape**. Although the initial responses to immunotherapies such as antibodies and CAR T cells are often impressive, many patients become refractory or relapse. A common mechanism for the relapse to these therapies is loss of the expression of the CAR-targeted antigen such as CD19 from target cells. Because gamma delta T cells also express innate cytotoxic immune receptors, they can recognize and kill dysfunctional cells even in the absence of the CAR-targeted tumor antigen.
- **Ability to manufacture more efficiently and cost-effectively**. Unlike alpha beta T cells, therapies based on gamma delta T cells can potentially be manufactured in bulk and used in the allogeneic or "off-the-shelf" setting, addressing many of the shortcomings of conventional alpha beta T cell therapy.
- **Lack of Graft-versus-host disease (GvHD)**. A body of published evidence, mainly in the field of haematopoietic stem cell transplantation (HSCT), supports the safety profile of transfer of allogeneic gamma delta T cells to patient recipients from unrelated donors. HSCT procedures containing significant numbers of gamma delta T cells were able to proceed with no signs of acute or chronic GvHD. In many cases, the presence of gamma delta T cells in the HSCT products correlated with improved clinical outcomes, indicating the antitumor potential of gamma delta T cells. Additionally, a study performed by Martin Wilhelm and colleagues in 2014 indicated that gamma delta T cells from haploidentical donors could be successfully expanded and infused in large numbers ($2.17x10^6$ cells/kg (range, 0.9-3.84)), followed by further expansion (mean, 68-fold) in the patients without any observed GvHD.
- **Limited cytokine secretion**. Unlike alpha beta T cells, gamma delta T cells can be made to secrete lower levels of certain cytokines such as interleukin 6 (IL-6). This, combined with lack of recognition of normal, non-malignant, cells by of gamma delta T cells, may lower the risk of life-threatening cytokine release syndrome.
- **Potential for re-dosing**. Along with increased availability of material due to the ability to utilize "off-the-shelf" donor-derived starting material from unrelated donors compared to conventional CAR T-cell therapies, the lack of MHC-dependent GvHD also opens up the possibility of being able to re-dose patients to achieve further clinical activity if they do not obtain an adequate clinical response from initial treatment or if they relapse. A number of studies with other CAR T-cell therapies have linked the development of cytokine release syndrome with high numbers of circulating CAR T cells following rapid alpha beta T cell proliferation. Having the option to retreat patients with gamma delta T cells provides the option of starting with a low dose and re-dosing if required.

- **Safety Potential.** Prula-cel has shown to be well tolerated to date with no significant CRS, ICANS and an inherently lower risk of T-cell malignancies compared to autologous CAR-Ts. This profile and prula-cel's off-the-shelf availability makes it suitable for the treatment of autoimmune diseases and provides the potential to treat patients in the community setting.

Our Allogeneic Gamma Delta T Cell Technology

Human gamma delta T cells can be divided into three main subsets based on their TCR delta chain usage: Vδ1, Vδ2 and Vδ3. The most abundant subset of gamma delta T cells in the circulatory system, the Vδ2 cells, is also the most well-studied. However, it is the Vδ1 subset which primarily resides in tissues and presents a favorable cytotoxic profile against target cells that we are activating and manufacturing using our proprietary platform technology.

Vδ1 Gamma Delta T Cells

Vδ1 cells have properties of both the innate and adaptive immune system, meaning that they can be activated by tumor-specific antigens as well as by general activators common to damaged or otherwise abnormal cells. Similar to other T cells, they express TCRs, but also express cytotoxicity receptors that are found on innate immune cells such as natural killer (NK) cells. These gamma delta T cells can induce tumor cell death through multiple mechanisms including the secretion of cytotoxic proteins such as granzymes and perforin as well as through the secretion of cytokines such as interferon gamma (IFNγ), and tumor necrosis factor alpha (TNFα).

In in vitro and in vivo preclinical models, Vδ1 cells are more cytotoxic and may have a longer durability than Vδ2 cells. Vδ1 cells are also more resistant to activation induced cell death (AICD), which has posed significant problems in clinical trials following chronic stimulation of Vδ2 cells. Vδ1 cells normally reside within tissues and they are able to adapt to lower nutrient availability and decreased oxygen levels, conditions which are similar to those in the microenvironments or localized areas associated with certain solid tumors. Incubation of these gamma delta T cells in conditions of low oxygen (hypoxia) that are typical of tumors has been shown to enhance their cytotoxicity.

Anticipated Advantages of Vδ1 Gamma Delta T Cells Over NK Cell Based Therapies

An alternate approach to the development of allogeneic CAR T cells consists of engineered NK cell-based therapy. While both gamma delta T cell and NK cell therapy generally are not expected to cause GvHD, NK cells express a broad repertoire of both inhibitory and activating receptors and have more limited tumor induced secretion of multiple cytokines. We believe that the gamma delta T cell technology we are developing has several advantages over this approach. Unlike engineered NK cells, Vδ1 gamma delta T cells have the following advantages:

- The presence of cytotoxic gamma delta cells in tumors and disease-associated tissues is strongly correlated with positive clinical outcomes;
- Can secrete multiple cytokines associated with potent cytotoxicity including expressing high levels of interferon-gamma;
- Can be produced as highly homogeneous cell populations that display potent non-clinical anti-tumor activity;
- Express activating receptors more predominantly; and
- Display features of adaptive immunity including, TCR-mediated, but MHC-independent, antigen recognition against those commonly displayed on malignant and abnormal cells, a long lifespan and persistence for protracted periods of time.

We believe these advantages position gamma delta T cell-based therapies to become an attractive alternative to NK based therapies for many autoimmune and cancer indications and lines of therapy.

Anticipated Advantages of Vδ1 Gamma Delta T Cells Over Other Approaches to Generate Allogeneic CAR T Cells

An alternative approach to the development of allogeneic gamma delta CAR T cells consists of introducing genetic modifications that disable the TCR in alpha beta T cells derived from donors that are unrelated to the patient. This process prevents these cells from attacking the patient's healthy cells. We believe that the unrelated donor-derived gamma delta T cell

technology, which lacks the ability to attack healthy cells from unrelated individuals, has a number of advantages over this approach. In an allogeneic paradigm, unlike alpha beta T cells, Vδ1 gamma delta T cells have the following advantages:

- Do not rely on genetic manipulations to inactivate the alpha beta TCR;
- Display properties of both adaptive and innate immune systems and are capable of killing cells even if their specifically targeted CAR antigen is expressed at low levels or not present;
- May not be prone to exhaustion and are likely to persist longer;
- May maintain the capacity to home to tissues and tumors rather than predominantly residing in circulation; and
- May be less likely to induce cytokine release syndrome due to more limited endogenous IL-6 secretion by activated cells.

We believe these advantages position gamma delta T cell based therapies to become an attractive alternative to alpha beta T cell based therapies.

Anticipated Advantages of Vδ1 Gamma Delta T Cells Over Bispecific Antibody T Cell Recruitment for Tumor Immunotherapy

An alternative approach to the development of allogeneic CAR T cells consists of bispecific antibodies that are designed to crosslink T cells to specific targets on the tumor. This approach generally requires healthy and functional T cells able to attack the tumor when guided to the tumor expressing the target antigen. We believe that the unrelated donor-derived gamma delta T cell technology has a number of potential advantages over this approach. Unlike bispecific antibodies, Vδ1 gamma delta T cells have the following advantages:

- Do not rely on functional T cells derived from the patient for clinical activity;
- Display properties of both adaptive and innate immune systems and are capable of killing cells even if their specifically targeted CAR antigen is not present;
- Maintain the capacity to home to tissues and tumors rather than predominantly residing in circulation and can actively distribute into localized tumors; and
- May be less likely to induce cytokine release syndrome due to more limited endogenous IL-6 secretion by activated cells.

We believe these advantages position gamma delta T cell-based therapies to become an attractive alternative to bispecific-based therapies for many autoimmune and cancer indications and lines of therapy.

Our Key Anticipated Differentiation from Gamma Delta T Cell Competitors

We believe that the gamma delta T cell technology that we are developing has a number of potential advantages over the technology of gamma delta T cell competitor companies, including the following:

- Robust and practical proprietary antibody-based manufacturing method for gamma delta T cells;
- Large-scale expansion of blood-derived gamma delta T cells;
- Ability to selectively expand multiple gamma delta T cell subpopulations including highly potent Vδ1 cells;
- No potentially pro-tumorigenic or pro-autoimmune Th17-type responses in our Vδ1 subpopulation;
- In-house CAR target identification and verification process; and
- Ability to effectively target tumor-specific intracellular protein-derived peptides using proprietary T cell receptor-like (TCRL) antibodies.

We believe these advantages position our gamma delta T cell based therapies to become an attractive approach to the technologies used by other gamma delta T cell competitor companies.

Production of Gamma Delta T Cells

To produce gamma delta T cell-based product candidates, we isolate peripheral blood mononuclear cells from unrelated donors that meet all the safety criteria for human cells, tissues, and cellular and tissue-based products (HCT/P) for donors as

outlined by the FDA in Title 21 of the Code of Federal Regulations (CFR), Part 1271. We then activate Vδ1 gamma delta T cells using a proprietary agonistic antibody and cytokines which expands these cells before transduction with replication-incompetent retroviral vectors containing the coding sequence for CAR constructs. These CAR-modified cells are further expanded at significant orders of magnitude, routinely greater than 6,000-fold at clinical scale, resulting in cell cultures that primarily consist of the desired gamma delta T cells. To reduce the chance of a patient developing GvHD, the remaining alpha beta T cells are then depleted using alpha-beta-specific, antibody-based techniques. The resulting gamma delta T cells are then formulated in an infusible solution to form the final drug product, which is filled into vials and then frozen to enable delivery of a post-thaw cell dose of CAR T cells. A schematic of our large-scale manufacturing process is summarized in the diagram below.

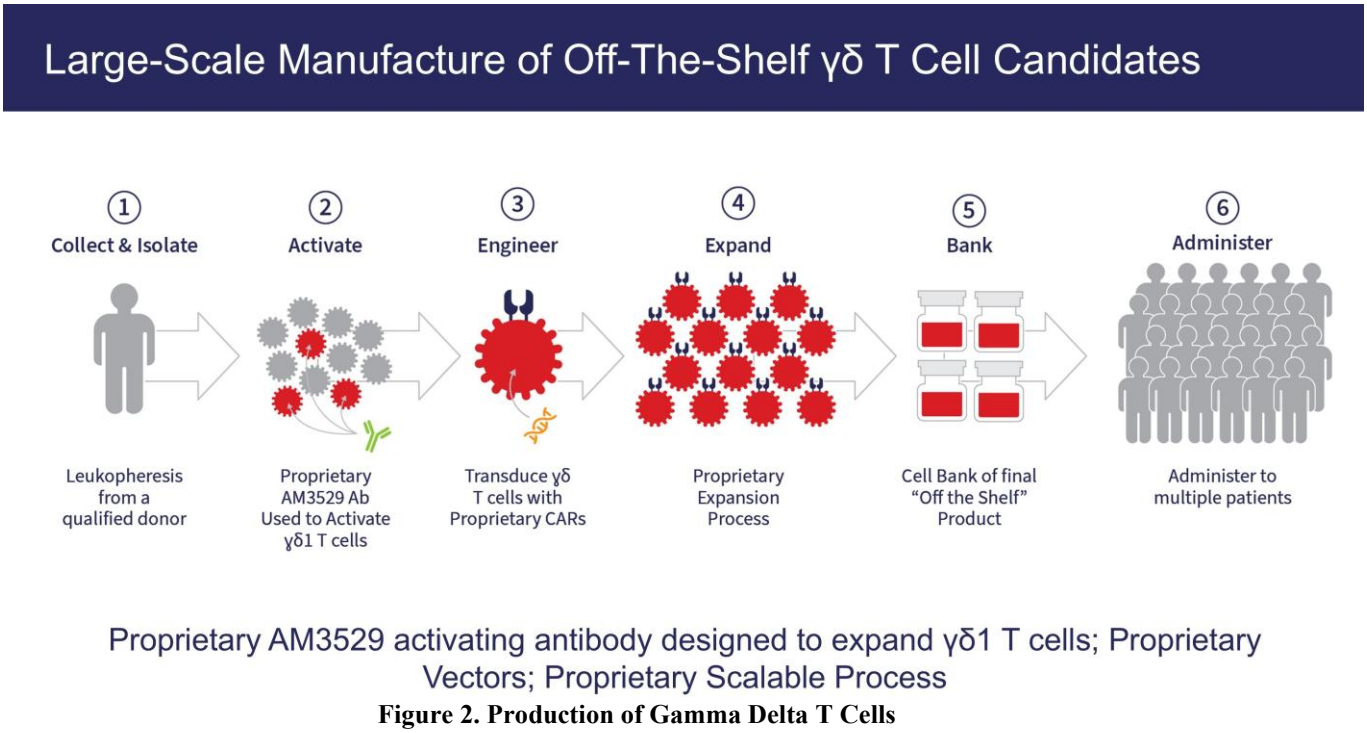


Figure 2. Production of Gamma Delta T Cells

Prula-cel, an Anti-CD20 CAR Gamma Delta T Cell Product Candidate Targeting Autoimmune Diseases

Our Solution, Prula-cel

Prula-cel is our gamma delta CAR T cell product candidate that is designed to target malignant B cells via an anti-CD20 CAR and via the gamma delta T cell endogenous receptors, which we are developing as an allogeneic immunocellular therapy for the treatment of multiple autoimmune diseases. Prula-cel is created from Vδ1 gamma delta T cells isolated from unrelated donors. It is manufactured in bulk under current Good Manufacturing Practices (cGMP) -compliant conditions and is intended to be supplied as an immediately available "off-the-shelf" anti-CD20 CAR T-cell therapy.

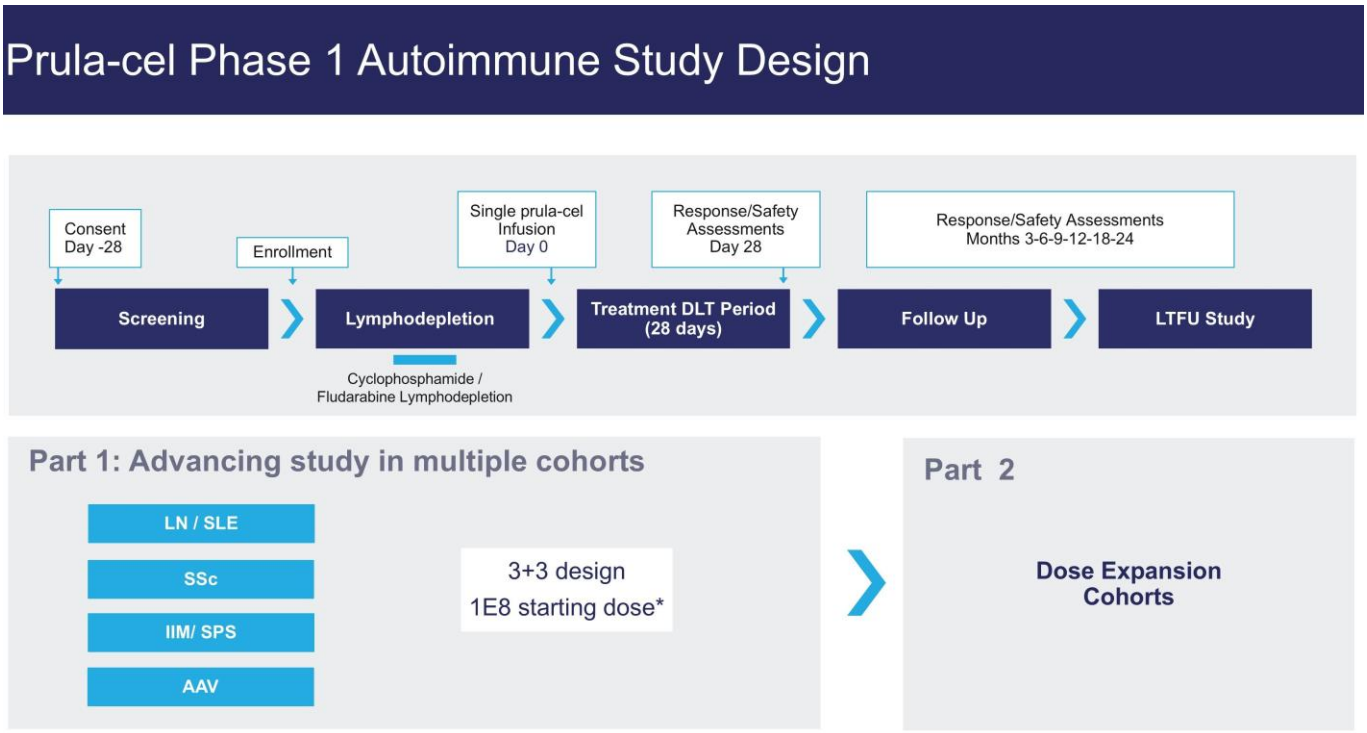
Prula-cel contains an anti-CD20 CAR that has a proprietary antigen-binding domain that recognizes a region of CD20 distinct from that recognized by rituximab. Similar to other CAR Ts cells including the one used to create Kymriah®, our CAR T cells contain the clinically validated costimulatory domain from 4-1BB and the CD3ζ.

Prula-cel Development Program

Autoimmune Diseases

In November 2024, we dosed our first LN patient in the Phase 1 trial of prula-cel in autoimmune indications and have since expanded the trial to enroll patients with LN, SLE, SSc, IIM, SPS, and AAV. Our trial involves a 3+3 dose escalation starting at 100 or 300 million CAR+ cells flat dose. Subject to safety findings, higher doses will be explored up to one billion CAR+ cells. Before prula-cel infusion, each patient will be conditioned with cyclophosphamide and fludarabine lymphodepletion. The dose limiting toxicity reporting window is set to 42 days; safety events during this period will be driving dose escalation decisions. The first safety assessment is scheduled on Day 28 after infusion, and then on months 3-6-9-12-18

and 24 thereafter. Once the maximum tolerated dose is determined, a dose expansion cohort will be opened to further characterize the safety and efficacy of prula-cel in lupus nephritis patients. Primary endpoints will be focused on safety. For an illustration of our prula-cel Phase 1 study design in autoimmune diseases, please refer to Figure 3 below.



The first patients enrolled in the trial were dosed at 1E8. Following an IND amendment, the starting dose for all subsequent cohorts was increased to 3E8 with potential to escalate up to 1E9 (based on 3+3 design) or de-escalate down to DL1 of 1E8 (in all cases CAR+ cells); LTFU = Long term follow up

Figure 3. Prula-cel Phase 1 Study Design in Autoimmune Diseases

In October 2025, we announced the dosing of the first treatment-refractory RA patient with prula-cel in a Phase 1 study. The study will evaluate two conditioning regimens: cyclophosphamide alone and cyclophosphamide with fludarabine. The primary objectives of the study are to evaluate the safety and tolerability of prula-cel. Secondary objectives include measuring cellular kinetics, pharmacodynamics, and disease activity scores. The Phase 1 study in RA testing prula-cel using two different conditioning regimens is in the context of a broader initiative at Adicet that seeks to deliver a best-in-class portfolio of therapies for autoimmune patients. This initiative includes additional ongoing preclinical programs, including gene-edited CAR T and in vivo CAR T programs targeting B cells with the potential for reducing or eliminating the need for conditioning.

ADI-212 Development Program

ADI-212 is a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen. ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and deliver multiple anti-tumor mechanisms of action within the tumor microenvironment. We expect to submit a regulatory filing for ADI-212 for the treatment of mCRPC in the third quarter of 2026. Subject to regulatory clearance to proceed with a clinical trial, we expect to initiate patient enrollment in the fourth quarter of 2026.

ADI-270 Discontinuation and Data Read Out

In July 2025, we announced that we discontinued the development of ADI-270 for patients with metastatic/advanced ccRCC due to a strategic reprioritization our pipeline intended to optimize the development of assets.

As a result of our strategic pipeline prioritization, enrollment in the ADI-270 Phase 1 clinical trial was closed. As of the July 23, 2025 data cut, five patients with ccRCC who received the planned target dose level in the Phase 1 (1 billion CAR+

cells of ADI-270) with a second dose of (300 million CAR+ cells of ADI-270) demonstrated 100% disease control rate and 20% best overall response rate with no patient experiencing disease progression following ADI-270 dosing. ADI-270 demonstrated consistent and robust expansion and exposure in both blood and tumor biopsies. Additionally, in the Phase 1 study, ADI-270 demonstrated a favorable tolerability profile, with no reports of cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome.

Additional Preclinical Programs (CAR and Other Technologies)

Our pipeline also includes additional internal gamma delta T cell therapy programs in discovery and preclinical development for autoimmune diseases, hematological malignancies and solid tumors. These pipeline programs were selected by integrating aspects of gamma delta one tissue homing, differentiated mechanisms of action, targeting enhancement and engineered armoring. We believe that the combination of our gamma delta T cells engineered with CAR or other technology provides the basis for a new generation of gamma delta T cell therapies that have the potential to transform the treatment of solid tumors. Additionally, we have ongoing preclinical programs and activities based on a differentiated approach using lentiviral vector to transduce functional CAR T cells in vivo, targeting B cells with the potential for reducing or eliminating the need for conditioning.

Our Strategic Agreements

We have entered into multiple strategic agreements and collaborations, including our License and Collaboration Agreement with Regeneron, our Antibody Discovery Agreement with Twist Bioscience Corporation, our License and Collaboration Agreement with CRISPR Therapeutics AG, and our Non-Exclusive License Agreement with the City of Hope. We have also entered into amendments to these original agreements. For additional information regarding our significant agreements, refer to Note 9. Third Party Agreements to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Our Intellectual Property

Our gamma delta T cell-based product candidates and substantially all of our intellectual property have been developed by us, with certain antigen binding domains derived from our collaboration with Regeneron. Additional intellectual portfolio assets were acquired in 2016 via acquisition of Applied Immune Technologies Ltd. (AIT), which is now our wholly owned subsidiary, Adicet Bio Israel, Ltd. We strive to protect and enhance proprietary technology, inventions and improvements that are commercially material to our business, including seeking, maintaining and defending our patent rights.

Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing United States and foreign patents and applications related to our technology, inventions, and improvements that are material to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position.

Our patent portfolio includes composition of matter, method of treatment and manufacturing process protection for our lead product candidates, prula-cel and ADI-212, as well as for our partnered program ADI-002 and several additional research-stage candidates. As of March 12, 2026, there are multiple granted patents and pending non-provisional applications in the United States and internationally directed to our gamma delta T cell expansion platform, including several pending patent families directed to particular reagents and related protocols for gamma delta T cell expansion and resulting gamma delta T cell compositions of matter, including engineered gamma delta CAR T cells which are expected to expire between 2035 and 2038, absent any patent term adjustment and/or extension. The first U.S. non-provisional application in our original patent family was granted as U.S. Patent No. 11,135,245, expiring on May 19, 2038; the first U.S. non-provisional application in our second patent family was granted as U.S. Patent No. 11,299,708, expiring on December 26, 2037; the second non-provisional application in this patent family was granted as U.S. Patent No. 12,364,714, expiring on May 30, 2039; and the first U.S. non-provisional application in our third patent family was granted as U.S. Patent No. 12,221,480, expiring on February 1, 2042.

We also have two pending international PCT applications directed to certain improvements in gamma delta CAR T cell engineering and armoring, where any subsequent national stage applications claiming the benefit of these PCT applications would expire in 2045 assuming they are filed and issued in due course. We also have one pending international PCT application directed to certain improvements in gamma delta CAR T cell manufacturing, where any subsequent national stage applications claiming the benefit of this PCT application would expire in 2045 assuming they are filed and issued in due course.

For our prula-cel program in particular, there is one patent family with multiple granted patents and pending non-provisional applications in the U.S. and internationally directed to CAR constructs and antigen binding domains relating to prula-cel, as well

as their methods of use for certain indications, preconditioning methods, and dosing regimens, which, if issued, would expire in 2039, absent any patent term adjustment and/or extension. Additionally, we have a second patent family with pending non-provisional applications in the U.S. and internationally directed to certain methods of treating B cell malignancies using prula-cel which, if issued, are expected to expire in 2042, absent any patent term adjustment and/or extension. We also have a pending international PCT application directed to certain methods of treating autoimmune disorders using prula-cel, where any subsequent national stage applications claiming the benefit of this PCT application would expire in 2045 assuming they are filed and issued in due course.

For our ADI-212 program in particular, there is one patent family with pending non-provisional applications in the U.S. and internationally directed to CAR constructs with PSMA binding domains relating to ADI-212, as well as their methods of use for certain indications, which, if issued, would expire in 2044, absent any patent term adjustment and/or extension.

For our research-stage programs, we have several patent families with pending non-provisional applications in the U.S. and internationally focusing on dap10 which, if issued, would expire between 2042 and 2043, absent any patent term adjustment and/or extension. We also have one pending international PCT application directed to a companion diagnostic and related adjunctive therapy for use in adoptive cell therapies in general, where any subsequent national stage applications claiming the benefit of this PCT application would expire in 2044 assuming they are filed and issued in due course.

Finally, we also have a pending U.S. provisional patent application directed to certain aspects of in vivo CAR engineering, where any subsequent applications claiming the benefit of this provisional application would expire in 2047 assuming this application is converted, prosecuted and issued in due course.

For our ADI-002 program, partnered with Regeneron, there is one patent family with multiple granted patents and pending non-provisional applications in the United States and internationally directed to CAR constructs and antigen binding domains relating to ADI-002, as well as their methods of use for certain indications, preconditioning methods, and dosing regimens, which, if issued, would expire in 2039, absent any patent term adjustment and/or extension. We also have one patent family with pending non-provisional applications in the U.S. and internationally directed to certain proprietary antibodies to GPC3 and methods of use thereof which, if issued, would expire in 2042, absent any patent term adjustment and/or extension.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the U.S., patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the U.S., the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, core technologies, and know-how, as well as our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights.

The patent positions of companies like us are generally uncertain and involve complex legal, scientific, and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents or if our patent filings will be commercially useful in protecting our commercial products and methods of using and manufacturing the same. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold, or control may be challenged, circumvented or invalidated by third parties. In addition, while we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. Further, our trade secrets may otherwise become known or independently discovered by competitors.

We have licensed various intellectual property and trade secrets to third parties for purposes of collaboration, product development and research and development.

Manufacturing

We are developing and enabling scalable and proprietary cGMP-compliant manufacturing processes. We have invested resources to optimize our manufacturing process and plan to maintain that investment to continuously improve our production and supply chain capabilities over time.

We manufacture cell-based immunotherapy products utilizing gamma delta T cells obtained from the blood of donors who are unrelated to the patients that will be treated. These products are classed as allogeneic cell therapy products. Donor-derived blood product is fractionated and the fraction enriched for gamma delta T cells is frozen prior to use in future manufacturing campaigns. We believe that freezing and storing the donor blood products allows us to efficiently schedule subsequent manufacturing steps. After obtaining blood products from unrelated donors the manufacturing process begins with the activation of a subpopulation of gamma delta T cells, referred to as Vd1 T-cells, using an antibody that is proprietary to us. This antibody, in combination with other factors including cytokines, induces gamma delta T cells to proliferate, whereupon we expose the cells to a viral vector that transfers a gene sequence encoding a CAR or other gene sequences, to the proliferating cells. This step is referred to as the transduction step. Following the transduction step, gamma delta T cells are induced to proliferate further. During the manufacturing process, there are depletion steps that increase the proportion of gamma delta T cells by removing unwanted residual alpha beta T cells, resulting in an enriched CAR-modified gamma delta T cell drug product. CAR-modified gamma delta T cell products are then frozen in single-use vials for long-term storage at cryogenic temperatures. These storage conditions are designed to ensure stability of the cell-based drug products for protracted periods of time. The storage in single use vials is designed to simplify the handling and treatment administration. Just prior to administration of treatment, the vials will be thawed and then the contents infused into the patient. We believe that the manufacturing processes we are developing will be able to be completed in approximately two to three weeks and will result in sufficient quantities of drug product to treat numerous patients.

We conduct internal GMP cell processing and vector manufacturing operations at our 1000 Bridge Parkway, Redwood City, California facility (1000 Bridge Parkway) for the production of viral vector and drug products intended for Phase 1/2 clinical trials. We have established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations. We also utilize separate third-party contractors to manufacture cGMP-compliant starting and critical materials that are used for the manufacturing of our product candidates, such as donor blood products, gamma delta T cell activating antibody, and guide ribonucleic acid. We believe all materials and components utilized in the production of the activating antibody producing cell line are available from qualified suppliers and suitable for pivotal process development in readiness for registration and commercialization. Going forward, we intend to continue to expand our manufacturing capability through agreements with leading cell therapy and viral vector CDMOs.

If there is a setback or delay with our own internal cell or vector manufacturing, we believe that there are a number of potential replacements, although we would likely incur some delay in identifying and qualifying such replacements. We plan to continue to create a robust supply chain with redundant sources of supply comprised of both internal and external infrastructure.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including existing and novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

Novartis and Kite Pharma (now Gilead) were the first to achieve FDA approval for autologous T cell therapies. In August 2017, Novartis obtained FDA approval to commercialize Kymriah®, for the treatment of children and young adults with B cell acute lymphoblastic leukemia (ALL) that is refractory or has relapsed at least twice. In May 2018, Kymriah® received FDA approval for adults with relapsed or refractory (R/R) large B cell lymphoma. In October 2017, Kite Pharma obtained FDA approval to commercialize Yescarta®, the first CAR T-cell product candidate for the treatment of adult patients with R/R large B cell lymphoma. In July 2020, Gilead obtained FDA approval to commercialize Tecartus™, the first CAR T-cell product candidate for the treatment of adult patients with R/R mantle cell lymphoma. In February 2021, Bristol Myers Squibb obtained

FDA approval to commercialize Breyanzi® for the treatment of adults with R/R large B cell lymphoma. In 2022, both Yescarta and Breyanzi were approved by the FDA for treating a subset of adult patients with LBCL in the second line, representing a line-expansion from the earlier third-line approvals.

Due to the promising therapeutic effect of T cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies, as well as in the development of allogeneic T cell therapies generally. Potential T cell therapy competitors include, but are not limited to:

Autoimmune Competition

- *Allogeneic immune cell therapy competition:* CRISPR Therapeutics AG, Fate Therapeutics, Inc., Nkarta, Inc., Century Therapeutics, Inc., Allogene Therapeutics, Inc., and Legend Biotech.
- *Autologous T-cell therapy competition:* Novartis AG, Bristol-Myers Squibb Company, Autolus Therapeutics PLC, Cartesian Therapeutics, Inc., iCell Gene Therapeutics Inc., Cabaletta Bio, Inc., AstraZeneca PLC, Legend Biotech, and Kyverna Therapeutics, Inc.

Cancer Competition

- *Allogeneic T-cell therapy competition:* Allogene Therapeutics, Inc., Caribou Biosciences, Inc., Century Therapeutics, Inc., Cellectis, S.A., CRISPR Therapeutics AG, Fate Therapeutics Inc., Precision Biosciences, Inc., Immatics Biotechnologies GmbH, TC BioPharm Limited, and IN8Bio, Inc.
- *Autologous T-cell therapy competition:* Adaptimmune Therapeutics PLC, Autolus Therapeutics plc, Bristol-Myers Squibb Company, Gilead Sciences, Inc., Johnson & Johnson, Iovance Biotherapeutics, Inc., Mustang Bio, Inc., Legend Biotech, and Novartis International AG.

Although we believe our development of proprietary processes for engineering and manufacturing gamma delta T cells expressing CARs is unique due to what we believe is the enormous potential of these cells, it is likely that additional competition may arise from existing companies currently focusing on development of alpha beta or gamma delta T cell therapies, or from new entrants in the field.

Competition may also arise from non-cell based immune cancer platforms. For instance, we may experience competition from companies, such as Amgen Inc., Bristol-Myers Squibb Company, Cullinan Therapeutics, Inc., F. Hoffmann-La Roche AG, Genmab A/S, GlaxoSmithKline plc, GSK plc, MacroGenics, Inc., Merck & Co., Inc., Merus N.V., Regeneron Pharmaceuticals, Inc., Candid Therapeutics, Janux Therapeutics, and Xencor Inc., that are pursuing bispecific antibodies, which target both an antigen on the cancer or target B-cell and the T cell receptor, thus bringing both target cells and T cells in close proximity to maximize the likelihood of an immune response. Further, companies such as Novartis AG, F. Hoffmann-La Roche AG, Biogen Inc., AstraZeneca PLC, Climb Bio Inc., and GSK plc are developing antibody-based therapies targeting B cell antigens and other targets for the treatment of autoimmune diseases. Additionally, companies, such as Amgen Inc., AbbVie Inc., Daiichi Sankyo Company, Limited, GSK plc, Immunomedics, Inc., Johnson & Johnson, and Pfizer Inc., are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our own products, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and tolerability profile, convenience, price, reimbursement and cost of manufacturing.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, and investor capital, as well as for technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell therapy candidates are regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics, and if applicable, the FDA's current good tissue practices (cGTPs). The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA to the FDA for marketing authorization. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a Biologics License Application (BLA) before we can market them. Generally, before a new biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

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 the 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 appropriate foreign regulatory agency 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 U.S., 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. 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. Even after obtaining initial marketing approval, a product and its manufacturer remain subject to extensive, continuing regulatory requirements, including with respect to manufacturing, quality control, adverse event reporting, advertising and promotion and periodic inspections by regulatory authorities.

United States Product Development Process

In the U.S., the FDA regulates biological products under the Federal Food, Drug and Cosmetic Act (the FDCA), the Public Health Service Act (the PHSA), and their implementing 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 United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, FDA Form 483, untitled letters, 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, debarment, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and key animal studies according to good laboratory practices (GLPs), and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND application, which is subject to a waiting period of 30 calendar days, must become effective before human clinical trials may begin;

- approval by an independent Institutional Review Board (IRB) or ethics committee for each clinical site before the trial is commenced;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for our intended use;

- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (cGTPs) for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA prior to any commercial marketing or sale of the biologic in the U.S.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate undergoes preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the key preclinical tests must comply with federal regulations and requirements including GLPs. An IND application is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND application is submitted. 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 requests additional information and or places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators at independent clinical sites/hospitals, physicians not employed by or under the trial sponsor's control. 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, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. 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 form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is typically introduced into healthy human subjects and tested for safety. However, in the case of some products for severe or life-threatening diseases, such as cancer, initial human testing is routinely

conducted directly in patients with the approval of relevant ethics committee(s), and under the supervision of a licensed physician.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In case of an accelerated BLA approval, FDA may mandate a Phase 4 clinical trial prior to full approval. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information.

Sponsors of applicable clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information within specific timeframes for publication on www.clinicaltrials.gov. Sponsors also must disclose certain results of these clinical trials, although disclosure of results may be delayed until after the new product or new indication has been approved by the FDA. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs, as well as clinical trial design.

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 or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. 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 biological product has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements, and if applicable, cGTP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product according to the requirements of the phase of clinical development. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product safety, efficacy, development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance or guarantee that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products.

Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that 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.

During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. 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. For cellular immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with cGTPs, to the extent applicable. These are FDA regulations and guidance documents that in part govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTPs is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, cGTPs and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Pediatric Information

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness 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 FDA may grant deferrals for submission of data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (PSP), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., 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 available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

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. In addition, 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 the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

FDA provides programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, priority review designation, accelerated approval, Regenerative Medicine Advanced Therapy (RMAT) designation, and breakthrough therapy designation. Additionally, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), sponsors of designated platform technologies may receive expedited development and review of any subsequent application for a drug or biologic that uses or incorporates the platform technology.

The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A

product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies and, under FDORA, the FDA is now permitted to require that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product.

RMAT designation was established by the FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Fast track designation, priority review, RMAT and breakthrough therapy designation do not change the standards for approval but may expedite the development or regulatory approval process for our products.

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

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA 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 uses (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

Further, additional FDA 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 if problems occur following initial marketing. 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 may also require the implementation of other risk management measures, including a REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the adequate stability of the product. 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. 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 and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance, and if applicable, cGTP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. Under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a product, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

We rely, and expect to continue to rely, on third parties to produce clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an 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, 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.

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

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits 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 a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of 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 BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States Pediatric exclusivity that, if granted, adds six months to existing regulatory exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the United States Department of Health and Human Services (HHS) (e.g., the Office of Inspector General, the United States Department of Justice (DOJ), and individual United States Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any of our research and future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of the facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the Affordable Care Act (ACA) codified case law that a claim that includes 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 (discussed below).

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

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the United States government. For example, pharmaceutical and other healthcare companies have been, and continue to be, investigated or prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery.

HIPAA created additional federal criminal statutes that prohibit 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 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. In addition, certain state and local laws require the registration of pharmaceutical sales representatives.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, impose requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, numerous federal and state laws and regulations govern the collection, use, disclosure, storage and transmission of health information, which may be even more restrictive and not preempted by HIPAA. thus complicating compliance efforts. Data protection laws outside of the U.S., including for example the General Data Protection Regulation in Europe, also govern the privacy and security of health information in. Such privacy and data protection laws and regulations are rapidly evolving and are subject to varying interpretations in their compliance requirements. In addition, regulators and legislators around the world are increasingly scrutinizing certain data transfers and have imposed data localization requirements, which could impact our ability to conduct our business across international borders.

We may also be subject to federal government price reporting laws, which 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 that potentially harm consumers.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, 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) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians, as defined by such law, certain other licensed health care practitioners and teaching hospitals, or to entities or individuals at the request of, or designated on

behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or 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, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the European Union (EU), governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines but monitor and control company profits. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained

for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- created a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability under the Medicaid Drug Rebate Program;
- expanded eligibility criteria for Medicaid programs, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expanded healthcare fraud and abuse laws, including the Anti-Kickback Statute and the Foreign Corrupt Practices Act (FCPA), created new government investigative powers, and enhanced penalties for noncompliance;
- required reporting of certain financial arrangements with physicians and teaching hospitals;
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- created a licensure framework for follow on biologic products.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2031 unless additional Congressional action is taken. Subsequent legislation extended the 2% payment reduction which remains in effect through 2030. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation;

- The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years;
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces;
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. 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; and
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Additionally, 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 United States Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Former President Biden issued multiple executive orders that sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from former President Biden that included a proposed prescription drug pricing model that would test whether targeted Medicare payment adjustments would sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these measures, Congress has indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025 ("OBBBA"), this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general is not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities.

On December 19, 2025, CMS released two proposed rules that would incorporate most-favored nation ("MFN") pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single-source drugs and sole-source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole-source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five-year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Individual states in the United States have also increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits (UPLs) on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

We anticipate that these and other healthcare reform efforts will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could materially harm our business. Any reduction in reimbursement from Medicare and 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 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.

The Foreign Corrupt Practices Act

The FCPA prohibits any United States individual or business from offering, paying, promising to pay, or authorizing payment of money or anything of value, to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, political party or candidate to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage 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 us 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. 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 owned and operated by the government, and doctors and other hospital employees are considered foreign officials for the purposes of the statute. Certain payments made in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products.

Accordingly, if we expand our presence outside of the United States, we will need to dedicate additional resources to complying with the laws and regulations in each jurisdiction in which it plans to operate. Therefore, this 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 development costs.

Packaging and Distribution in the United States

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

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

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.

Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover costs and expenses it may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against it. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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.

EU / Rest of World Government Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, 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 must 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 authorization 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 authorization application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In China specifically, in addition to GCP, the conduct of clinical trials for investigational drugs is subject to the oversight and regulation of the National Medical Products Administration (NMPA), including without limitation to requirement of obtaining formal or tacit (as the case may be) authorization from NMPA for the clinical trials. Investigator-initiated trials of somatic cell products are also strictly regulated in China. Additionally, the use of China's human genetic resources in such clinical trials must strictly comply with human genetic resources and biosecurity regulations in China, such as the Administrative Regulations of the People's Republic of China on Human Genetic Resources, and the Implementing Rules for the Administrative Regulation on Human Genetic Resources, under which the use of China's human genetic resources shall complete mandatory filings and/or approvals with designated authorities. For market approval in China, we need to submit MAA and obtain an NMPA-issued drug registration certificate, which is a centralized procedure for the whole China, and the Center for Drug Evaluation (CDE) of NMPA will conduct the scientific evaluation of the product and make the final decision. For some specific products, such as (i) a drug for the treatment of life-threatening illnesses for which there is no effective treatment approach, and the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value, or (ii) a drug used for

prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug has obvious clinical advantages over existing treatment approach(es), the evaluation and approval procedure of CDE may be expedited.

Drug manufacturing in China must comply with China's Good Manufacturing Practice (GMP) standards. In terms of pricing, drugs not included in national reimbursement programs retain commercial pricing flexibility. However, inclusion in China's national reimbursement drug list requires participation in government-led price negotiations. These negotiations may lead to significant price adjustments to align with public health priorities.

In April 2014, the EU adopted the Clinical Trials Regulation (EU) No 536/2014 (Regulation), which replaced the Clinical Trials Directive 2001/20/EC (Directive), on January 31, 2022. The Clinical Trials Regulation, which is directly applicable in all EU member states (meaning that no national implementing legislation in each EU member state is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials.

To obtain regulatory approval of a medicinal product under EU regulatory systems, we must submit an MAA. The centralized procedure provides for the grant of a single marketing authorization by the European Commission (EC) that is valid across all of the EU, and in the additional countries of the European Economic Area (Iceland, Liechtenstein and Norway). The scientific evaluation of MAAs for Advanced Therapy Medicinal Products (ATMPs) (which comprise gene therapy, somatic cell therapy and tissue engineered medicines) is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies (CAT). The CAT prepares a draft opinion on the quality, safety and efficacy of the ATMP which is the subject of the MAA, which is sent for final approval to the Committee for Medicinal Products for Human Use (CHMP). The maximum timeframe for the evaluation of an MAA for an ATMP is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the EC, which makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major public health interest, particularly from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Products with an orphan designation in the EU can receive ten years of market exclusivity, during which time "no similar medicinal product" for the same indication may be granted a marketing authorization. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the EU where an agreed pediatric investigation plan for pediatric studies has been complied with. The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) the prevalence of such condition is no more than five in 10,000 persons in the EU when the application is made, or (ii) without the benefits derived from orphan status, it is unlikely that the marketing of the medicine would generate sufficient return in the EU to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan designation must be submitted before the application for marketing authorization. The applicant may receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the MAA is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Otherwise, orphan medicine marketing exclusivity may be revoked only in very select cases, such as if: (i) a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder of the authorized orphan product consents to a second application; or (iii) the marketing authorization holder of the authorized orphan product cannot supply enough orphan medicinal product.

All of the aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

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

Regulatory framework in the UK

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK, however, new legislation such as the EU Clinical Trials Regulation is not applicable in the UK. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's standalone medicines and medical devices regulator. On January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. A single United Kingdom-wide marketing authorization is granted by the MHRA for all novel medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. In addition, the new arrangements require all medicines placed on the UK market to be labelled "UK only", indicating they are not for sale in the EU.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. On January 1, 2024, the MHRA put in place a new international recognition framework which means that the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for a new UK marketing authorization. There is now no pre- marketing authorization orphan designation in the United Kingdom. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the United Kingdom market, i.e., the prevalence of the condition in the United Kingdom (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the United Kingdom.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

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

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

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation (EU GDPR) and the United Kingdom's General Data Protection Regulation ("UK GDPR", together with the EU GDPR, "GDPR"). The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of

processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States and other third countries. In addition, the GDPR provides 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 EU, 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 (or £17,500,000 in the UK) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Company may also face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Although the UK is regarded as a third country under the EU's GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. In December 2025, the EC adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the UK's adoption of the Data (Use and Access) Act 2025 (the "DUAA") on 19 June 2025. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the European Economic Area (EEA) remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. There are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework ("Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework). We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost. These mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Restrictions on Transfers of Sensitive Data from the U.S. To China

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. The Department of Justice's January 8, 2025, Rule on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, prohibits transfers of data, including certain health data, biometric identifiers, and human genomic and other omic data, along with biospecimens from which such genomic or omic data can be derived, to countries of concern, including China and Hong Kong, as well as certain individuals and entities associated with those countries. The regulations also restrict or prohibit certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern or related persons, absent limited exemptions or, in some cases, specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, may result in exclusion from participation in federal and state programs and could restrict our ability to use certain vendors, sites, investigators, or service providers in global clinical trials. Given our business operations in China, we may be at a heightened risk of non-compliance and enforcement. The regulation may require us to modify our data processing practices, stop or restrict certain data access or transfers, and dedicate significant resources in an effort to understand and to comply with its requirements. The scope and interpretation of the rule is not yet clear, including with respect to enforcement, and any failure or perceived failure by us to comply with its requirements could damage to our reputation, lead to a loss of business and result in substantial fines and penalties.

U.S. Data Privacy Law

At the federal level, in addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (the FTCA), 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities.

At the state level, numerous state laws govern privacy and security of personal information, including health information. For example, the California Consumer Privacy Act (CCPA), has created certain requirements for data use, sharing and transparency, and provides California residents certain rights concerning their personal information, such as access, correction, deletion and opt out of selling or sharing such data. The CCPA was amended by the California Privacy Rights Act (CPRA) which created a state agency that is vested with authority to implement and enforce the CCPA which is likely to lead to greater risk of enforcement.

Similar laws have been passed and proposed in numerous other states. These laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. Such laws may differ in their scope and enforcement, and may require us to dedicate significant resources in our efforts to comply with them. There are also states that are specifically focused on regulating health information, such as Washington's My Health My Data Act (MHMDA), which became effective on March 31, 2024. The MHMDA imposes restrictions and requirements on the processing and sale of consumer health data and has a private right of action, which further increases compliance risk. Other states, including Connecticut and Nevada, have passed similar laws regulating consumer health data, and additional states are considering and may pass similar laws. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Such enacted and proposed legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

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

Human Capital

As of December 31, 2025, we had 102 full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We have built a strong culture by collaboratively creating company values, a Mission and Vision. We seek input from employees on our culture through regular employee engagement surveys. We optimize employee performance through goal setting and regular written feedback. We offer attractive benefits, including competitive salaries, equity grants, an employee stock purchase plan, excellent health insurance, and a 401(k) match. We are committed to pay equity, regardless of gender, race/ethnicity, or sexual orientation and conduct comprehensive pay equity analyses on a semi-annual basis. During the pay equity reviews, we assess and ensure equality in pay for various groups to ensure fairness. In addition to providing strong benefits packages to employees, we believe in fostering individual and organizational effectiveness by offering our employees various professional development opportunities. We believe that investing in our employees' career growth provides individuals and the organization with the knowledge and skills to respond effectively to current and future business demands and support the organization's development efforts. Our culture is one that actively supports the application of new knowledge and skills on the job. In addition, we recognize several cultural holidays during the year in support of our diverse workforce. In 2026, we plan to

continue adding to our human capital resources as we grow. We are also monitoring the current landscape of wage inflation and labor shortages in connection with our employees' overall compensation.

Corporate Information

We own or have rights to various trademarks, service marks and trade names that we use in connection with the operation of our business. This Annual Report on Form 10-K may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Annual Report on Form 10-K is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K may appear without the ®, ™ or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Available Information

Our Internet address is www.adicetbio.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. In evaluating the Company and our business, you should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our other filings with the SEC, before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment in our common stock. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements and Industry Data" section in this Annual Report on Form 10-K.

Risks Related to Our Business and Industry

Risks Related to Operating History

We have a limited operating history and face significant challenges and expenses as we build our capabilities.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We began operations in November 2014. We have a limited operating history upon which someone can evaluate our business and prospects and is subject to the risks inherent in any early stage company, including, among other things, risks that we may not be able to hire sufficient qualified personnel and establish operating controls and procedures. We currently do not have complete in-house resources to enable our gamma delta T cell platform. As we build our own capabilities, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred net losses since our inception and anticipate that we will incur substantial net losses in the future.

We are an early clinical stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will 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 net losses since our inception. To date, we have financed our operations primarily with proceeds from our license and collaboration agreements and the issuance and sale of our capital stock, including most recently: (i) net proceeds of approximately $19.3 million, after deducting sales agent commissions, but before deducting any expenses related to such sales, from sales of our common stock under our "at-the-market" program in January 2024; (ii) net proceeds of approximately $91.7 million, after deducting the underwriting discount and commissions and other estimated offering expenses, from the sale of our common stock and pre-funded warrants in an underwritten public offering in January 2024; and (iii) net proceeds of approximately $74.8 million, after deducting the underwriting discount and commissions and other estimated offering expenses, from the sale of our common stock and pre-funded warrants in an underwritten registered direct offering in October 2025. For the year ended December 31, 2025, we recorded net loss of $116.8 million. As of December 31, 2025, we had an accumulated deficit of $614.7 million.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seek regulatory approvals for, product candidates based on our gamma delta T cell platform, including prula-cel and ADI-212. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, certain of our existing license and collaboration agreements require cash payments upon the achievement of milestone events, royalties and profit-sharing, or other cash payments. These payment obligations, in addition to any payment obligations we may have under future arrangements with third parties, may have a substantial impact on our business, financial condition and profitability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future

growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects and cause investors to lose all or part of their investments.

Risks Related to Our Product Candidates

Our business is highly dependent on the success of prula-cel. If we are unable to obtain regulatory approval for prula-cel in one or more indications and effectively commercialize this product candidate for the treatment of patients in indications for which we receive approval (if any), our business would be significantly harmed.

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize prula-cel, our most advanced product candidate. In November 2024, we dosed our first LN patient in our Phase 1 clinical study of prula-cel in autoimmune diseases. In April 2025, we expanded enrollment to include patients with SLE in our Phase 1 clinical trial. In July 2025, we reported that the first systemic sclerosis (SSc) patient had been dosed in the second cohort of the Phase 1 clinical trial evaluating prula-cel in autoimmune diseases and we anticipate providing a clinical update in SSc patients in the first half of 2026. We have also opened enrollment for patients with IIM, SPS and AAV and RA. In October 2025, we announced preliminary data from our prula-cel Phase 1 study in patients with LN and SLE.

Our preclinical results or clinical results to date may not predict results for our planned or ongoing trials or any future studies of prula-cel, ADI-212, or any other product candidates. Because of the lack of evaluation of allogeneic products and gamma delta T cell therapy products in the clinic to date, any such product's failure, or the failure of other allogeneic T cell therapies or gamma delta T cell therapies, may significantly influence physicians' and regulators' opinions in regards to the viability of our entire pipeline of allogeneic T cell therapies, which could have a material adverse effect on our reputation. If our gamma delta T cell therapy is viewed as less safe or effective than autologous therapies or other allogeneic T cell therapies, our ability to develop other allogeneic gamma delta T cell therapies may be significantly harmed.

All of our product candidates, including prula-cel and ADI-212, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because prula-cel is our most advanced product candidate, and because our other product candidates are based on similar technology, if prula-cel encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed, which could have a material adverse effect on our business, reputation and prospects.

Our gamma delta T cell candidates represent a novel approach to the treatment of autoimmune diseases and cancer indications that creates significant challenges for us.

We are developing a pipeline of gamma delta T cell product candidates and a novel antibody platform that are intended for use in patients with certain autoimmune diseases and cancers. Advancing these novel product candidates creates significant challenges for us, including:

- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;

- delays in enrolling or inability to enroll subjects in our clinical trials;

- manufacturing our product candidates to our specifications and in a timely manner to support our current and future clinical trials, and, if approved, commercialization;

- sourcing current and future clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;

- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to produce product in a reliable and consistent manner;

- inability to achieve efficacy in autoimmune disease and cancer patients following treatment with our product candidates;

- achieving a side effect profile from our product candidates in autoimmune diseases and cancer indications that makes them clinically and commercially attractive for further development;

- educating medical personnel regarding the potential side effect profile of our product candidates, if approved;

- using medicines to manage adverse side effects of our product candidates which may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;

- conditioning patients with chemotherapy or other lymphodepletion agents in advance of administering our product candidates, which may increase the risk of adverse side effects;

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with development of allogeneic T cell therapies for autoimmune diseases and cancer; and

- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

The success of our business, including our ability to obtain financing and generate any revenue in the future, will primarily depend on the positive efficacy and safety profile and durability of our product candidates in our clinical trials, regulatory approval, successful development and commercialization of our novel product candidates, and our ability to build out our manufacturing capabilities, any of which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety or durability for any of our product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business, which could have a material adverse effect on our results of operations and prospects.

Our product candidates are based on novel technologies, which makes it difficult to predict the likely success of such product candidates and the time and cost of product candidate development and obtaining regulatory approval.

We have concentrated our research and development efforts on our allogeneic gamma delta T cell therapy and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our platform and product candidates and there can be no assurance that any development problems we have experienced or may experience in the future will not cause significant delays or result in unforeseen issues or unanticipated costs, or that any such development problems or issues can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our future clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to the advantages of an allogeneic gamma delta T cell therapy platform relative to other therapies may not materialize or materialize to the degree we anticipate. Further, our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

In addition, the clinical study requirements of the FDA, the European Medicines Agency (EMA) and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Allogeneic gamma delta T cell therapies are novel therapies, with no T cell therapies licensed to date in

the United States or the European Union to treat autoimmune diseases. Approvals by the EMA and FDA for existing autologous CAR T cell therapies, such as Kymriah® and Yescarta®, as well as other pathways to approval, may not be indicative of what these regulators may require for approval of our therapies. Also, while we expect reduced variability in our product candidates compared to autologous products, we do not have significant clinical data supporting any benefit of lower variability. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agencies may require for approval or what such regulatory agencies may require for approval in connection with new product candidates.

Our product candidates may also not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T-cell therapies that have previously been approved or alpha beta T cell therapies that may be approved in the future. Unexpected clinical outcomes could materially and adversely affect our business, results of operations and prospects.

Our product candidates may cause undesirable side effects or have other properties that could halt our clinical development, prevent our regulatory approval, limit our commercial potential or result in significant negative consequences.

Undesirable or unacceptable 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, the EMA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T-cell therapies and those under development have shown frequent rates of cytokine release syndrome and neurotoxicity, and adverse events have resulted in the death of patients. In January 2024, the FDA determined that new boxed warning language related to T-cell malignancies should be included in the labeling for all BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. While we believe our gamma delta T cell approach may lessen such results, similar or other adverse events for our allogeneic gamma delta T cell product candidates may occur and could result in increased government regulation, unfavorable public perception and publicity, potential impacts on enrollment in our clinical trials, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. In addition, while we anticipate our focus on gamma delta T cells may lessen the likelihood of graft versus host disease relative to therapies relying on unrelated alpha beta T cells, similar or other adverse events for our allogeneic gamma delta T cell product candidates may occur.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. A data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Novel therapeutic candidates, such as those we are developing, may result in novel side effect profiles that may not be appropriately recognized or managed by the treating medical staff. We anticipate having to train medical personnel using our product candidates to understand the side effect profile of our product candidates for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in serious adverse events including patient deaths. Based on available preclinical data and clinical experience with other cell therapy agents, the safety profile of our pipeline product candidates is expected to include cytokine release syndrome, neurotoxicity, and possibly additional adverse events. Any of these occurrences may have a material adverse effect our business, financial condition and prospects.

In addition to side effects and adverse events caused by any product candidates we may develop, the conditioning, administration process or related procedures that may be used with our product candidates may also cause adverse side effects. A T cell therapy patient is generally administered cytotoxic drugs to remove stem cells from the bone marrow to create sufficient space in the bone marrow for the modified stem cells to engraft and produce new cells. This procedure causes side effects and, among other potential risks, can transiently compromise the patient's immune system, known as neutropenia, and reduce blood clotting, known as thrombocytopenia. If we are unable to demonstrate that such adverse events were caused by the conditioning regimens used, administration process or related procedure, or were otherwise unrelated to the therapy candidate being studied, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we may develop for any or all target indications. Even if we are able to demonstrate that adverse events are not related to our product candidate, such occurrences could affect patient recruitment, the ability of enrolled patients to complete the clinical trial or the commercial viability of any product candidates that obtain regulatory approval.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If the FDA believes that the safe and effective use of any of our product candidates depends on an in vitro diagnostic, then it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our product candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities. In January 2024, FDA announced its intention to initiate the reclassification process for most in vitro diagnostics, including companion diagnostics. Further, FDA indicated that in addition to the reclassification process, FDA will continue taking a risk-based approach in the initial classification of individual in vitro diagnostics to determine whether a new test may be classified into class II through the de novo classification process. In so doing, FDA indicated that it may regulate most future companion diagnostics as class II devices. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, any of which may prevent us from completing our clinical trials or, if approved, commercializing our product candidates on a timely or profitable basis, if at all.

Risks Related to Clinical Trials

Our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

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 both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved.

In addition, for the ongoing Phase 1 study of prula-cel and any future clinical trials that may be completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit marketing applications for our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application,

approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Any of the foregoing could have a material adverse effect on our business, prospects and financial condition.

We may not be able to file IND applications, or comparable regulatory submissions outside the United States, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or analogous regulatory authorities may not permit us to proceed.

We have received clearance for INDs to evaluate prula-cel in clinical trials in a number of indications. Our pipeline also includes ADI-212, an optimized next-generation gene-edited and armored clinical candidate targeting prostate specific membrane antigen (PSMA). We expect to submit a regulatory filing for ADI-212, such as an IND application or comparable regulatory submission outside the United States, for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in the third quarter of 2026. We aim to submit a new regulatory submission, such as an IND application or equivalent every 12-18 months. We may not be able to make these filings on the timelines we expect, which may cause delays in commencing additional clinical trials. Even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND application or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. Moreover, we cannot be sure that submission of an IND application for any of our other product candidates will result in the FDA allowing trials to begin, or that, once begun, issues will not arise that result in a decision by us, by independent institutional review boards (IRBs) or independent ethics committees, or by the FDA, the EMA or other regulatory authorities to suspend or terminate clinical trials. For example, we may experience manufacturing delays or other delays with IND-enabling studies or the FDA, the EMA or other regulatory authorities may require additional preclinical studies that we did not anticipate. The inability to initiate clinical trials any of our product candidates on the timeline we currently anticipate or at all could have a material adverse effect on our business, results of operations and prospects.

We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could result in the suspension, or termination, or clinical hold of such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our ongoing or future clinical studies may not be successful. Factors that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- obtaining regulatory authorization to begin a trial, which may include the evaluation of a companion diagnostic, if applicable;
- delays in reaching an agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a safety finding that presents unreasonable risk to clinical trial participants; a negative finding from

an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in recruiting eligible patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs or other third parties to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's Good Clinical Practices (GCPs) requirements or applicable regulatory guidelines in other countries;
- challenges in transferring manufacturing processes to any new contract development and manufacturing organizations (CDMOs) or our manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients' complete participation in a study or failure to return for post-treatment follow-up;
- developing and implementing processes and procedures with collaborators, if applicable, relating to the collection and transfer of patient samples and the timely performance of a companion diagnostic on such samples;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials;
- political conditions or conflicts in regions where we conduct or may seek to conduct our clinical trials; and
- manufacturing challenges, including delays in testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Timelines for filing INDs for our product candidates are dependent on further preclinical and manufacturing success, which we work on with various third parties. We cannot be sure that we will be able to submit our INDs in a timely manner, if at all, or that submission of an IND application or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension, termination, or clinical hold of such clinical trials.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have

patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

In our current and planned clinical trials of our product candidates, we have contracted with and expect to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. Any such difficulties could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending, terminating, or issuing a clinical hold on one or more of our clinical trials, and which could jeopardize regulatory approval. Medicines used at centers to help manage adverse side effects of prula-cel or our other product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates, any of which could have a material adverse effect on our ability to obtain regulatory approval and commercialize on the timelines anticipated or at all, which could have a material adverse effect on our business and results of operations.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the patient eligibility criteria and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the number and location of clinical sites, including the potential impact of global or regional conflicts;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent unproven methods for the treatment of autoimmune diseases and cancer, potential patients and their doctors may be inclined to use conventional therapies rather than enroll in our clinical trial. For cancer, they may use chemotherapy and hematopoietic cell transplantation or autologous CAR T cell therapies. Patients eligible for allogeneic CAR T cell therapies but ineligible for autologous CAR T cell therapies due to aggressive cancer and inability to wait for autologous CAR T cell therapies may be at greater risk for complications and death from therapy. For autoimmune diseases, potential patients may use therapies that focus on symptomatic relief.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our gamma delta T cell product candidates are based on novel technologies and will require the creation of inventory of mass-produced, "off-the-shelf" products, we expect that we will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with autoimmune diseases and cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products, which is expected to have a material adverse effect on our financial position and ability to achieve profitability.

As a result, because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, in January 2024, we announced we had deprioritized enrollment of large B cell lymphoma patients in our Phase 1 clinical trial of prula-cel in non-Hodgkin's lymphoma and in September 2024 we announced a strategic prioritization to focus prula-cel development resources on autoimmune indications. In July 2025, we also announced that we discontinued the development of ADI-270 for patients with metastatic/advanced clear renal cell carcinoma to prioritize corporate resources on prula-cel and ADI-212. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business, financial condition and results of operations.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We are currently conducting research and development activities outside of the United States, including in China, and plan to continue to globally develop our product candidates. Accordingly, we expect that our development programs will be subject to additional risks related to operating in foreign countries, including but not limited to:

- differing and changing regulatory requirements in foreign countries, including for clinical trial activities and product approvals;
- unexpected changes in tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability and/or armed conflicts in particular foreign countries and markets;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- increasing geopolitical tensions between the U.S. and other countries in which we may operate and changes in a specific country's or region's political or economic environment especially with respect to a particular country's treatment of or stance towards other countries;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Furthermore, conducting clinical trials in countries outside the United States presents additional risks, including political and economic risks, such as armed conflict and economic embargoes or boycotts. We currently conduct and plan in the future to initiate clinical trials of prula-cel at sites outside of the United States, which may be located in countries involved in or impacted by political unrest and conflicts. For example, while we currently do not expect armed conflicts, such as the conflicts between Russia and Ukraine or Israel and Hamas, or related developments to have a significant impact on our ability to obtain results from our clinical trials, further escalation (whether in these countries or surrounding areas) may adversely affect our ability to adequately conduct certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence, or other governmental action or other events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in such countries and surrounding regions. Clinical trial sites may suspend or terminate the trials being conducted and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in such trials. Alternative sites in these areas may not be available and we may need to find other countries to conduct the relevant trials. Furthermore, military action may prevent the FDA or other regulatory agencies from inspecting clinical sites in these countries. Such interruptions may delay our plans for clinical development and approvals for our product candidates.

We have conducted, and may in the future conduct, certain clinical trials for our product candidates outside of the U.S. However, the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We conducted our Phase 1 clinical trial for prula-cel in RA outside the U.S., and may conduct one or more of our subsequent clinical trials for our product candidates outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are 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. For studies that are conducted only at sites outside of the U.S. and not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, and require us to conduct additional clinical trials. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. If the FDA does not accept data from our clinical trials of our product candidates, we would likely need to conduct additional clinical trials, which would be costly and time consuming and could delay or halt our development of our product candidates.

These and other risks associated with our potential international operations may materially adversely affect our ability to develop our product candidates and attain or maintain profitable operations, which could have a material adverse effect on our business and results of operations.

Risks Related to Marketing Our Product Candidates

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new therapies initially only for use in patients who are currently not adequately treated with currently approved therapies. We expect to initially seek approval of prula-cel and our other product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials, including potentially comparative trials against approved therapies. We are also targeting a similar patient population as autologous CAR T-cell product candidates, including approved autologous CAR T-cell products. Our therapies may not be as safe and effective as autologous CAR T-cell therapies and may only be approved for patients who are ineligible for autologous CAR T-cell therapy.

Our projections of both the number of people who have the indications we are targeting, as well as the subset of people with these indications in a position to receive second or later lines of therapy and 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, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

One of our core strategies is to pursue clinical development of additional product candidates beyond prula-cel. Our pipeline also includes ADI-212, an optimized next-generation gene-edited and armored clinical candidate targeting PSMA. We plan to submit one new IND to the FDA every 12-18 months, including a regulatory filing for ADI-212 for the treatment of mCRPC in the third quarter of 2026. Developing, obtaining regulatory approval for and commercializing additional gamma delta T cell product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market our product candidates for the treatment of our targeted indications, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate which could have a material adverse effect on our business and prospects.

We currently have no marketing and sales organization and as a company have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. We may develop a marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements with third parties regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that it will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product that receives regulatory approval in the United States or overseas. If we are unable to successfully market and distribute our products, either on our own or in collaboration with third parties, our business, results of operations and prospects could be materially adversely affected.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds, drugs, or biological products that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Specifically, engineered T cells face significant competition in both the CAR and T cell receptor (TCR) technology space from multiple companies. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is affected by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Risks Related to Manufacturing

Although we have commenced manufacturing operations at our manufacturing facility, we currently depend on the ability of our third-party suppliers and manufacturers with whom we contract to perform adequately, particularly with respect to the timely production and delivery of our product candidates, including prula-cel. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

Although we commenced manufacturing operations at our Redwood City facility, we rely and expect to continue to rely to a significant extent on third parties for the manufacture of our product candidates for preclinical and clinical development. We may not be able to achieve clinical or commercial manufacturing and cell processing on our own or through our CDMOs, including timely supply of "off-the-shelf" product to satisfy demands to support clinical trials of any of our product candidates. To the extent we are not able to obtain timely supply of "off-the-shelf" product, the anticipated timing for our clinical trials and the development of our product candidates could be adversely impacted. Very few companies have experience in manufacturing gamma delta T cell therapy derived from blood of unrelated donors, and gamma delta T cells require several complex manufacturing steps before being available as a mass-produced, "off-the-shelf" product. We have limited experience in managing the allogeneic gamma delta T cell engineering process, and our allogeneic processes may be more difficult or more expensive than the approaches taken by our competitors. We cannot be sure that the manufacturing processes employed by or on our behalf will result in T cells that will be safe and effective.

Our operations remain subject to review and oversight by the FDA and the FDA could object to our use of any manufacturing facilities. Even if our product candidates are approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practices (cGMPs) and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The occurrence of any of such problems could adversely impact the availability of products for our clinical trials and commercial sale. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We have experienced manufacturing delays due to these issues in the past and cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

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

We may fail to manage the logistics of storing and shipping our product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients.

We may also experience both internal and external manufacturing difficulties due to resource constraints or as a result of labor disputes. We have experienced external manufacturing difficulties in the past; if we were to continue to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized, which could have a material adverse effect on our business, results of operations and prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Although we announced a workforce reduction in July 2025, we expect that we will have a need to recruit and hire qualified personnel as we advance our programs and expand operations. Our recent workforce reduction could impede future recruiting and hiring efforts. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines.

We conduct substantially all of our operations at our facilities in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in this market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control. Declines in our stock price generally reduce the value of equity awards granted to its employees. To the extent our stock price declines, our ability to incentivize, retain or attract qualified talent could be negatively impacted. Such declines in stock price may result in additional "underwater" stock options held by certain employees and officers. For example, in August 2024, certain of our executive officers entered into an option cancellation agreement to surrender certain underwater stock options.

The value of our stock options may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our

key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. To provide added incentives to retain and motivate key contributors, our board of directors approved a stock option repricing in August 2023. Despite this, we may have difficulty retaining key personnel, which could adversely affect our business and further development of our product candidates.

We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

We expect to spend a substantial amount of capital for the clinical development of our product candidates, including the ongoing and future clinical trials for prula-cel and preparations for a regulatory filing for ADI-212. We will need substantial additional financing to develop our products and implement our operating plans. In particular, we will require substantial additional financing to enable commercial production of our products and initiate and complete registration trials for multiple products. Further, if approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of the date of this Annual Report on Form 10-K, we believe that with $158.5 million in cash, cash equivalents, restricted cash and short-term investments in treasury securities as of December 31, 2025, we are capitalized into the second half of 2027. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. In addition, certain of our license and collaboration agreements require us to make cash payments upon the achievement of certain milestone events. In the event we are unable to meet the payment obligations under these agreements, the agreements may be terminated in accordance with the terms of such agreements. Further, we could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Additionally, United States and global economic uncertainty, higher interest rates and diminished credit availability may limit our ability to incur indebtedness on favorable terms. Furthermore, the impact of geopolitical tension, such as a deterioration in the bilateral relationship between the United States and China, an escalation in conflict between Russia and Ukraine or the ongoing armed conflict in Israel and the Gaza strip, including any resulting sanctions, export controls or other restrictive actions, also could lead to disruption, instability and volatility in the global markets, which may have an impact on our ability to obtain additional funding.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We have grown rapidly and will need to continue to grow the size of our organization, and it may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we have transitioned into operating as a public company, we have rapidly expanded our employee base. Current and future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants, pursuant to arrangements which expire after a certain period of time, to provide certain services, including certain research and development as well as general and administrative support. 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 or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain 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 our product candidates and, accordingly, may not achieve our research, development and commercialization goals, which could have a material adverse effect on our business, results of operations and prospects.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. For instance, our License and Collaboration Agreement (the Regeneron Agreement) with Regeneron Pharmaceuticals, Inc. (Regeneron) requires significant research and development commitments that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction, which could have a material adverse effect on our business and results of operations.

Our cash preservation activities, including the workforce reduction plan, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In July 2025, we implemented our workforce reduction plan. In connection with the workforce reduction plan, we expect to incur costs of approximately $2.3 million, which are primarily one-time severance benefits. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our workforce reduction plan may be disruptive to our operations. For example, headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of remaining employees.

Risks Related to Doing Business in China and Our International Operations

The pharmaceutical industry in China is highly regulated and such regulations, including the Foreign Investment Law and the "negative list," are subject to change which may affect development approval and commercialization of our product candidates.

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the development, approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For example, under the People's Republic of China (PRC) law, before we or our subsidiaries commence a clinical trial with Shanghai Adicet Biotechnology Co., Ltd., (Shanghai Adicet), an approval or filing, as the case may be, needs to be obtained in advance for any projects in respect of human genetic resources in order to collect any biological samples that contain the genetic material of Chinese human subjects. Any failure to obtain such approval or filing could cause such projects to be suspended by governing authorities, and may result in fines. Investigator-initiated trials cannot be implemented in a medical and healthcare institution without first being approved by such medical and healthcare institutions. Such medical and healthcare institutions shall file such approval to the medical and healthcare authority which issues its operating license for record. Furthermore, under relevant PRC laws, a license for use of laboratory animals is required for performing experimentation on animals. Any failure to fully comply with such requirements may result in the invalidation of our experimental data. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

In addition, the Foreign Investment Law in China grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list" published by the Ministry of Commerce, and the National Development and Reform Commission (2024 Negative List). We and our PRC subsidiaries, Adicet (Shanghai) Biotechnology Co., Ltd. (Adicet Shanghai), and Shanghai Adicet, each a wholly foreign-owned enterprise (WFOE), are currently considered to be a foreign invested entity in China.

The 2024 Negative List provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies. To date, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" and the application of this regulation remains unclear. If discovering and developing our allogeneic gamma delta T cell therapies are deemed by relevant PRC regulatory agencies as falling into the category of "human stem cell or gene diagnostic and therapeutic technologies," Adicet Shanghai and Shanghai Adicet would be prohibited from engaging in the research or development of such technologies. It is also noted that in September 2024, Ministry of Commerce, National Healthcare Commission and National Medical Products Administration of PRC jointly announce a pilot policy (2024 Pilot Policy) to allow foreign invested entities in Free Trade Zone of Beijing, Shanghai, Guangdong and Hainan to develop human stem cell or gene diagnostic and therapeutic technologies, pursuant to which Shanghai Adicet, whose registered address is within the territory of Free Trade Zone of Shanghai, conduct our research and development activities in PRC.

Any of the above factors may affect the development, approval and commercialization of our product candidates, which could have a material adverse effect on our business and financial condition.

The uncertainties in the PRC legal system regarding the Foreign Investment Law may subject our contractual arrangements to different interpretations or enforcement challenges, or subject us to severe penalties or force us to relinquish our interests in our operations.

In May 2024, we formed Adicet Shanghai, located in Shanghai, PRC, as a wholly owned subsidiary of Adicet Therapeutics. Through Adicet Shanghai, we operate our business in PRC pursuant to a series of contractual arrangements between Adicet Shanghai and Shanghai Adicet, and the Shanghai Adicet's shareholders, which enable us to (i) direct the activities of Shanghai Adicet that most significantly impact Shanghai Adicet's economic performance, (ii) receive substantially all of the economic benefits of Shanghai Adicet and its subsidiary, and (iii)

have an exclusive option to purchase all or part of the equity interests and assets in Shanghai Adicet, when and to the extent permitted by PRC laws. As a result of these contractual arrangements, Adicet Therapeutics is considered the primary beneficiary of Shanghai Adicet and Shanghai Adicet's subsidiaries (if any) for accounting purposes and is able to consolidate the financial results of Shanghai Adicet in the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. Investors in our common stock do not hold any ownership interest, directly or indirectly, in Shanghai Adicet in China, and we merely have a contractual relationship with the operating entity in China.

Our PRC legal counsel based on its understanding of the relevant laws and regulations, is of the opinion that (i) the ownership structure of Adicet Shanghai and Shanghai Adicet are in compliance with applicable PRC laws or regulations and (ii) such contractual arrangements constitute valid, legal and binding obligations enforceable against each party of such agreements in accordance with the terms of each agreement, and will not result in any violation of PRC laws or regulations currently in effect. However, our PRC legal counsel has also advised us that there are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules. Accordingly, the PRC regulatory authorities may take a view that is contrary to the opinion of our PRC legal counsel.

Following the 2024 Pilot Policy which allows foreign invested entities in Free Trade Zone of Beijing, Shanghai, Guangdong and Hainan to develop human stem cell or gene diagnostic and therapeutic technologies, Adicet Therapeutics entered into an equity transfer agreement with the then-stockholders of Shanghai Adicet to acquire 100% equity interests of Shanghai Adicet from its then-stockholders (the Acquisition). In connection with the Acquisition, tax filings and registration with the Administration for Market Regulation of Shanghai Adicet were completed in August 2025. Upon completion of the registration, Shanghai Adicet is now a wholly owned subsidiary of Adicet Therapeutics and will continue to conduct research and development activities in China, and the contractual arrangements between Adicet Shanghai and Shanghai Adicet is terminated accordingly.

Changes in U.S. and Chinese regulations may impact our business, financial condition, and our operating results.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with certain operations based in China. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct research activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with certain operations based in China, capital controls or tariffs, may affect the competitive position of our product candidates, the hiring of scientists and other research and development personnel, the demand for our product candidates, the import or export of raw materials in relation to drug development, our ability to raise capital, or prevent us from selling our product candidates in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with certain operations based in China, such as us. For example, in 2021, the Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which he stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with certain operations based in China. The statement also addressed risks inherent in companies with variable interest entity structures.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data (the Scientific Data Measures), which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, researchers conducting research funded, at least in part, by the PRC government may be required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Currently, as the term "state secret" is not clearly defined, there is

no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to specific administrative penalties imposed by those government authorities.

Compliance with China's Data Security Law, Cyber Security Law, Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business.

China has implemented an extensive legal framework governing data security, protection and privacy. China's Data Security Law took effect in September 2021 and provided that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government.

Additionally, China's Cyber Security Law, promulgated by the Standing Committee of the National People's Congress, which came into effect in 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets Protection, State Cryptography Administration and other government authority in 2007, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopts a multi-level protection scheme (MLPS), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity's information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Also, the Standing Committee of the National People's Congress released the Personal Information Protection Law, which became effective in 2021. The Personal Information Protection Law provided a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to Renminbi 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. Meanwhile, the State Council of the PRC promulgates the Regulations on the Administration of Network Data Security, which came into effect on January 1, 2025, and put forward a series of detailed requirements regarding data protection. With regard to the cross-border transfer of personal information, the Cyberspace Administration of China (CAC) released the Regulations on Promoting and Regulating Cross-border Data Flows in 2024. The Regulations on Promoting and Regulating Cross-border Data Flows establishes the latest regulatory framework for the cross-border transfer of personal information. The personal information handler should pass the security assessment, submit the standard contract signed for the provision of personal information abroad, or be certified by a specialized agency for the protection of personal information authentication before the cross-border transfer of the personal information when certain threshold provided in the Regulations on Promoting and Regulating Cross-border Data Flows is reached. Over the past year, the CAC has issued regulatory measures focused on data security and cross-border data flows, including the February 14, 2025, "Administrative Measures for Personal Information Protection Compliance Audits", June 27, 2025, "Guidelines for the Declaration of Data Outbound Security Assessment (3rd Edition)", and September 11, 2025, "Measures for the Administration of National Cybersecurity Incident Reporting". In addition, the National Information Security Standardisation Technical

Committee (TC260) issued its finalized "Cybersecurity Standard Practice Guidelines: Personal Information Protection Compliance Audit Requirements". The CAC has also increased its enforcement activity, including a regulatory sweep focused on app and SDK developers. We expect the CAC and additional Chinese regulators to maintain a high level of scrutiny in the data security, cross-border data transfer and artificial intelligence space.

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the HGR Regulation), promulgated by the State Council, came into effect in 2019 and was thereafter revised in 2024. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required filing and information backup procedures have been gone through. In 2020, the Standing Committee of the National People's Congress promulgated the Biosecurity Law of the PRC, which was later amended in 2024, and it reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the HGR Implementing Rules), which came into effect in 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China's human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China's human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with China's new Cyber Security Law and Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market.

Pharmaceutical companies operating in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our current and planned operations in China.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product

development activities, clinical trials, registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business by impacting Shanghai Adicet through which we conduct certain research and development activities. The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

We may be exposed to liabilities under the FCPA, and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. 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.

In addition, 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.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In 2012, the State Administration of Foreign Exchange (SAFE) promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the Stock Option Rules). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary

of such overseas listed company, and complete certain procedures. Our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our employees under Chinese law.

Risks Related to Business Disruptions

Business disruptions, including armed conflicts, could substantially delay our clinical trials or seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMO, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, armed conflicts, medical epidemics, such as public health crises or other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to manufacture our product candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster, the severity and frequency of which may be amplified by global climate change, or other business interruptions. We have facilities located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Global conflicts may increase the likelihood of supply or clinical trial interruptions which could impact our ability to find the materials we need to make our product candidates or conduct our clinical trials.

Ongoing conflicts, including conflicts between Russia and Ukraine and Israel and Hamas and a deterioration in the bilateral relationship between the United States and PRC, may increase the likelihood of supply or clinical trial interruptions and hinder our ability to find the materials we need to make our product candidates or conduct our clinical trials. Supply disruptions make it more difficult for us to find favorable pricing and reliable sources for the materials we need, which increases pressure on our costs and increases the risk that we may be unable to acquire the necessary goods and services to successfully manufacture our product candidates. If we were to encounter difficulties related to global conflicts, our ability to provide our product candidates and to conduct our preclinical studies or clinical trials, such as our ongoing, planned, or future clinical trials of prula-cel, could be delayed or suspended. Any delay or interruption in the supply of trial materials or disruption to the clinical trial itself could delay the completion of such trials, increase the costs associated with maintaining these research and development activities and, depending upon the period of delay, require us to commence new preclinical studies or clinical trials at additional expense or terminate such trials completely.

Changes in the political and economic policies or in relations between China and the United States may affect our business, financial condition, and results of operations.

Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a certain degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. The Chinese government may intervene in or influence our operations, which could result in a change in our operations. Any economic downturn, whether actual or perceived, further decrease in economic growth rates or an otherwise uncertain economic outlook could affect our business, financial condition and results of operations. In addition, the global macroeconomic environment is facing challenges. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions, and our business operations in the long term. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. Due to our operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in China could affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United

States or other governments deteriorate and geopolitical tensions between China and the United States increase, our business in China and United States may also be affected.

Inadequate funding and/or staffing for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the approval of our product candidates rely, which would negatively impact our business.

Without appropriation of necessary funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, adequate staffing, furloughs, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, in 2025, changes and cuts in FDA staffing have been reported as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or marketing applications. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

For example, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, in some instances have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs or a widespread freeze on federal funding continues or occurs in the future, it 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, including our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

In addition, with the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and manner in which the U.S. government will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regualotry frameworks in a manner that could impact our operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We operate globally and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, the implementation of tariffs by the U.S. government have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented and may in the future implement additional retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Healthcare Regulation

Our relationships with customers, physicians including clinical investigators, CROs and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, transparency laws, government price reporting and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, vendors, or other agents violate these laws, we could face substantial penalties.

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. For further discussion on U.S. healthcare regulations, see the section entitled "*Business–Government Regulation and Product Approval—Other U.S. Healthcare Laws and Compliance Requirements*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending themselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, debarment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Data protection, privacy and similar laws restrict access, use, and disclosure of information, and failure to comply with or adapt to changes in these laws could materially and adversely harm our business.

We are subject to federal and state data privacy and security laws and regulations, and laws and expectations relating to privacy continue to evolve. Changes in these laws may limit our data access, use and disclosure, and may require increased expenditures. In addition, data protection, privacy and similar laws protect more than patient information and, although they vary by jurisdiction, these laws can extend to employee information, business contact information, provider information, and other information relating to identifiable individuals. For example, the California Consumer Privacy Act (CCPA) requires covered businesses to, among other things, provide notices to California consumers regarding the collection, use and disclosure of such consumers' personal information and afford such consumers new rights with respect to their personal information, including the right to opt out of certain sales of

personal information. In addition, the California Privacy Rights Act (CPRA), which amended the CCPA, became effective on January 1, 2023 and imposed additional obligations on companies covered by the legislation. The CPRA modified the CCPA and has created a state agency that is vested with authority to implement and enforce the CCPA. There are also states that are specifically regulating health information or specific types of information, such as biometric information, and regulators and legislators are continuing to propose and adopt new laws and regulations protecting privacy and certain types of personal information. For example, Washington's My Health My Data Act (MHMDA) regulates the collection and sharing of consumer health information and includes a private right of action, which further increases compliance risks.

Given the breadth and depth of changes in privacy, data protection and consumer protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and ongoing review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that store, process or transfer personal data on our behalf. Compliance with such laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Any failure or perceived failure by us to comply with such laws and regulations could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. There is also the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation (EU GDPR) and the United Kingdom's General Data Protection Regulation ("UK GDPR", together with the EU GDPR, "GDPR"). The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for controllers of personal data, including stringent requirements relating to ensuring an appropriate legal basis or condition applies to the processing of personal data, stricter requirements relating to obtaining consent from data subjects, stricter requirements around the collection of sensitive data (such as health data), expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, implementing safeguards to protect the security and confidentiality of personal data and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the GDPR. On June 19, 2025, the UK Government adopted the Data (Use and Access) Act 2025 (the "DUAA"). This may lead to additional compliance costs and could increase our overall risk. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU GDPR, the European Commission issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted ("UK Adequacy Decision"). In December 2025, the European Commission adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The UK government has confirmed that personal data transfers from the United Kingdom to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. The European Commission has issued forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The UK is not subject to

the EC's new standard contractual clauses but has published the UK International Data Transfer Agreement and International Data Transfer Addendum to the new standard contractual clauses (the IDTA), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, and must be in place for all existing transfers from the UK from March 21, 2024 Companies relying on standard contractual clauses to govern transfers of personal data to third countries (in particular the United States) will need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework has already been challenged and could be invalidated like its predecessor frameworks. We are required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million (or £17.5 million in the UK) or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR or UK GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

In addition, many other jurisdictions outside of Europe are also considering and/or enacting new and/or amended comprehensive data protection legislation. We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs. Because the interpretation and application of many privacy and data protection laws (including the GDPR), commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

Data protection, privacy and similar laws protect more than patient information and, although they vary by jurisdiction, these laws can extend to employee information, business contact information, provider information, and other information relating to identifiable individuals. Failure to comply with these laws may result in, among other things, civil and criminal liability, negative publicity, damage to our reputation, and liability under contractual provisions. In addition, compliance with such laws may require increased costs to us or may dictate that we not offer certain types of services in the future.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act (AI Act) — the world's first comprehensive AI law – which has entered into force on August 1, 2024 and most provisions of which will become effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Furthermore, in the U.S., a number

of states have proposed and passed laws regulating various uses of AI, and federal regulators have issued guidance affecting the use of AI in regulated sectors.

We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security, including as informed by regulatory guidance. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Risks Related to Our Financial Position

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

We have in the past failed and may in the future fail to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended. We will remain a non-accelerated filer as long as we qualify to be a "smaller reporting company" under Rule 12b-2 of the Exchange Act, which will be for as long as either (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. To continue to achieve and maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, from time to time we may not be able to conclude that our internal control over financial reporting is effective as required by Section 404.

We expect to continue our efforts to improve our control processes, though there can be no assurance that our efforts will ultimately be successful or avoid potential future material weaknesses, and we expect to continue incurring additional costs as a result of these efforts. If we are unable to successfully remediate any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities

law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

We have previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate a material weakness or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During the fourth quarter of 2024, we identified a material weakness in our internal control over financial reporting which relates to cash disbursements. We concluded that this material weakness in our internal control over financial reporting occurred due to our internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements. We concluded that the remediation steps taken have been sufficient to remediate this material weakness as of the date of our Annual Report on Form 10-K for the year ended December 31, 2024.

We are focused on designing and implementing effective internal controls measures to improve our evaluation of disclosure controls and procedures, including internal control over financial reporting, and remediating the material weaknesses. We have taken steps to remediate including consulting with experts on technical accounting matters and in the preparation of our financial statements.

However, we cannot assure you that the measures we are taking to remediate the material weaknesses will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such a case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of Nasdaq, investors may lose confidence in our financial reporting and our stock price may decline as a result.

Risks Related to Taxation

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

Under Section 382 and Section 383 of the Internal Revenue Code of 1986 (IRC), as amended, if a corporation undergoes an "ownership change" (generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by a greater than 50 percentage point change (by value) over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2025, we had federal net operating loss carryforwards of approximately $472.7 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above or subject to other limitations, which could potentially result in increased future tax liability to us.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (IRS) and the U.S. Treasury Department. For example, the One Big Beautiful Bill Act (OBBBA) was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the IRC, in taxable years beginning after December 31 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development

performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future.

In addition, since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. You are urged to consult your tax advisor regarding the implications of potential changes in tax laws on an investment in our common stock.

Risks Related to Third Parties

If our collaboration with Regeneron is terminated, or if Regeneron materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed.

Our financial performance may be significantly affected by our Regeneron collaboration that we have entered into to develop next-generation engineered immune-cell therapeutics with fully human CARs and TCRs directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells. Under the Regeneron Agreement, Regeneron paid us a non-refundable upfront payment of $25.0 million and an aggregate of $20.0 million of additional payments for research funding as of December 31, 2025, and we will collaborate with Regeneron to identify and validate targets and develop a pipeline of engineered immune-cell therapeutics for selected targets. Regeneron has the option to obtain development and commercial rights for a certain number of the product candidates developed by the parties, subject to an option payment for each product candidate. On January 28, 2022, we received a payment of $20.0 million from Regeneron for exercise of its option to license exclusive rights to ADI-002, and we completed the transfer of the associated license rights to Regeneron in the first quarter of 2022. If Regeneron exercises its option on a given product candidate, we then have an option to participate in the development and commercialization for such product. If we do not exercise our option, we will be entitled to royalties on any future sales of such products by Regeneron. We did not exercise our option to participate in the development and commercialization of ADI-002. In addition to developing CARs and TCRs for use in novel immune-cell therapies as part of the collaboration, Regeneron will have the right to use these CARs and TCRs in our other antibody programs outside of the collaboration. Regeneron will also be entitled to royalties on any future sales of products developed and commercialized by us under the agreement. If Regeneron were to terminate our collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in development and/or commercialization efforts and result in substantial additional costs to us. Termination of such collaboration agreement or the loss of rights provided to us under such agreement may create substantial new and additional risks to the successful development and commercialization of our products and could materially harm our financial condition and operating results.

Regeneron may change its strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us under the agreement. Regeneron has a variety of marketed products and product candidates either by itself or under collaboration with other companies, including some of our competitors, and the corporate objectives of Regeneron may not be consistent with our best interests. Regeneron may change its position regarding its participation and funding of our and Regeneron joint activities, which may impact our ability to successfully pursue the program.

Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have entered, and plan to enter, into collaborations with other companies, including our collaboration agreement with Regeneron, our discovery agreement with Twist Bioscience Corporation (Twist), our license and

collaboration agreement with CRISPR Therapeutics AG (CRISPR), and our license agreement with the City of Hope, that we believe can provide us with additional capabilities beneficial to our business. For example, the collaboration with Regeneron has provided us with important technologies, expertise and funding for our programs and technology. Under our discovery agreement with Twist, Twist will utilize its proprietary platform technology to assist us with the discovery of novel antibodies related to our gamma delta T cell therapy programs. Further, our license and collaboration agreement with CRISPR provides us with certain propriety gene-editing technology, including the CRISPR/Cas platform, material to supporting the research, development and potential commercialization of ADI-212. Additionally, our non-exclusive license with the City of Hope provides access to their proprietary cytokine expression technology for cellular immunotherapy, which may also be material to the research, development and potential commercialization of ADI-212. We may receive additional technologies, expertise and funding under other collaborations in the future. If any of our existing or potential future collaboration partners does not perform in the manner that we expect or fulfill their responsibilities in a timely manner or at all, the research, clinical development, regulatory approval and commercialization efforts related to the product candidates that are the subject of such collaborations, or that potential future collaboration partner, could be delayed or terminated. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected.

Our existing collaborations, and any future collaborations we enter into, may pose a number of additional risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may dispute the amounts of payments owed;
- 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 or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may 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 develop independently, or with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the 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 products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- collaborators may dispute ownership or rights in jointly developed technologies or intellectual property;
- collaborators may fail to comply with applicable legal and regulatory requirements regarding the development, manufacture, sale, distribution or marketing of a product candidate or product;
- collaborators with sales, marketing, manufacturing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the sale, marketing, manufacturing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, payment obligations or the preferred course of discovery, development, sales or marketing, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional and burdensome responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend their or our relevant intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation and liability;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination or cessation, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates, or potentially lose access to the collaborator's intellectual property.

If our collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding or support we expect under these agreements, our development and commercialization of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product discovery, development, regulatory approval and commercialization described in these risk factors also apply to the activities of our therapeutic collaborators.

In addition to existing collaborations, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for discovery, development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators because, for example, third parties also have rights to allogeneic T cell technologies. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail discovery efforts or the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential manufacture or commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our expense. If we elect to fund and undertake discovery, development, manufacturing or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary discovery, development, manufacturing and commercialization activities, we may not be able to further develop our product candidates, manufacture the product candidates, bring them to market or continue to develop our technology and our business may be materially and adversely affected.

We are subject to certain exclusivity obligations under our agreement with Regeneron.

Under the Regeneron Agreement, both parties have obligations not to research, develop, manufacture or commercialize an immune cell product (ICP) with the same target as one being developed under a research program or commercialized by a party (and royalty bearing under the agreement), for so long as such activities are occurring. These exclusivity obligations are limited to engineered gamma delta immune cells to targets reasonably considered to have therapeutic relevance in cancer. If our collaboration with Regeneron is not successful, including any failure caused by the risks listed in the preceding paragraphs, and the agreement and research programs are not terminated, we may not be able to enter into collaborations with other companies with respect to ICPs and our business could be adversely affected.

The restrictions on internal development under the Regeneron Agreement could lead to delays in our ability to discover and develop gamma delta immune cell therapeutics for targets not covered by the collaboration with Regeneron and loss of opportunities to obtain additional research funding and advance our own technologies separately from the Regeneron collaboration. If we are delayed in our ability to advance our technologies due to the Regeneron Agreement, our business could be harmed.

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We currently depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us.

We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely heavily and expect to continue to rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, 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 before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs requirements, and if applicable, cGTP requirements, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials will involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We currently rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

In addition to our own internal manufacturing capabilities, we currently utilize, and expect to continue to utilize, third parties to manufacture our product candidates. If the field of cell therapy continues to expand, we may encounter increasing competition and costs for these materials and services. Demand for third-party manufacturing in cell therapy may grow at a faster rate than existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of our product candidates at an acceptable cost or at all. We have also not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing at a commercial scale and therefore may be unable to create an inventory of mass-produced, "off-the-shelf" product to satisfy demands for any of our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, we anticipate reliance on a limited number of third-party manufacturers may adversely affect our operations and exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products; and
- Our third-party manufacturers could breach or terminate their agreement(s) with us.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidates that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, including viral vectors that deliver the targeting moiety and other genes to the product candidate. We currently manufacture through contract manufacturers, some of which have limited resources and experience supporting a commercial product, and such suppliers may not be able to deliver raw materials to our specifications. Those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical

firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials utilized in the manufacture of our candidates are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Further, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. We may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, incidents, or compromises.

Our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to cybersecurity threats. Additionally, we operate in a hybrid work environment. As our employees and our business partners' employees work from home and access our systems remotely, we may be subject to heightened security and privacy risks, including the risks of cyber attacks and privacy incidents. Cybersecurity threats include, but are not limited to, social-engineering attacks (including through phishing attacks), business email compromise, online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, and telecommunications failures, among other cybersecurity risks. Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. We may expend significant resources to try to protect against these threats to our systems. Certain data privacy and security laws, as well as industry best practice standards, may require us to implement and maintain security measures. While we have implemented security measures designed to protect our systems and confidential and sensitive data, there can be no assurance that these measures will be effective. Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We and certain of our service providers have in the past and may in the future experience cybersecurity incidents, including incidents related to social engineering, business email compromise, and wire fraud. System failures and security breaches could cause interruptions in our operations, and could result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further

development and commercialization of our product candidates could be delayed. Other consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Further, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices.

We may not realize the benefits of acquired assets or other strategic transactions.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies, and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and possible write-offs or impairment charges relating to acquired businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could have a material adverse effect on our financial condition.

Risks Related to Government Regulation

Risks Related to Regulatory Approval

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a biologics license application (BLA) from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to the EMA or comparable foreign authorities. A BLA must include extensive preclinical and clinical data and sufficient supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of allogeneic T cell therapies for autoimmune diseases and cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain marketing approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in obtaining regulatory approvals, including due to:

- delays in obtaining regulatory authorization to begin a trial, if applicable;
- the need to redesign our study protocols and/or conduct additional studies as may be required by a regulator;
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of our product candidate by the FDA, EMA or other comparable foreign regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities;
- the availability of financial resources to commence and complete the planned trials;
- negotiating the terms of any collaboration agreements we may choose to initiate or conclude;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements, including GCP standards;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- inability to recruit and enroll suitable patients to participate in a trial;
- having patients complete a trial, including patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or failure to return for post-treatment follow-up;
- addressing any patient safety concerns that arise during the course of a trial;
- inability to add new clinical trial sites;
- varying interpretations of the data generated from our preclinical studies or clinical trials;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- inability to manufacture, or obtain from third parties, sufficient quantities of qualified materials under cGMPs, or if applicable, cGTPs, for the completion of in preclinical studies and clinical trials;
- problems with biopharmaceutical product candidate storage, stability and distribution resulting in global supply chain disruptions;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; or
- potential unforeseen business disruptions or market fluctuations that delay our product development or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA, EMA or other regulatory authorities 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, EMA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenue may be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition from biosimilar products.

The Biologics Price Competition and Innovation Act (BPCIA) established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of our product candidates that are approved in the United States as a biological product under a BLA should qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, potentially creating the opportunity for biosimilar competition sooner than anticipated. During this 12-year exclusivity period, a competing product may still be marketed if the FDA approves a full BLA containing the applicant's own preclinical and clinical trial data demonstrating safety, purity and potency. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors. State pharmacy laws govern whether interchangeable products can be readily substituted for the reference product.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

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

Because we are developing novel allogeneic cell immunotherapy product candidates, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the category of cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in the regulation of existing cell therapy products.

Complex regulatory environments also exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the EU a special committee called the Committee for Advanced Therapies was established within the EMA in accordance with Regulation No 1394/2007 on advanced-therapy medicinal products (ATMPs) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include somatic cell therapy products and tissue engineered products. These various regulatory review committees and advisory groups and new or revised guidelines

that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our gamma delta CAR T-cell product candidates is new, we may face even more cumbersome and complex regulations than those emerging for cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

The general approach for FDA approval of a new biologic is for the sponsor to provide dispositive data from one or two well-controlled, Phase 3 clinical studies of the relevant biologic in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect registrational trials for our product candidates to be designed to evaluate the efficacy of the product candidate in an open-label, non-comparative, two-stage, pivotal, multicenter, single-arm clinical trial in patients who have exhausted available treatment options. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, the process of clinical development is inherently uncertain and we do not have any agreement or guidance from the FDA that our future regulatory development plans are acceptable or will be sufficient to support submission of a BLA. For example, we may seek an accelerated approval pathway for our one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. If we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all.

The FDA may grant accelerated approval for our product candidates that meet the criteria for accelerated approval. As a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. Even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval. Further, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, EMA or other regulatory agencies requesting additional studies to evaluate our product candidate relative to the new products.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications, or that a related companion diagnostic test is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;

- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will inspect our manufacturing facility (or our CDMO's facility) and may not find it acceptable; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our products.

We may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations. Further, the FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A fast track 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 does not increase the likelihood that our product candidates will receive marketing approval.

We have received fast track designation for prula-cel for the treatment of relapsed/refractory Class III or IV LN, refractory SLE with extrarenal involvement, and SSc. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the product candidate sponsor may apply for fast track designation for a particular indication. We may seek fast track designation for certain of our product candidates, but there is no assurance that the FDA will grant this status to any of our product candidates. Marketing applications filed by sponsors of product candidate with fast track designation may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Regenerative Medicine Advanced Therapy (RMAT) designation, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek RMAT designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Positive results from early preclinical studies and clinical trials are not necessarily predictive of the results of any future clinical trials of our product candidates, and may change as more patient data becomes available and is subject to audit and verification procedures that could result in material changes in the final data. If we cannot replicate the positive results from our earlier preclinical studies and clinical trials of our product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidate.

From time to time, we may publish interim, top-line or preliminary results from our preclinical studies or clinical trials. Such clinical results 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 top-line 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. Data 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. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or top-line data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. It is also difficult to predict the timing of announcing interim results.

Accordingly, any positive results from our preclinical studies and ongoing and future clinical trials of our product candidates may not necessarily be predictive of the results from required later clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials according to our current development timeline, the positive results from such preclinical studies and clinical trials may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidate performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or similar regulatory approval.

Additionally, our ongoing clinical trial utilizes an "open-label" trial design, as may be the case in planned future clinical trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a controlled environment with a placebo or active control.

If the clinical updates, or the interim, "top-line", 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, our business, operating results, prospects or financial condition may be harmed.

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 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 studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we 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.

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 and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require post-market surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy (REMS), in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, quality control, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for our

product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers are required to register establishments with the FDA and certain state agencies, and will be subject to continual review and unannounced inspections by the FDA and state agencies to assess compliance with cGMPs and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information.

Further, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We will also be required to comply with FDA's promotion and advertising rules, 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 uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturers' communications on the subject of off-label use of their products. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, FDA Form 483s, untitled letters, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive 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.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community, adversely affecting our ability to achieve our commercial and financial projections.

The use of engineered gamma delta T cells as potential treatments for autoimmune diseases and cancer is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians, including rheumatologists, nephrologists and oncologists, to be particularly important to the market acceptance of our products and we may not be able to educate them on the

benefits of using our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of autoimmune diseases and cancer, we cannot accurately estimate the potential revenue from our product candidates. For further discussion on coverage and reimbursement matters, see the section entitled "Business—Government Regulation and Product Approval Coverage, Pricing and Reimbursement" in our Annual Report on Form 10-K for the year ended December 31, 2025.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, Centers for Medicare and Medicaid Services (CMS) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Because our product candidate may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidate. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures. Specifically, there have been several United States Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. Increased 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 candidate. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates, if approved, profitably. For further discussion on healthcare reform matters, see the section entitled "*Business – Government Regulation and Product Approval – Healthcare Reform*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, which has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (the "IRA"), for example, 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 to $2,000 starting in 2025, eliminating the prescription drug coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering MFN Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "MFN" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021. Recent CMS proposals, including the GLOBE, GUARD, and GENEROUS, could materially impact the Company's revenue.

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. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in various congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

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.

In addition, 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 issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision 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 or as a result of legal challenges, 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, our business could be materially harmed.

Risks Related to Intellectual Property

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Additional patent applications have been filed, and we anticipate additional patent applications will be filed, both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products such as CAR-based product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the patentability, validity, enforceability or scope thereof, for example through inter partes review (IPR) post-grant review or ex parte reexamination before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions, which may result in such patents being cancelled, narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. United States patent applications containing or that at any time contained a claim not entitled to a priority date before March 16, 2013 are subject to the "first to file" system implemented by the America Invents Act (2011).

This first to file system will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that it was the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For United States applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the United States patent laws, including new procedures for challenging patent applications and issued patents.

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

We may require access to additional intellectual property to develop our current or future product candidates. Accordingly, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or

other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and 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. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. In addition, there could 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 substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patient's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

We may in the future 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. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. 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.

Issued patents covering our product candidates could be found unpatentable, invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include IPR, ex parte re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Risks Related to Third Party Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We depend substantially on our license agreements with Regeneron, CRISPR and City of Hope. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. To the extent these licensors fail to meet their obligations under their license agreements, which we are not in control of, we may lose the benefits of our license agreements with these licensors. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

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

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. 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, we will 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.

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

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

We are aware of United States and foreign patents held by a third party relating to gamma delta T cell expansion protocols and related compositions which, on information and belief, are invalid and/or not infringed. In the event that these patents are successfully asserted against our product candidates, such as prula-cel, or the use of our precursor cells in manufacture of these product candidates, such litigation may negatively impact our ability to commercialize these product candidates in such jurisdictions. We are also aware of several United States and foreign patents held by third parties relating to certain CAR compositions of matter, methods of making and methods of use which, on information and belief, are invalid and/or not infringed. Nevertheless, third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when prula-cel, or another CAR-based product candidate is approved by the FDA, third parties may then seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid and/or not infringed.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Risks Related to Intellectual Property Laws

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent United States Court of Appeals for the Federal Circuit and Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

We may not be able to protect our intellectual property rights outside the United States. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions outside of the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions 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 it develops or licenses.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of Our Common Stock

Risks Related to Ownership Generally

The trading price of our common stock is highly volatile, which could result in substantial losses for purchasers of our common stock. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.

Our stock price is highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition, if the market for pharmaceutical and biotechnology stocks or the broader stock market continues to experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition or results of operations. As a result of this volatility, you may not be able to sell your common stock at or above the purchase price and you may lose some or all of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of prula-cel;
- our ability to obtain FDA clearance of additional INDs for prula-cel in autoimmune indications;
- the initiation, timing and results of clinical studies of ADI-212;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- issues or delays regarding the manufacturing of our product candidates and, if approved, products by us or by our third-party suppliers;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. We have been, and may in the future be, subject to securities litigation related to corporate governance matters determined in good faith by our board of directors, including the stock option repricing in August 2023 in accordance with the terms of our 2015 Plan and 2018 Plan. Even if the allegations against us are unfounded or we ultimately are not held liable, we may experience related negative publicity resulting in damage to our reputation. Further, the costs to defend ourselves may be significant and the litigation may subject us to substantial settlements, fines, penalties or judgments against us and may consume management's bandwidth and attention, some or all of which may negatively impact our financial condition and results of operations.

An active trading market for our common stock may not be sustained. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.

Our common stock began trading on The Nasdaq Global Market on January 26, 2018 and now trades on The Nasdaq Capital Market under the symbol "ACET." Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect your ability to sell shares you purchased. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and impair our ability to acquire other companies or technologies by using our shares as consideration.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially own a significant percentage of our outstanding stock. Accordingly, these stockholders will have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Risks Related to Market Uncertainties

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, volatile interest rates, rising and fluctuating inflation rates, reduced corporate profitability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. In addition, inflation rates in the U.S. have recently increased to levels not seen in decades.

We believe that the state of global economic conditions are particularly volatile and uncertain and may negatively impact our ability to conduct clinical trials on the scale and timelines anticipated. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business or political environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make obtaining any necessary debt or equity financing more difficult, more costly and more dilutive. For example, as a result of political, social, and economic instability abroad, including as a result of armed conflict, war or threat of war, in particular, the current conflict between Russia and Ukraine, including resulting sanctions, terrorist activity and other security concerns in general, there could be a significant disruption of global financial markets, impairing our ability to raise capital when needed on acceptable terms, if at all. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. To the extent that our profitability and strategies are negatively affected by downturns or volatility in general economic conditions, our business and results of operations may be materially adversely affected.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted our net income. Recent supply chain constraints have led to higher inflation, which, if sustained, could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Current capital market conditions, including the impact of inflation, have increased borrowing rates and can be expected to significantly increase our cost of capital as compared to prior periods and could also affect our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Risks Related to our Charter and Bylaws

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation (certificate of incorporation) and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of not less than 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions 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, employees or agents.

Our amended and restated bylaws specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or amended and restated bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine (Delaware Forum Provision); provided, however, that the Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. This choice of forum provision contained in our amended and restated bylaws will not apply to any causes of action arising under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated bylaws described above; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' bylaws or certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated bylaws 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, financial condition or results of operations.

General Risk Factors

We are a Smaller Reporting Company (SRC) and the reduced disclosure requirements applicable to SRCs may make our common stock less attractive to investors.

We are considered a SRC under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. 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 common stock prices may be more volatile. We will remain a smaller reporting company for as long as (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30.

We have broad discretion over the use of our cash, cash equivalents and short-term investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents and short-term investments to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending our use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the future clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are 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 or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend themselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product

candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceeds 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. Even if our agreements with any future corporate collaborators entitle it to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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 could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act of 1933, as amended (Securities Act) would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

On March 6, 2025, we filed a registration statement on Form S-3 (File No. 333-285609) with the SEC, which was declared effective on March 14, 2025 (2025 Shelf Registration Statement), in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. Under the 2025 Shelf Registration Statement and a prospectus supplement filed on October 7, 2025, we completed an underwritten registered direct offering of 4,375,062 shares of our common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 625,000 shares of common stock. The shares of common stock were sold at a price of $16.00 per share and the pre-funded warrants were sold at a price of $15.9984 per pre-funded warrant, which represents the pre share price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. We received $80.0 million in aggregate gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses. As a result of this offering, our stockholders experienced significant dilution. If we sell, or the market perceives that we intend to sell, substantial amounts of our common stock under the 2025 Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

We have also filed registration statements on Form S-8 registering the issuance of shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume

limitations applicable to affiliates and the lock-up agreements described above. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

The Company relies on electronic systems and information technologies to conduct its operations. We have adopted and maintain a cybersecurity risk management program, in accordance with our risk profile and business, that is informed by industry standards. The risk management program and the security policies that have been established as part of it, are reviewed annually as part of our overall risk management procedures.

We leverage the support of third-party information technology and security providers, including to perform penetration testing, threat intelligence analysis and remediation, when necessary. We have previously conducted a cybersecurity risk assessment that was intended to take into account the evolving cyber threat landscape and industry best practices, and we have endeavored to adapt our cyber risk strategy to mitigate emerging cybersecurity risks. We implement a multi-layered approach to cybersecurity that includes, for example, employee security awareness training, various security tools and technologies, and incident response planning and remediation.

Although risks from cybersecurity threats have to date not materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations or financial condition, we do, from time to time, experience threats and security incidents relating to our, and our third party vendors', information systems. For more information, please see the section entitled "*Risk Factors*" in this Annual Report on Form 10-K.

Governance Related to Cybersecurity Risks

Our Senior Director of Information Technology (IT) reports directly to our Chief Financial Officer (CFO) and is responsible for the strategic leadership and direction of our cybersecurity program, with support from our Associate Director of IT. With over 20 years of experience in IT and cybersecurity risk management, our Senior Director of IT works alongside individuals across other Company management functions to establish and implement our cybersecurity risk management strategy. Our Senior Director of IT is informed of and monitors cybersecurity incidents through communications with system users as well as monitoring our intrusion detection systems and firewalls.

Our audit committee, which reports directly to the board of directors, is responsible for overseeing our cybersecurity risk management program pursuant to the audit committee's charter. The audit committee receives periodic updates on cybersecurity risks, mitigation strategies, and, if necessary, incident response activities from our Senior Director of IT or CFO. The audit committee may update the full board of directors on matters relating to cybersecurity risk management as needed.

Item 2. Properties.

We have offices in Boston, Massachusetts, and Redwood City, California. Our principal executive offices are located at 131 Dartmouth Street, 3rd Floor, Boston, Massachusetts. On January 31, 2024, our Boston, Massachusetts lease at 200 Berkeley Street was terminated by the landlord due to closing of the office space. On January 19, 2024, we entered into a membership agreement with Industrious Bos 131 Dartmouth Street LLC for office space at 131 Dartmouth Street, Boston, Massachusetts (the Dartmouth Street Agreement). The Dartmouth Street Agreement commenced on February 1, 2024 and was set to originally expire on January 31, 2025. On March 12, 2024 and on November 25, 2024, we amended the Dartmouth Street Agreement to include additional office space and extend the term of the lease. As amended on November 25, 2024, the extended lease commenced on February 1, 2025 and was set to expire on January 31, 2026. As further amended on November 20, 2025, the extended lease commenced on February 1, 2026 and will expire on January 31, 2027.

We also lease office and laboratory space located at 1000 Bridge Parkway, Redwood City, California. The lease commenced on March 31, 2020 and expires on February 28, 2030. In addition, we had leased office space at 1200 Bridge Parkway, Redwood City, California. This lease commenced on June 17, 2022 and expired on June 30, 2025.

We believe that our office and laboratory space is sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock trades on The Nasdaq Capital Market under the symbol "ACET". Trading of our common stock commenced on January 26, 2018 on The Nasdaq Global Market, in connection with our initial public offering of resTORbio. Prior to that time, there was no established public trading market for our common stock.

As of March 10, 2026, we had approximately 8 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Equity Compensation Plan

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. [Reserved].

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. We are advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients.

Our approach to activate, engineer and manufacture allogeneic gamma delta T cell product candidates derived from the peripheral blood cells of unrelated donors allows us to generate new product candidates in a rapid and cost-efficient manner. Our allogeneic "off-the-shelf" manufacturing process is designed to allow product from unrelated donors to be stored and sold on demand to treat patients without inducing a graft versus host immune response. This is in contrast to products based on alpha beta T cells, which either must be manufactured for each patient from his or her own T cells, or require significant gene editing to manufacture if the T cells are derived from donors that are unrelated to the patient.

Our lead product candidate, prula-cel, a first-in-class allogeneic gamma delta T cell therapy expressing a CAR targeting CD20, is being developed for the potential treatment of autoimmune diseases. We are also pursuing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen (PSMA). ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and to deliver multiple anti-tumor mechanisms of action to the tumor microenvironment. We aim to submit a new regulatory submission, such as an Investigational New Drug (IND) application or equivalent every 12-18 months.

Prula-cel

In December 2023, the U.S. Food and Drug Administration (FDA) cleared our IND application for prula-cel in lupus nephritis (LN). In August 2024, we expanded our prula-cel autoimmune clinical development program to include systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and anti-neutrophil cytoplasmic autoantibody associated vasculitis (AAV). In September 2024, we activated sites for our Phase 1 clinical trial of prula-cel in autoimmune diseases and opened enrollment for patients with LN. In October 2024, we received clearance for our IND amendment to evaluate prula-cel in idiopathic inflammatory myopathies (IIM) and stiff person syndrome (SPS) as part of our Phase 1 clinical trial in autoimmune diseases. We believe the favorable safety profile, cellular kinetics and B cell depletion in peripheral blood and secondary lymphoid tissue demonstrated with prula-cel clinical experience to date is favorable for development in autoimmune diseases. We believe the potential market opportunity for prula-cel in B cell mediated autoimmune diseases is substantial based on the prevalence in the U.S., EU5, China and Japan of greater than 1.7 million patients with autoimmune diseases where CAR-T cell therapy has demonstrated clinical proof-of-concept, including SLE (which includes LN), SSc, IIM and SPS. In June 2024, the FDA granted Fast Track Designation to prula-cel for the potential treatment of relapsed/refractory class III or class IV LN. In February 2025, the FDA granted Fast Track Designation to prula-cel for the potential treatment of adult patients with refractory SLE with extrarenal involvement and for SSc. In April 2025, we expanded enrollment to include patients with SLE for our Phase 1 clinical trial evaluating prula-cel in autoimmune diseases and in July 2025, we reported that the first SSc patient has been dosed in the second cohort of the Phase 1 clinical trial. In October 2025, we announced positive preliminary results from seven SLE and LN patients dosed in our ongoing Phase 1 trial of prula-cel in autoimmune diseases as of the August 31, 2025 data cut-off date. We plan to meet with the FDA in the second quarter of 2026 to inform potential pivotal trial design. Subject to regulatory clearance to proceed, we expect to initiate a potential pivotal study in LN or LN and SLE patients in the second half of 2026. In November 2025, we reached alignment with the FDA to allow LN and SLE patients to be dosed with prula-cel in the outpatient setting in ongoing and future clinical trials. Phase 1 enrollment is ongoing and we expect to provide a clinical update for this trial in LN, SLE and SSc patients in the first half of 2026, with a plan to provide an additional update in the second half of 2026. We also reported in October 2025 that the first patient was dosed in a Phase 1 clinical trial of prula-cel in patients with treatment-refractory rheumatoid arthritis (RA). The study will evaluate two conditioning regimens:

cyclophosphamide alone and cyclophosphamide with fludarabine, to explore the potential to reduce the need for conditioning. The next clinical update on this trial is expected in the second half of 2026.

ADI-212

We are advancing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen. ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 (mbIL-12) armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and deliver multiple anti-tumor mechanisms of action within the tumor microenvironment. We expect to submit a regulatory filing for ADI-212 for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in the third quarter of 2026. Subject to regulatory clearance to proceed with a clinical trial, we expect to initiate patient enrollment in the fourth quarter of 2026. We believe the potential market opportunity for ADI-212 in mCRPC is significant based on the prevalence in the U.S., EU5, China and Japan of approximately 75,000 patients with second or third line advanced disease.

ADI-270

Due to the prioritization of prula-cel in autoimmune indications and ADI-212 in mCRPC, we have discontinued the development of ADI-270 and closed enrollment in the Phase 1 clinical trial in patients with metastatic/advanced clear renal cell carcinoma.

Recent Developments

Reverse Stock Split

On December 30, 2025, our 1-for-16 reverse stock split (Reverse Stock Split) was effective following approval by our stockholders at our special meeting in December 2025. As a result, every 16 shares of our issued common stock were combined into one share of our common stock. No fractional shares of our common stock were issued as a result of the Reverse Stock Split. Stockholders who would otherwise be entitled to receive fractional shares were automatically entitled to receive cash in lieu of such fractional share. The shares of our common stock retained a par value of $0.0001 per share. Trading of the common stock on the Nasdaq Capital Market commenced on a split-adjusted basis at market open on December 30, 2025, under the existing trading symbol “ACET.”

Financial Operations Overview

Revenue

We have no products approved for commercial sale and do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for our product candidates, which we expect will not be for at least several years, if ever.

Expenses

Research and Development

Research and development expenses, which consist primarily of costs incurred in connection with the development of our product candidates, are expensed as incurred. Research and development expenses consist primarily of:

- employee related costs, including salaries, benefits and stock-based compensation expenses for research and development employees;
- costs incurred under agreements with consultants, contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs);
- lab materials, supplies and maintenance of equipment used for research and development activities; and
- allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

We allocate our external costs by product candidate. We do not allocate our internal costs by product candidate as a significant amount of internal research and development expenses are not tracked by product candidate, and we believe the allocation of such costs would be arbitrary and would not provide a meaningful assessment as we have used our employee and infrastructure resources across multiple product candidate research and development programs.

We are focusing substantially all of our resources on the development of our product candidates. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of clinical trials and other research and development activities;
- clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the FDA's or other regulatory authority's influence on clinical trial design;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- expenses incurred in connection with our license and collaboration agreements, including license payments, program expenses and milestone obligations payable by us;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for product candidates;
- continued applicable safety profiles of the products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

General and Administrative

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock based compensation expenses, professional fees for legal, consulting, accounting and tax services,

allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase for the foreseeable future due to expenses related to operating as a public company, including expenses related to personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable Nasdaq and SEC requirements, investor relations costs and director and officer insurance premiums.

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents, restricted cash and short-term investments in treasury securities.

Interest Expense

Interest expense consists primarily of interest on finance lease liabilities.

Other Expense, Net

Other expense, net primarily consists of state franchise and capital taxes not related to income and losses on disposal of fixed assets.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Twelve Months Ended December 31,			
	2025	2024	Change	% Change
Operating expenses				
Research and development	$ 99,127	$ 99,323	$ (196)	(0%)
General and administrative	22,987	28,292	(5,305)	(19%)
Total operating expenses	122,114	127,615	(5,501)	(4%)
Loss from operations	(122,114)	(127,615)	(5,501)	(4%)
Interest income	5,777	10,714	(4,937)	(46%)
Interest expense	(36)	(4)	32	800%
Other expense, net	(430)	(217)	213	98%
Loss before income tax benefit	(116,803)	(117,122)	(319)	(0%)
Income tax provision	—	—	—	0%
Net loss	$ (116,803)	$ (117,122)	$ (319)	(0%)

Research and Development

	Twelve Months Ended December 31,	
	2025	2024
Payroll and personnel expenses(1)	$ 37,564	$ 42,693
Costs incurred under agreements with consultants, CDMOs, and CROs	27,832	22,269
Lab materials, supplies and maintenance of equipment used for research and development activities	10,940	11,670
Other research and development expenses(2)	22,791	22,691
Total research and development expenses	$ 99,127	$ 99,323

(1) Employee related costs, including salaries, benefits, bonuses, and stock-based compensation expenses for research and development employees.

(2) Allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

Research and development expenses decreased by $0.2 million, or less than 1%, during the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease in research and development expenses was primarily due to a $5.1 million decrease in payroll and personnel expenses related to lower headcount and a $0.7 million decrease in lab supplies and materials. This decrease was partially offset by a net $5.6 million increase in contracted research and development costs primarily related to CRO costs associated with autoimmune studies.

General and Administrative

General and administrative expenses decreased by $5.3 million, or 19%, during the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease in general and administrative expenses was primarily due to a decrease in payroll and personnel expenses primarily related to a decrease in stock-based compensation of $3.6 million, a decrease in recruiting and employee travel expenses of $0.3 million, decreases in rent, office related expenses and allocated facility expense of $1.5 million and a decrease of $0.2 million related to corporate insurance and property taxes. This decrease was partially offset by a $0.3 million increase in professional fees.

Interest Income

Interest income decreased by $4.9 million, or 46%, during the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily due to lower interest rates and lower cash balances for the period.

Other Expense, Net

Other expense, net increased by $0.2 million, or 98%, during the year ended December 31, 2025 compared to the year ended December 31, 2024. This was primarily due to a loss on disposal of assets related to furniture and equipment located in 1200 Bridge Parkway, due to expiration of lease in June 2025.

Income Tax Benefit

There was no income tax expense or benefit for the years ended December 31, 2025 and 2024.

Liquidity and Capital Resources

Sources of Liquidity

We have historically funded our operations primarily through a collaboration and licensing arrangement, public and private placements of equity securities and debt, and cash received in our merger with resTORbio, Inc.

In January 2024, we raised aggregate net proceeds of approximately $19.3 million through the JonesTrading ATM Program. In March 2024, we terminated the JonesTrading ATM Program and entered into the Jefferies ATM Program. As of December 31, 2025, no shares of common stock have been sold through the Jefferies ATM Program.

On January 22, 2024, we entered into an underwriting agreement (the Underwriting Agreement) with Jefferies LLC (Jefferies) and Guggenheim Securities, LLC, as representatives of the underwriters (the Underwriters), related to an underwritten public offering (the Offering) of 2,023,729 shares of our common stock, which included 332,813 shares sold and issued upon the exercise in full by the Underwriters of their option to purchase additional shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 527,833 shares of common stock. The shares of common stock were sold at a public offering price of $38.40 per share and the pre-funded warrants were sold at a public offering price of $38.3984 per pre-funded warrant, which represents the per share public offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the Underwriters to us was $36.096 per share and $36.0944 per pre-funded warrant, representing a discount to the Underwriters of 6.0%. We received net proceeds from the Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $91.7 million. We may receive nominal proceeds, if any, from the exercise of the pre-funded warrants.

On October 7, 2025, we entered into an underwriting agreement related to an underwritten registered direct offering (the 2025 Offering) of 4,375,062 shares (the 2025 Shares) of Common Stock, and, in lieu of Common Stock to an investor, pre-funded warrants (the 2025 Pre-Funded Warrants) to purchase 625,000 shares of Common Stock (the 2025 Warrant Shares). The 2025 Shares were sold at a price of $16.00 per share and the 2025 Pre-Funded Warrants were sold at a price of $15.9984 per underlying share, which represents the per share offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the Underwriters to us was $15.04 per 2025 Share and $15.03856 per 2025 Pre-Funded Warrant, representing a discount to the Underwriters of 6.0%. We received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $74.8 million. We may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

As of December 31, 2025, we had cash, cash equivalents and short-term investments of $158.5 million and restricted cash of $2.9 million. We expect that our cash, cash equivalents and short-term investments will be sufficient to fund our forecasted operating expenses, capital expenditure requirements and debt service payments for at least the next twelve months from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K.

Loan Agreement

On April 28, 2020, we entered into a Loan and Security Agreement (the Loan Agreement) with Banc of California (formerly known as Pacific Western Bank) to finance leasehold improvements for our facilities in Redwood City, CA and other purposes permitted under the Loan Agreement. On October 21, 2021, we amended the Loan Agreement (as amended, the 2021 Loan Amendment) under which Banc of California will provide one or more Term Loans (as defined in the 2021 Loan Amendment), as well as certain Non-Formula Ancillary Services which shall not exceed $5.5 million in the aggregate. Non-Formula Ancillary Services are defined as automated clearinghouse transactions, corporate credit card services, letters of credit, or other treasury management services. Per the terms of the Loan Agreement, the aggregate sum of the outstanding Term Loans and Non-Formula Ancillary Services shall at no time exceed $15.0 million, which each Term Loan to be in an amount of not less than $1.0 million. Pursuant to the 2021 Loan Amendment, the interest rate for the Term Loans shall be set at an annual rate equal to the greater of (i) 0.25% above the Prime Rate then in effect and (ii) 4.25%.

On December 2, 2022, we further amended the Loan Agreement (the 2022 Loan Amendment). The 2022 Loan Amendment extended the drawdown period for any Term Loan by one year, which expired on April 19, 2024. Furthermore, the 2022 Loan Amendment extended the final maturity date of any Term Loan by one year from October 19, 2025 to October 19, 2026, and the maturity date of non-formula ancillary services to November 30, 2023.

On May 30, 2023, we entered into the 2023 Loan Amendment. Pursuant to the 2023 Loan Amendment, we must maintain the lesser of (i) $35.0 million or (ii) all of our combined balances in demand deposit accounts, money market accounts, and/or insured cash sweep accounts with Banc of California. If our total cash and investments drop to less than $35.0 million, the 2023 Loan Amendment permits us to maintain cash and/or investments in one or more accounts outside of Banc of California up to a total of $2.5 million.

In April 2024, the Term Loan availability under our Loan Agreement expired. The Non-Formula Ancillary Services, which shall not exceed $5.5 million in the aggregate, remained available. On November 27, 2024, we executed a payoff letter (the Payoff Letter) with Banc of California to repay in full all outstanding indebtedness and terminate all commitments and obligations, subject to certain exceptions, under the Loan Agreement. Under the Payoff Letter, we agreed to pay Banc of California approximately $10,000 in administrative fees and establish cash collateral accounts and execute pledge and security agreements to secure ancillary services provided by Banc of California. We paid the $10,000 administrative fees in December 2024. As of December 31, 2025, we have $2.9 million of restricted cash held in cash collateral accounts. No termination penalty was paid in connection with the Payoff Letter.

Future Funding Requirements

We have incurred losses since inception and have incurred losses of $116.8 million and $117.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $614.7 million.

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $158.5 million. We believe that our cash, cash equivalents and short-term investments will be sufficient for us to fund our operations for at least twelve months from the issuance date of our consolidated financial statements for the year ended December 31, 2025 included elsewhere in this Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we expect. Because of the risks and uncertainties associated with research, development, and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements.

All of our revenue to date has been generated from the Regeneron Agreement, which is a collaboration and license agreement. We do not expect to generate any significant product revenue until we obtain regulatory approval of and commercialize any of our product candidates or enter into additional collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the timing, number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems;
- the impact of potential health emergencies on United States and global economic conditions that may impact our ability to access capital on terms anticipated, or at all; and
- the post-merger costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. Adequate funding may not be available to us on acceptable terms or at all.

Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section of this Annual Report on Form 10-K entitled "*Risk Factors*" for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of our cash and cash equivalents for each of the periods presented below (in thousands):

	Twelve Months Ended December 31,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (95,246)	$ (92,378)
Investing activities	2,393	(119,242)
Financing activities	75,245	111,307
Net decrease in cash, cash equivalents and restricted cash	$ (17,608)	$ (100,313)

Cash Flows from Operating Activities

Net cash used in operating activities was $94.6 million for the year ended December 31, 2025. Cash used in operating activities consisted of net loss offset by non-cash adjustments of $20.1 million and a net increase in operating assets and liabilities of $1.5 million. Non-cash items primarily included stock-based compensation expense of $14.3 million, depreciation and amortization of $6.4 million and non-cash lease expense of $3.4 million. The net increase in assets and liabilities was primarily due to an increase of $1.9 million in accrued and other current and non-current liabilities, an increase of $1.7 million in prepaid expenses and other current assets, an increase in accounts payable of $1.0 million and an increase of $0.3 million in other non-current assets. The increase was partially offset by a decrease of $3.4 million in operating lease liability.

Net cash used in operating activities was $92.4 million for the year ended December 31, 2024. Cash used in operating activities consisted of net loss offset by non-cash adjustments of $30.3 million and a net decrease in operating assets and liabilities of $5.5 million. Non-cash items primarily included stock-based compensation expense of $22.2 million, depreciation and amortization of $6.5 million and non-cash lease expense of $3.2 million. The net decrease in assets and liabilities was primarily due to a decrease of $3.7 million in operating lease liability, a decrease of $2.0 million in accrued expenses and other current and non-current liabilities, and a decrease of $1.3 million in prepaid expenses and other current assets. The decrease was partially offset by an increase in accounts payable of $1.1 million and an increase in other non-current assets of $0.4 million.

Cash Flows from Investing Activities

Net cash provided by investing activities was $2.4 million for the year ended December 31, 2025, which consisted of $145.0 million related to maturities of short-term treasury securities, net of $140.9 million of purchases of short-term treasury securities and $1.7 million of purchases of lab equipment for our GMP cell processing suite at 1000 Bridge Parkway.

Net cash used in investing activities was $119.2 million for the year ended December 31, 2024, which consisted of $129.1 million of purchases of short-term treasury securities and $1.1 million of purchases of lab equipment for our GMP cell processing suite at 1000 Bridge Parkway. We received $11.0 million related to the maturities of short-term treasury securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $75.2 million for the year ended December 31, 2025, which included approximately $75.2 million in net proceeds from the issuance of our common stock and pre-funded warrants in the 2025 Offering and $0.3 million in net proceeds from the issuance of common stock in connection with our employee stock purchase plan. This was partially offset by $0.1 million cash paid for taxes withheld on the net share settlement of equity awards and $0.2 million cash paid for the principal payment on finance leases.

Net cash provided by financing activities was $111.3 million for the year ended December 31, 2024, which included approximately $91.7 million in net proceeds from the issuance of our common stock and pre-funded warrants in the Offering and approximately $19.3 million in net proceeds from the issuance of our common stock under the JonesTrading ATM Program.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting practices (GAAP). The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets,

liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in our consolidated financial statements. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results. While our significant accounting policies are more fully described in the Notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our consolidated financial statements:

Accrued CDMO, CRO, and Research and Development Expenses

We have entered into various agreements with CDMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued and other current liabilities on the consolidated balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CDMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the consolidated balance sheets until the services are rendered. To date, our estimated accruals have not differed materially from the actual costs.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and restricted stock awards. Our determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option pricing model. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. For awards that have a performance condition, we recognize compensation expense based on its assessment of the probability that the performance condition will be achieved, using an accelerated attribution model, over the explicit or implicit service period. We account for forfeitures as they occur. In determining fair value of the stock options granted, we use the Black–Scholes option-pricing model, which requires the input of subjective assumptions, including but not limited to, expected term, volatility and risk-free interest rates. Changes in these assumptions can materially affect the estimate of the fair value of stock-based compensation:

Smaller Reporting Company

We are a "smaller reporting company" as defined in the Exchange Act. As a smaller reporting company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not smaller reporting companies. These provisions include (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act of 2002, as amended; (ii) scaled executive compensation disclosures; and (iii) the option to provide only two years of audited financial statements, instead of three years.

We will continue to be a smaller reporting company for as long as we continue to have (i) less than $250 million in market value of our shares held by non-affiliates as of the last business day of our second fiscal quarter or (ii) less than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates of less than $700 million as of the last business day of our second fiscal quarter.

We may choose to take advantage of some but not all of these exemptions. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We have elected to avail ourselves of the exemption for the delayed adoption of certain accounting standards and, therefore, are not subject to the same new or revised accounting standards as other public companies that are not smaller reporting companies.

Recently Issued and Adopted Accounting Pronouncements

See the section entitled "*Summary of Significant Accounting Policies*" in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

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

Interest Rate Risk

As of December 31, 2025, we had cash, cash equivalents and short-term investments of $158.5 million, which consisted of cash and funds invested in treasury securities and money market funds. Interest income is sensitive to general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material impact on our cash and cash equivalents, financial position, or results of operations.

Foreign Currency Exchange Risk

Our headquarters are located in the United States, where a majority of our general and administrative expenses and research and development costs are incurred in U.S. Dollars. As we grow our business, our results of operations and cash flows may be subject to fluctuations due to foreign currency exchange rates. To date, we do not believe foreign currency exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Inflation Risk

Our assets are primarily monetary, consisting of cash, cash equivalents, restricted cash and short-term investments in treasury securities. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture, fixtures and office equipment, computer hardware and software and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. Inflation generally affects us by increasing our cost of labor, clinical trial and manufacturing costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2025 and 2024.

Item 8. Financial Statements and Supplementary Data.

All financial statements and supplementary data required to be filed hereunder are filed as listed under Item 15(a) of this Annual Report on Form 10-K and are incorporated herein by this reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO) (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute assurance, of achieving their objectives.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is designed to

provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. GAAP, and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed our internal control over financial reporting as of December 31, 2025. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2025.

This Annual Report on Form 10-K does not include an attestation report from our registered public accounting firm regarding internal control over financial reporting. As we are a non-accelerated filer, management’s report is not subject to attestation by our registered public accounting firm.

We cannot assure you that 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, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. For additional information, see the related risks in the section entitled "*Risk Factors*" of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

Other than the remediation plan described in our Annual Report on Form 10-K filed with the SEC on March 6, 2025, no change in our internal control over our financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding directors, executive officers and corporate governance will be included in our 2026 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference (excluding pay versus performance disclosure).

We have adopted a code of business conduct and ethics for directors, officers, and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at https://investor.adicetbio.com/corporate-governance/governance-highlights. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Code of Business Conduct and Ethics from our Compliance Officer, c/o Adicet Bio, Inc., 131 Dartmouth Street, 3rd Floor, Boston, Massachusetts 02116.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2026 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference (excluding pay versus performance disclosure).

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management and securities authorized for issuance under equity compensation plans will be included in our 2026 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2026 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Our independent public accounting firm is KPMG LLP, Boston, Massachusetts (PCAOB Auditor ID: 185).

The information required by this item regarding principal accounting fees and services will be included in our 2026 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are included in this Annual Report on Form 10-K:

(1) The following Report and Consolidated Financial Statements of the Company are included in this Annual Report:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets
- Consolidated Statements of Operations and Comprehensive Loss
- Consolidated Statements of Stockholders' Equity
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

- All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

ADICET BIO, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Adicet Bio, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Adicet Bio, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

Boston, Massachusetts
March 12, 2026

Adicet Bio, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 38,918	$ 56,495
Short-term investments in treasury securities	119,612	119,808
Prepaid expenses and other current assets	2,396	3,833
Total current assets	160,926	180,136
Restricted cash	2,872	2,903
Property and equipment, net	16,532	22,524
Operating lease right-of-use asset	10,927	14,228
Finance lease right-of-use asset	1,022	—
Other non-current assets	76	428
Total assets	$ 192,355	$ 220,219
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,739	$ 4,830
Accrued and other current liabilities	13,606	11,430
Operating lease liability	2,837	3,132
Finance lease liability	349	—
Total current liabilities	21,531	19,392
Operating lease liability, net of current portion	10,910	14,102
Finance lease liability, net of current portion	642	—
Other non-current liabilities	62	116
Total liabilities	33,145	33,610
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; none issued and outstanding as of December 30, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 9,586,770 and 5,160,545 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	10	5
Additional paid-in capital	773,795	684,482
Accumulated deficit	(614,697)	(497,894)
Accumulated other comprehensive income	102	16
Total stockholders' equity	159,210	186,609
Total liabilities and stockholders' equity	$ 192,355	$ 220,219

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

Adicet Bio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	For the Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 99,127	$ 99,323
General and administrative	22,987	28,292
Total operating expenses	122,114	127,615
Loss from operations	(122,114)	(127,615)
Interest income	5,777	10,714
Interest expense	(36)	(4)
Other expense, net	(430)	(217)
Loss before income tax provision	(116,803)	(117,122)
Income tax provision	—	—
Net loss	$ (116,803)	$ (117,122)
Net loss per share, basic and diluted	$ (16.95)	$ (21.33)
Weighted-average common shares used in computing net loss per share, basic and diluted	6,891,336	5,491,652
Other comprehensive income		
Unrealized gain on treasury securities, net of tax	86	16
Total other comprehensive income	86	16
Comprehensive loss	$ (116,717)	$ (117,106)

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

Adicet Bio, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	2,704,370	$ 1	$ 550,946	$ (380,772)	—	$ 170,175
Issuance of common stock upon exercise of stock options	5,768	—	195	—	—	195
Issuance of common stock upon vesting of restricted stock	11,524	—	—	—	—	—
Shares withheld for taxes	(4,238)	—	(141)	—	—	(141)
Issuance of common stock pursuant to at-the-market offering, net of issuance costs of $0.6 million	396,875	1	19,265	—	—	19,266
Issuance of common stock and pre-funded warrants pursuant to underwritten public offering, net of issuance costs of $6.3 million	2,023,729	3	91,649	—	—	91,652
Purchase of common stock under Employee Stock Purchase Plan	22,517	—	335	—	—	335
Stock-based compensation expense	—	—	22,233	—	—	22,233
Net income	—	—	—	(117,122)	—	(117,122)
Other comprehensive income	—	—	—	—	16	16
Balance at December 31, 2024	5,160,545	$ 5	$ 684,482	$ (497,894)	$ 16	$ 186,609
Issuance of common stock upon exercise of stock options	50	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock	17,912	—	—	—	—	—
Shares withheld for taxes	(7,213)	—	(104)	—	—	(104)
Issuance of common stock and pre-funded warrants pursuant to underwritten public offering, net of issuance costs of $5.2 million	4,375,062	5	74,823	—	—	74,828
Purchase of common stock under Employee Stock Purchase Plan	40,414	—	326	—	—	326
Stock-based compensation expense	—	—	14,267	—	—	14,267
Net loss	—	—	—	(116,803)	—	(116,803)
Other comprehensive loss	—	—	—	—	86	86
Balance at December 31, 2025	9,586,770	$ 10	$ 773,795	$ (614,697)	$ 102	$ 159,210

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

Adicet Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Twelve Months Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (116,803)	$ (117,122)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	6,381	6,468
Noncash lease expense	3,383	3,197
Stock-based compensation expense	14,267	22,233
Loss on disposal of property and equipment	103	—
Net amortization of premiums and accretion of discounts on investments	(4,093)	(1,668)
Amortization of deferred transaction costs	43	39
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,681	(1,271)
Other non-current assets	308	353
Accounts payable	1,029	1,106
Operating lease liability	(3,449)	(3,691)
Accrued and other current and non-current liabilities	1,904	(2,022)
Net cash used in operating activities	(95,246)	(92,378)
Cash flows from investing activities		
Purchases of short-term treasury securities	(140,869)	(129,124)
Maturities of short-term treasury securities	145,000	11,000
Purchases of property and equipment	(1,738)	(1,118)
Net cash provided by (used in) investing activities	2,393	(119,242)
Cash flows from financing activities		
Proceeds from issuance of common stock pursuant to at-the-market offering, net of issuance costs	—	19,266
Proceeds from issuance of common stock and pre-funded warrants pursuant to underwritten public offering, net of issuance costs	75,172	91,652
Proceeds from exercise of stock options	1	195
Proceeds from Employee Stock Purchase Plan	326	335
Taxes withheld and paid related to net share settlement of equity awards	(104)	(141)
Principal payments on finance leases	(150)	—
Net cash provided by financing activities	75,245	111,307
Net change in cash, cash equivalents and restricted cash	(17,608)	(100,313)
Cash, cash equivalents and restricted cash at the beginning of period	59,398	159,711
Cash, cash equivalents and restricted cash at the end of period	$ 41,790	$ 59,398
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets:		
Cash and cash equivalents	$ 38,918	$ 56,495
Restricted cash	2,872	2,903
Cash, cash equivalents and restricted cash in consolidated balance sheets	$ 41,790	$ 59,398
Supplemental cash flow information		
Supplemental disclosures of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 209	$ 1,454
Right-of-use asset acquired under finance leases	$ 1,104	—
Offering costs in accounts payable and accrued expenses	$ 344	—

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

Adicet Bio, Inc.
Notes to Consolidated Financial Statements

1. Organization and Nature of the Business

Adicet Bio, Inc. (formerly resTORbio, Inc. (resTORbio), together with its subsidiaries, the Company) is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. The Company is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients.

Adicet Bio, Inc. (when referred to prior to the merger, Former Adicet) was incorporated in November 2014 in Delaware. On September 15, 2020, Former Adicet completed a merger (Merger) with resTORbio, pursuant to which Former Adicet merged with a wholly owned subsidiary of resTORbio in an all-stock transaction with Former Adicet surviving as a wholly owned subsidiary of resTORbio and changing its name to "Adicet Therapeutics, Inc." (Adicet Therapeutics). In connection with the Merger, the Company changed its name from "resTORbio, Inc." to "Adicet Bio, Inc." The Company's principal executive offices are located in Boston, Massachusetts. The Company also has offices in Redwood City, California.

Adicet Bio Israel Ltd. (formerly Applied Immune Technologies Ltd.) (Adicet Israel) is a wholly owned subsidiary of the Company and is located in Haifa, Israel. Adicet Israel was founded in 2006. During 2019, the Company consolidated its operations, including research and development activities, in the United States and as a result, substantially reduced its operations in Israel.

Adicet (Shanghai) Biotechnology Co., Ltd. (Adicet Shanghai) is a wholly owned subsidiary of Adicet Therapeutics and is located in Shanghai, China. Adicet Shanghai was founded in May 2024.

In May 2024, the Company initiated research and development activities in China through a series of contractual agreements entered into and among Shanghai Adicet Biotechnology Co., Ltd., a variable interest entity (the Adicet VIE), Adicet Shanghai, and the shareholders of the Adicet VIE. The Company was the primary beneficiary of the Adicet VIE which was considered a consolidated entity under accounting principles generally accepted in the United States of America (U.S. GAAP). In July 2025, Adicet Therapeutics entered into an equity transfer agreement with the then-stockholders of the Adicet VIE to acquire 100% equity interests of the Adicet VIE from its then-stockholders (the Acquisition). In connection with the Acquisition, tax filings and registration were completed in August 2025. In August 2025, upon completion of the registration, the Adicet VIE is now a wholly owned subsidiary of Adicet Therapeutics and will continue to conduct research and development activities in China. The transaction did not have a material impact on the financial statements. The Company consolidates the financial results of this entity into its consolidated financial statements in accordance with U.S. GAAP.

Liquidity

The Company has incurred significant net operating losses and negative cash flows from operations and has an accumulated deficit of $614.7 million as of December 31, 2025. The Company has historically financed its operations primarily through a collaboration and licensing arrangement, public and private placements of equity securities and debt, and cash received in the Merger with resTORbio. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. Management expects operating losses and negative cash flows to continue for the foreseeable future, until such time, if ever, that it can generate significant sales of its product candidates currently in development.

On March 12, 2021, the Company entered into a Capital On Demand™ Sales Agreement (the JonesTrading Sales Agreement) with JonesTrading Institutional Services LLC, as sales agent, to provide for the offering, issuance and sale of up to an aggregate amount of $75.0 million of shares of common stock from time to time in "at-the-market" (ATM) offerings. In August 2022, pursuant to the JonesTrading Sales Agreement and subject to the limitations thereof, the Company sold an aggregate of 163,233 shares of common stock at $275.68 per share resulting in net proceeds to the Company of $43.4 million after deducting sales agent commissions and expenses. In November 2022, the Company filed a new prospectus supplement to the 2021 Shelf Registration Statement for the offer and sale of up to $100.0 million of shares of common stock from time to time through the sales agent, which includes the $30.0 million of shares of common stock not sold under the original prospectus and up to an additional $70.0 million of shares of common stock (the JonesTrading ATM Program). In January 2024, the Company raised aggregate net proceeds of approximately $19.3 million through the JonesTrading ATM Program. In March 2024, the Company terminated the JonesTrading ATM Program.

On January 22, 2024, Adicet entered into an Underwriting Agreement (the Underwriting Agreement) with Jefferies LLC (Jefferies) and Guggenheim Securities, LLC (the Underwriters) related to an underwritten public offering (the Offering) of 1,690,917 shares (the Shares) of common stock of the Company, par value $0.0001 per share (the Common Stock), and, in lieu of Common Stock to an investor, pre-funded warrants (the Pre-Funded Warrants) to purchase 527,833 shares of Common Stock (the Warrant Shares). The Shares were sold at a public offering price of $38.40 per share and the Pre-Funded Warrants

were sold at a public offering price of $38.3984 per underlying share, which represents the per share public offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the Underwriters to the Company was $36.096 per Share and $36.0944 per Pre-Funded Warrant, representing a discount to the Underwriters of 6.0%. In addition, the Company granted the Underwriters an option exercisable for 30 days from the date of the Underwriting Agreement to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 332,813 shares of Common Stock. On January 23, 2024, the Underwriters exercised this option in full. The Company received net proceeds from the Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $91.7 million. The Company may receive nominal proceeds, if any, from the exercise of the Pre-Funded Warrants.

In March 2024, the Company entered into an Open Market Sales Agreement℠ (the Jefferies Sales Agreement) with Jefferies to sell shares of its Common Stock from time to time, through an ATM equity offering program under which Jefferies will act as sales agent or principal. As of December 31, 2025, no shares of common stock have been sold under the Jefferies Sales Agreement.

On October 7, 2025, the Company entered into an Underwriting Agreement (the 2025 Underwriting Agreement) related to an underwritten registered direct offering (the 2025 Offering) of 4,375,062 shares (the 2025 Shares) of Common Stock, and, in lieu of Common Stock to an investor, pre-funded warrants (the 2025 Pre-Funded Warrants) to purchase 625,000 shares of Common Stock (the 2025 Warrant Shares). The 2025 Shares were sold at a price of $16.00 per share and the 2025 Pre-Funded Warrants were sold at a price of $15.9984 per underlying share, which represents the per share offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the Underwriters to the Company was $15.04 per 2025 Share and $15.03856 per 2025 Pre-Funded Warrant, representing a discount to the Underwriters of 6.0%. The Company received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $74.8 million. The Company may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

The Company expects that its cash, cash equivalents and short-term investments, including the proceeds raised through the 2025 Offering, will be sufficient to fund its forecasted operating expenses, capital expenditure requirements and debt service payments for at least the next twelve months from the issuance of these consolidated financial statements.

All of the Company's revenue to date has been generated from a collaboration and license agreement (the Regeneron Agreement) with Regeneron Pharmaceuticals, Inc, (Regeneron). The Company does not expect to generate any significant product revenue until it obtains regulatory approval of and commercializes any of the Company's product candidates or enters into additional collaborative agreements with third parties, and it does not know when, or if, either will occur. The Company expects to continue to incur significant losses for the foreseeable future, and it expects the losses to increase as the Company continues the development of, and seeks regulatory approvals for, its product candidates and begins to commercialize any approved products. The Company is subject to all of the risks typically related to the development of new product candidates, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, risk of failure in preclinical and clinical studies, safety and efficacy of its product candidates in clinical trials, the risk of relying on external parties such as contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs), the regulatory approval process, market acceptance of the Company's products once approved, lack of marketing and sales history, dependence on key personnel and protection of proprietary technology and it may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect its business.

Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through the sale of equity, debt financings, collaborative or other arrangements with corporate or other sources of financing. Adequate funding may not be available to the Company on acceptable terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and the Company's ability to pursue its business strategies. Although the Company continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements and related disclosures have been prepared in conformity with accounting principles generally accepted in the United States of America (United States GAAP or GAAP).

Reverse Stock Split

On December 26, 2025, the Company announced that the Board of Directors determined to effect a one-for-16 reverse stock split (the "Reverse Stock Split") of the Company's common stock, par value $0.0001 per share.

The Reverse Stock Split ratio is within the previously disclosed range of ratios for reverse stock split authorized by the stockholders of the Company at the 2025 Special Meeting of Stockholders of the Company held on December 19, 2025. The Reverse Stock Split took effect at 12:01 a.m. Eastern Time on December 30, 2025, and the Company's common stock began trading on a split-adjusted basis on The Nasdaq Capital Market as of the opening of trading on December 30, 2025.

On the effective date, every sixteen (16) of Adicet's issued shares of common stock were combined into one issued share of common stock, without any change to the par value per share. This reduced the number of outstanding shares of common stock from approximately 153.3 million shares to approximately 9.6 million shares. The Reverse Stock Split did not affect the absolute number of the Company's authorized shares of common stock, which remains at 300,000,000, but the total number of shares of the Company's common stock available for future issuance increased.

Proportional adjustments have also been made to the number of shares of common stock awarded and available for issuance under the Company's equity incentive plans, as well as the exercise price and the number of shares issuable upon the exercise or conversion of the Company's outstanding stock options and other equity securities under the Company's equity incentive plans. All outstanding pre-funded warrants have also been adjusted in accordance with their terms, which will result in proportionate adjustments being made to the number of shares issuable upon exercise of such warrants and to the exercise prices of such warrants, as applicable. No fractional shares will be issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to receive fractional shares will automatically be entitled to receive cash in lieu of such fractional share. Accordingly, unless otherwise noted, all share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. The shares of our common stock retained a par value of $0.0001 per share.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the date of the consolidated financial statements as well as the reported amounts of revenues and expenses during the reporting period. Such estimates include deferred tax assets, useful lives of property and equipment, accruals for research and development activities, revenue recognition and stock-based compensation and the Company’s incremental borrowing rate. Actual results could differ from those estimates.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of research and development of allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. The Company’s Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Chief Operating Decision Maker (CODM) uses consolidated net loss to monitor budget versus actual results, assess cash runway, and benchmark against the Company’s competitors. The Company adopted ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* in the fourth quarter of 2024. Refer to Note 17. Segment Reporting for the Company's significant segment items.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents, restricted cash and short-term investments in treasury securities. The Company’s cash and cash equivalents, as well as its short-term investments in treasury securities, are held at two financial institutions in the U.S., one financial institution in China and one financial institution in Israel and such amounts may, at times, exceed insured limits. The Company invests its cash equivalents in treasury securities and money market funds. The Company limits its credit risk associated with cash equivalents and short-term investments in treasury securities by placing them with banks and institutions it believes are highly creditworthy and in highly rated investments. The Company has not experienced any losses on its deposits of cash and cash equivalents or its short-term investments in treasury securities to date.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials, and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

The Company's product candidates are still in development and, to date, none of the Company's product candidates have been approved for sale and, therefore, the Company has not generated any revenue from product sales.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2025, and 2024, cash and cash equivalents consist of cash deposited with banks, investments in money market funds and investments in treasury securities with maturities of three months or less from the date of purchase.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash for years ended December 31, 2025 and December 31, 2024 consists of collateral for letters of credit issued in connection with real estate leases and a letter of credit issued in connection with corporate credit card services. Refer to Note 18 for additional information regarding restricted cash.

Short-Term Investments

The Company classifies investments with original maturities of greater than three months and less than twelve months from the date of purchase as short-term investments on its consolidated balance sheets. The Company's short-term investments are maintained by investment managers and consist of treasury securities. Treasury securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Amortization and accretion of premiums and discounts are recorded in interest income, net on the Company's consolidated statements of operations and comprehensive loss.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments of the Company, including cash equivalents, restricted cash, accounts payable and accrued and other current liabilities approximate fair value due to their relatively short maturities. Financial instruments, such as money market funds and treasury securities are measured at fair value at each reporting date. Refer to Note 3. Fair Value Measurements.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three years. Leasehold improvements are amortized using the straight-line method over the lesser of the assets' estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability is measured by comparison of the carrying amount of the asset or asset group to the future net cash flows which the asset or asset group is expected to generate. If such asset or asset group is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset or asset group exceeds the fair value of the asset or asset group. No such impairments were recognized for the years ended December 31, 2024 and 2025.

Revenue Recognition

Under ASC 606, *Revenue from Contracts with Customers* (ASC 606), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps as prescribed by ASC 606:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the Company satisfies a performance obligation.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to these products or services, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the goods or services promised and determines the performance obligations by assessing whether each promised good or service is distinct. Goods or services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

For revenue recognition purposes, the Company determines the term of its license or collaboration agreements by evaluating the period during which present and enforceable rights and obligations exist. This determination is impacted by the existence of substantive termination penalties, among other factors.

The Company recognizes revenue under the Company's license or collaboration agreements that are within the scope of ASC 606. These agreements include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and at specified future dates, variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration to which it will be entitled for the contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered most likely to be achieved and estimates the amount to be included in the transaction price.

Payments or reimbursements for the Company's research and development efforts where such efforts are considered part of or a single performance obligation are recognized over time using a measure of progress that best reflects the Company's performance in satisfying the obligation.

Upfront payments are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligation under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangement.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including payroll and related expenses, costs for CDMOs, costs for CROs, materials, supplies, depreciation on and maintenance of research equipment, consulting costs, and the allocated portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, information technology costs and general support services. All costs associated with research and development are expensed within the consolidated statements of operations as incurred.

Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Accrued CRO, CDMO, and Research and Development Expenses

The Company has entered into various agreements with CDMOs and CROs. The Company's research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced are included in accrued and other current liabilities on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to CDMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the consolidated balance sheets until the services are rendered. Through December 31, 2025, there had been no material adjustments to the Company's prior period estimates of accrued research and development expenses.

Leases

Consistent with ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), the Company determines if an arrangement is a lease, or contains a lease, at inception. Leases with a term greater than 12 months are recognized on the balance sheet as Right-of-Use (ROU) assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plan to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

In accordance with ASU 2016-02, the ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate (IBR), which is the estimated rate the Company would be required to pay for a fully collateralized borrowing equal to the total lease payments over the term of the lease, to determine the present value of future minimum lease payments. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASU 2016-02, the Company does not combine lease and non-lease components. Variable lease payments are expenses as incurred.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the

additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company uses the Black-Scholes option-pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions. Changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award. For awards that have a performance condition, the Company recognizes compensation expense based on its assessment of the probability that the performance condition will be achieved, using an accelerated attribution model, over the explicit or implicit service period.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting purposes and for operating loss and tax credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company's deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce deferred tax assets if it is determined that it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings results, expectations of future taxable income, carryforward periods available and other relevant factors. The Company records changes in the required valuation allowance in the period that the determination is made.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the consolidated financial statements. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense (benefit).

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. The Company's potentially dilutive shares, which include outstanding stock options, Employee Stock Purchase Plan (ESPP) awards and unvested restricted stock units (RSUs), are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in undistributed earnings as if all income (loss) for the period had been distributed. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Since the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Subsequent Events Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. The Company has evaluated all subsequent events and determined

that there are no material recognized or unrecognized subsequent events requiring disclosure, other than as disclosed in these notes to the consolidated financial statements.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB under its ASC or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting *(Topic 280): Improvements to Reportable Segment Disclosures*, which enables investors to better understand an entity's overall performance and assists with assessing potential future cash flows. This amendment improves financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. It is applicable to all public entities that are required to report segment information in accordance with Topic 280, Segment Reporting. For SEC filers, this ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted ASU 2023-07 in the fourth quarter of 2024. Refer to Note 17. Segment Reporting.

In September 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the transparency and usefulness of income tax disclosures. This amendment requires public issuers to disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income, or loss, by the applicable statutory income tax rate. Additionally, this amendment requires issuers to disclose the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes as well as the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received). For SEC filers, this ASU is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted ASU 2023-09 in the fourth quarter of 2025 on a prospective basis. Refer to Note 14. Income Taxes.

Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"),* which requires the disaggregation of certain expense captions into specified categories in disclosures within the notes to the consolidated financial statements to provide enhanced transparency into the expense captions presented on the face of the statements of income and comprehensive income. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, with early adoption permitted, and may be applied either prospectively or retrospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its related disclosures.

3. Fair Value Measurements

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three level of inputs that may be used to measure fair value, as follows:

Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Treasury securities (1) (3)	$ 119,612	$ —	$ —	$ 119,612
Money market funds (2) (3)	31,641	—	—	31,641
Total fair value of assets	$ 151,253	$ —	$ —	$ 151,253

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Treasury securities (1) (3)	$ 119,808	$ —	$ —	$ 119,808
Money market funds (2) (3)	27,084	—	—	27,084
Total fair value of assets	$ 146,892	$ —	$ —	$ 146,892

(1) Included in short-term investments in treasury securities in the consolidated balance sheets. These securities have maturity dates of greater than three months, but less than twelve months from the date of purchase.
(2) Included in cash and cash equivalents in the consolidated balance sheets.
(3) Treasury securities and money market funds are included within Level 1 of the fair value hierarchy because they are actively traded and valued using quoted market prices.

4. Marketable Securities

The following tables show the Company's available-for-sale securities adjusted cost, net unrealized gains and losses and fair value by significant investment category as of December 31, 2025 and December 31, 2024, respectively.

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities:				
Treasury securities	$ 119,510	$ 102	$ —	$ 119,612
Total	$ 119,510	$ 102	$ —	$ 119,612

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities:				
Treasury securities	$ 119,792	$ 16	$ —	$ 119,808
Total	$ 119,792	$ 16	$ —	$ 119,808

For the years ended December 31, 2025 and 2024, the Company did not recognize any impairment.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepaid insurance	$ 829	$ 916
Prepaid software subscription and licensing fees	382	518
Interest receivable	342	97
Prepaid maintenance	338	427
Prepayments to CROs and CDMOs	185	1,138
Other prepaid expenses and current assets	320	737
Total prepaid expenses and other current assets	$ 2,396	$ 3,833

6. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	Useful life (in years)	December 31, 2025	December 31, 2024
Leasehold improvements	Lesser of useful life or lease term	$ 28,422	$ 28,228
Laboratory equipment	3	13,725	13,859
Furniture and fixtures	3	802	951
Construction in progress	—	198	198
Computer equipment	3	319	192
Software	3	453	411
		43,919	43,839
Less: Accumulated depreciation and amortization		(27,387)	(21,315)
Property and equipment, net		$ 16,532	$ 22,524

All of the Company's property and equipment as of December 31, 2025 and 2024 is located in the U.S. Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $6.4 million and $6.5 million.

7. Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued CRO costs	$ 5,707	$ 1,490
Accrued compensation	5,632	7,112
Accrued professional services	1,200	722
Accrued CDMO costs	479	1,685
Accrued other research and development expenses	367	398
Accrued other liabilities	221	23
Total accrued and other liabilities	$ 13,606	$ 11,430

8. Term Loan

On April 28, 2020, the Company entered into a Loan and Security Agreement (the Loan Agreement) as amended on July 8, 2020, September 14, 2020, September 15, 2020, October 21, 2021 (the 2021 Loan Amendment), December 2, 2022 (the 2022 Loan Amendment) and May 30, 2023 with Banc of California (formerly known as Pacific Western Bank) to finance leasehold improvements for the facilities in Redwood City, CA and other purposes permitted under the Loan Agreement. Under the 2021 Loan Amendment, Banc of California will provide one or more Term Loans (as defined in the 2021 Loan Amendment), as well as Non-Formula Ancillary Services which shall not exceed $5.5 million in the aggregate. Non-Formula

Ancillary Services are defined as automated clearinghouse transactions, corporate credit card services, letters of credit, or other treasury management services. Per the terms of the Loan Agreement, the aggregate sum of the outstanding Term Loans and Non-Formula Ancillary Services shall at no time exceed $15.0 million, which each Term Loan to be in an amount of not less than $1.0 million.

On March 13, 2023, the Company and Banc of California executed a letter agreeing that, notwithstanding the covenants included in the 2022 Loan Amendment, until June 30, 2023 (i) the Company and its subsidiaries will not be required to maintain the lesser of $200 million or seventy percent (70%) of its combined balances in demand deposit accounts, money market funds and/or insured cash sweep (ICS) accounts with Banc of California and (ii) the Company must maintain its combined balances at Banc of California or its affiliates, including Pacific Western Asset Management (the Letter).

On May 30, 2023, the Company further amended its Loan Agreement with Banc of California (the 2023 Loan Amendment). Pursuant to the 2023 Loan Amendment, the Company must maintain the lesser of (i) $35.0 million or (ii) all of the Company's combined balances in demand deposit accounts, money market accounts, and/or insured cash sweep accounts with Banc of California. If the Company's total cash and investments drop to less than $35.0 million, the 2023 Loan Amendment permits the Company to maintain cash and/or investments in one or more accounts outside of Banc of California up to a total of $2.5 million.

In April 2024, the Term Loan availability under the Loan Agreement expired. The Non-Formula Ancillary Services, which shall not exceed $5.5 million in the aggregate, remained available. On November 27, 2024, the Company executed a payoff letter (the Payoff Letter) with Banc of California to repay in full all outstanding indebtedness and terminate all commitments and obligations, subject to certain exceptions, under the Loan Agreement. Under the Payoff Letter, the Company agreed to pay Banc of California approximately $10,000 in administrative fees and establish cash collateral accounts and execute pledge and security agreements to secure ancillary services provided by Banc of California. The Company paid the $10,000 administrative fees in December 2024. As of December 31, 2025, the Company has $2.9 million of restricted cash held in cash collateral accounts. No termination penalty was paid in connection with the Payoff Letter.

9. Third Party Agreements

Regeneron

On July 29, 2016, the Company entered into a license and collaboration agreement with Regeneron, which was amended in April 2019, with such amendment becoming effective in connection with Regeneron's investment in the Company's Series B redeemable convertible preferred stock private placement transaction in July 2019 (as amended, the Regeneron Agreement).

Financial Terms. The Company received a non-refundable upfront payment of $25.0 million from Regeneron upon execution of the Regeneron Agreement and an aggregate of $20.0 million of additional payments for research funding from Regeneron as of December 31, 2025. In addition, Regeneron may have to pay the Company additional amounts in the future consisting of up to an aggregate of $80.0 million of option exercise fees, as specified in the Regeneron Agreement. Per the terms of the agreement, Regeneron must pay the Company high single digit royalties as a percentage of net sales for immune cell products (ICPs) to targets for which it has exclusive rights, and low single digit royalties as a percentage of net sales on any non-ICP product comprising a targeting moiety generated by the Company through the use of Regeneron's proprietary mice. The Company must pay Regeneron mid-single to low double digit, but less than teens, of royalties as a percentage of net sales of ICPs to targets for which the Company has exercised exclusive rights, and low to mid-single digit of royalties as a percentage of net sales of targeting moieties generated from the Company's license to use Regeneron's proprietary mice. Royalties are payable until the longer of the expiration or invalidity of the licensed patent rights or twelve (12) years from first commercial sale. No royalties have been earned or paid under the Regeneron Agreement through December 31, 2025.

On January 28, 2022, Regeneron exercised its option to license the exclusive, worldwide rights to ADI-002, an allogeneic gamma delta CAR T cell therapy directed against Glypican-3, pursuant to the Regeneron Agreement. In conjunction with the exercise of the option, Regeneron paid an exercise fee of $20.0 million to the Company on January 28, 2022, and the Company completed the transfer of the associated license rights to Regeneron during the first quarter of 2022. The $20.0 million option exercise fee, plus $5.0 million of revenue recognized relating to the combined performance obligation, resulted in an aggregate of $25.0 million recorded as revenue for the year ended December 31, 2022. The Company's obligations under the combined performance obligation were completed during the year ended December 31, 2022.

Regeneron is responsible, at its sole cost, for all development, manufacturing and commercialization of ADI-002 and must pay the Company high single digit royalties as a percentage of any net sales of ADI-002 for a period commencing on the first commercial sale until the longer of (i) the expiration or invalidity of the licensed patent rights or (ii) a low double digit amount of years from first commercial sale.

Twist Bioscience

In March 2021, the Company entered into an Antibody Discovery Agreement (the Twist Agreement) with Twist Bioscience Corporation (Twist). Under the terms of the Twist Agreement, Twist will utilize its proprietary platform technology to assist the Company with the discovery of novel antibodies related to target antigens selected by the Company. The Company maintains the sole and exclusive rights to any program antibodies discovered under the Twist Agreement and has the right to patent, assign, license or transfer any work product under the agreement. Furthermore, the Company has the right to sublicense its rights to program antibodies to third parties. The Company may terminate the Twist Agreement at any time, with or without cause, upon a specified period advance written notice.

Per the terms of the agreement, the Company will pay Twist an upfront, non-refundable project initiation fee, a technology access fee, as well as a project fee for each project entered into under the agreement. Additionally, the Company will pay fees for development and regulatory milestones in the tens of millions of dollars and low single digit royalties on net sales to Twist for programs initiated under the agreement. In November 2022, the Company entered into an amendment to the Twist Agreement (the Twist Amendment). The Twist Amendment updates the language associated with Twist's audit rights as well as the amounts associated with technology access fees.

On a cumulative basis as of December 31, 2025, the Company has incurred and expensed $1.1 million related to project initiation fees, technology access fees and projects fees as research and development expense related to this agreement.

CRISPR

On May 16, 2023, the Company entered into a license and collaboration agreement with CRISPR Therapeutics AG (CRISPR Agreement) to non-exclusively license CRISPR’s gene editing technology (CRISPR Technology) for use in up to a specified number of gamma delta licensed products. CRISPR also has an option to co-develop and co-commercialize a future gamma delta product (the Option Product). Additionally, the parties have agreed on prostate-specific membrane antigen (PSMA) as a collaboration target that the Company will develop an Option Product against. CRISPR has opt-in rights to participate in a 50/50 cost and profit split for the Option Product. If CRISPR elects to opt-in, the Option Product would be designated a collaboration product. If CRISPR elects to not opt-in, the Option Product becomes a licensed product. The Company will lead and be primarily responsible for the development, manufacturing, and commercialization of the Collaboration Product in accordance with plans agreed upon by both parties.

For each licensed product, the Company will retain worldwide rights and may be required to make potential future payments based on the achievement of development and regulatory approval milestones totaling low double digit million dollars for each non-collaboration product, sales milestones totaling low double digit million dollars for each non-collaboration product, and tiered royalties up to low-single digit percentages on net product sales of such product. Unless earlier terminated, the term of the CRISPR Agreement will terminate (i) on a country-by-country basis with respect to each licensed product until the end of the last royalty term in such country for such licensed product and (ii) when a party opts out for collaboration products.

As of December 31, 2025, the Company has not paid any amounts nor are any amounts owed by the Company under the CRISPR Agreement, and no milestones have been achieved.

City of Hope

On July 9, 2024, City of Hope (COH) and the Company entered into a license agreement (COH Agreement) under which COH granted the Company a non-exclusive, worldwide license to patent rights related to its membrane-bound IL12 technology for use in gamma delta T cell products (Licensed Products). The Company may sublicense Licensed Products through multiple tiers. Unless earlier terminated, the term of the COH Agreement continues, on a country-by-country and Licensed Product-by-Licensed Product basis, until the royalty expiration date for each Licensed Product in each country. The Company may terminate the COH Agreement at any time, with or without cause, upon advance written notice.

As consideration for the license, the Company may pay fees for development and regulatory milestones that together total in the single digit millions of dollars and sales milestones in the low-to-mid double digit millions of dollars. Additionally, the Company will pay low single digit percentage royalties on net sales to COH for licensed products covered under the COH Agreement. The Company will pay COH a portion of all consideration received for sublicensing a Licensed Product, ranging from low double digit percentage to a low single digit percentage, such percentage decreasing as development advances for the Licensed Product.

As of December 31, 2025, the Company has incurred no payments under the COH agreement.

10. Commitments and Contingencies

Leases

The Company has operating leases for office and laboratory space in Redwood City, California, and Boston, Massachusetts, as well as one finance lease for lab instruments.

Redwood City

In 2018, Adicet Therapeutics executed a non-cancelable lease agreement, as amended in 2022, pursuant to which the Company leases office and laboratory facility at 1000 Bridge Parkway and a portion of 1200 Bridge Parkway in Redwood City, California (the Redwood City Lease).

On January 9, 2023, Adicet Therapeutics entered into a third lease amendment with Westport Office Park, LLC (the Third Amendment). The Third Amendment further amends the Redwood City Lease and increases the tenant improvement allowance as of January 1, 2023 by an additional $3.0 million. The Company fully utilized the allowance for the continued buildout of office and laboratory space at 1000 Bridge Parkway in 2023. Per the terms of this amendment, this additional allowance will be repaid through equal monthly payments of principal amortization and interest on a monthly basis over the term of the lease at an interest rate of eight percent (8%) per annum. The Company received the allowance on February 21, 2023 and increased the operating lease liability accordingly.

On August 7, 2023, Adicet Therapeutics entered into a fourth lease amendment with Westport Office Park, LLC (the Fourth Amendment). The Fourth Amendment amends the period over which the tenant improvement allowance received in the Third Amendment will be amortized and identifies the monthly amortization payable by the Company.

On November 19, 2025, Adicet Therapeutics entered into a fifth lease amendment with Westport Office Park, LLC (the Fifth Amendment). The Fifth Amendment acknowledges that the portion of the Redwood City Lease related to 1200 Bridge Parkway expired on June 30, 2025.

Boston

In 2018, the Company entered into a lease agreement, as amended in 2019, for office space at 500 Boylston St, Boston, Massachusetts (500 Boylston Lease). Under the terms of the 500 Boylston Lease, the Company was permitted to assign, sublease or transfer this lease, with the consent of the landlord.

On July 19, 2021, the Company entered into a sublease agreement with RFS OPCO LLC (Sublessee), whereby the Company agreed to sublease to Sublessee all of the 9,501 rentable square feet of 500 Boylston St. The expected undiscounted cash flows to be received from the sublease as of December 31, 2025 is as follows (in thousands):

	December 31, 2025
2026	$ 438
2027 and thereafter	—
Total	$ 438

The Company recognized rent expense, net of sublease income, of $3.6 million and $4.0 million for the years ended December 31, 2025 and 2024, respectively.

Further, the Company remains liable for the remaining lease payments under the 500 Boylston Lease, totaling $0.4 million, which is included in the future minimum lease payments table below.

The future minimum lease payments under all non-cancelable operating lease obligations as of December 31, 2025 were as follows (in thousands):

	Operating Leases	Finance Leases
2026	$ 4,009	$ —
2027	3,714	425
2028	3,808	250
2029	3,906	250
2030	662	250
2031 and thereafter	—	—
Total undiscounted lease payments	16,099	1,175
Less: imputed interest	(2,352)	(184)
Total lease liability	13,747	991
Less: current portion	(2,837)	(349)
Lease liability, net of current maturities	$ 10,910	$ 642

The IBR and the remaining lease terms of our facilities and their weighted average IBR and remaining terms are as follows as of December 31, 2025:

Lease Locations	IBR	Remaining Terms (in years)
Redwood City, CA (1000 Bridge Parkway)	6.90%	4.20
Boston, MA	9.30%	0.60
Weighted Average	7.00%	4.10

Lease costs and information related to the lease right-of-use assets, net and lease liabilities consisted of the following (in thousands):

	Twelve months ended December 31,	
	2025	**2024**
Lease Cost		
Operating lease cost	$ 4,207	$ 4,557
Short-term lease cost	142	121
Finance lease cost:		
Amortization of right-of-use assets	83	—
Interest on lease liabilities	36	—
Sublease income	(674)	(727)
Total lease cost	$ 3,794	$ 3,951
Other Information		
Operating cash flows used for lease liabilities	$ (3,449)	$ (3,691)
Financing cash flows used for finance lease liabilities	(150)	—
Weighted-average remaining lease term - operating leases (in years)	4.1	4.9
Weighted-average remaining lease term - finance leases (in years)	4.6	—
Weighted-average discount rate - operating leases	7.00%	7.00%
Weighted-average discount rate - finance leases	10.00%	—

As of December 31, 2025 and 2024, operating right-of-use assets were $10.9 million and $14.2 million, respectively, and operating lease liabilities were $13.7 million and $17.2 million, respectively.

As of December 31, 2025 finance right-of-use assets were $1.0 million and finance lease liabilities were $1.0 million.. There were no finance right-of-use assets and finance lease liabilities as of December 31, 2024.

The Company maintains letters of credit in connection with the Company's office leases in Redwood City, CA and Boston, MA. Refer to Note 18. Restricted Cash for additional information about these letters of credit.

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that 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 to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' liability insurance.

11. Stockholders' Equity

Common Stock

The Company's Restated Certificate of Incorporation, which became effective as of June 6, 2024, authorized the Company to issue 300,000,000 shares of common stock, par value $0.0001 per share, as of December 31, 2025.

Common stockholders are entitled to dividends if and when declared by the Board of Directors of the Company subject to the prior rights of the preferred stockholders. As of December 31, 2025, no dividends on common stock had been declared by the Board of Directors.

The Company has the following shares of common stock reserved for future issuance:

	December 31, 2025	December 31, 2024
Stock options and restricted stock units available for future grant	682,713	192,627
Stock options issued and outstanding	763,464	935,329
Unvested restricted stock units	46,842	44,979
Common stock warrants issued and outstanding	1,152,833	527,833
Total common stock reserved	2,645,852	1,700,768

On January 22, 2024, the Company entered into the Underwriting Agreement with Jefferies and Guggenheim Securities, LLC, as representatives of the Underwriters, related to the Offering of 2,023,729 shares of our common stock, which included 332,812 shares sold and issued upon the exercise in full by the Underwriters of their option to purchase additional shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 527,833 shares of common stock. The pre-funded warrants were sold at a public offering price of $38.3984 per pre-funded warrant, which represents the per share public offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The pre-funded warrants do not have an expiration date and are exercisable at any time. The pre-funded warrants are classified as equity within the Company's consolidated balance sheet. The Company received net proceeds from the Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $91.7 million. The Company may receive nominal proceeds, if any, from the exercise of the pre-funded warrants.

On October 7, 2025, the Company entered into an underwriting agreement related to the 2025 Offering of 4,375,062 shares of Common Stock, and, in lieu of common stock to an investor, pre-funded warrants to purchase 625,000 shares of common stock. The 2025 Shares were sold at a price of $16.00 per share and the 2025 Pre-Funded Warrants were sold at a price of $15.9984 per underlying share, which represents the per share offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the Underwriters to us was $15.04 per 2025 Share and $15.03856 per 2025 Pre-Funded Warrant, representing a discount to the Underwriters of 6.0%. We received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $74.8 million. We may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

The following provides a roll forward of outstanding pre-funded warrants to purchase common stock as of December 31, 2025:

Issuance Date	Number of Shares of Common Stock Issuable	Weighted Average Exercise Price
Outstanding, December 31, 2024	527,833	$ 0.0016
Warrants issued	625,000	0.0016
Warrants exercised	—	—
Warrants forfeited	—	—
Outstanding, December 31, 2025	1,152,833	$ 0.0016

12. Stock-Based Compensation

Stock-based Compensation Expense

The following table presents stock-based compensation expense as reflected in the Company's consolidated statements of operations (in thousands):

	Twelve Months Ended December 31,	
	2025	2024
Research and development	$ 6,377	$ 10,714
General and administrative	7,890	11,519
Total stock-based compensation	$ 14,267	$ 22,233

The following table presents stock-based compensation expense by type of award (in thousands):

	Year Ended December 31,	
	2025	2024
Stock options	$ 12,902	$ 20,608
Restricted stock units	1,211	1,470
Employee Stock Purchase Plan	154	155
Total	$ 14,267	$ 22,233

Stock Options

A summary of stock option activity for the year ended December 31, 2025 is set forth below (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	935,167	$ 49.42	8.1	$ —
Options granted	339,108	$ 13.76		
Options exercised	(50)	$ 14.39		
Options forfeited or cancelled	(510,761)	$ 39.48		
Outstanding, December 31, 2025	763,464	$ 40.23	8.0	$ —
Options exercisable, December 31, 2025	392,811	$ 54.63	7.2	$ —
Vested and expected to vest, December 31, 2025	763,464	$ 40.23	8.0	$ —

The assumptions used in the Black Scholes Model to calculate stock-based compensation are as follows:

	Twelve Months Ended December 31,	
	2025	2024
Fair value of common stock	$8.48 - $12.0	$15.36 - $49.92
Expected term (years)	5.5 - 6.08	5.5 - 6.08
Volatility	88.28% - 93.97%	82.15% - 88.46%
Risk free rates	3.69% - 4.43%	3.63% - 4.52%
Dividend rate	0.0%	0.0%

The fair value of each stock option was estimated at the date of grant using a Black-Scholes option-pricing model using the following assumptions:

The assumptions are as follows:

- *Expected volatility.* The Company has limited trading history. As such, the expected volatility was determined by examining the historical volatilities for comparable publicly traded companies within the biotechnology and pharmaceutical industry using an average of historical volatilities of the Company's industry peers.

- *Risk-free interest rate.* The risk-free interest rate is based on the United States Treasury yield with a maturity equal to the expected term of the option in effect at the time of grant.

- *Dividend yield.* The expected dividend is assumed to be zero as dividends have never been paid and there are no current plans to pay dividends on common stock.

- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this

method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

The Company will continue to use judgment in evaluating the expected volatility, risk-free interest rates, dividend yield and expected term, utilized for stock-based compensation on a prospective basis.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at December 31, 2025 and 2024. The aggregate intrinsic value of stock options exercised was less than $0.1 million during the years ended December 31, 2025 and 2024.

The total fair value of options that vested during the years ended December 31, 2025 and 2024 was $9.3 million and $18.0 million, respectively. The options granted during the years ended December 31, 2025 and 2024 had a weighted-average per share grant-date fair value of $10.44 per share and $22.40 per share, respectively.

As of December 31, 2025, the total unrecognized stock-based compensation expense related to unvested stock options was $6.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.4 years.

In August 2024, certain of our executive officers entered into an option cancellation agreement to surrender certain underwater stock options. This voluntary surrender of stock options was determined to be a settlement for no consideration and the remaining unrecognized compensation cost was recognized immediately upon cancellation. This resulted in $1.6 million of stock-based compensation recognized in the third quarter of 2024 for these options.

In November 2025, an executive officer entered into an option cancellation agreement to surrender certain underwater stock options. This voluntary surrender of stock options was determined to be a settlement for no consideration and the remaining unrecognized compensation cost was recognized immediately upon cancellation. This resulted in $3.1 million of stock-based compensation recognized in the fourth quarter of 2025 for these options.

Restricted Stock Units

The summary of RSU activity and related information for the year ended December 31, 2025 is set forth below:

	Number of Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2024	44,951	$ 70.40
RSUs granted	38,653	$ 14.16
RSUs vested	(17,912)	$ 74.57
RSUs forfeited	(18,850)	$ 30.81
Outstanding, December 31, 2025	46,842	$ 37.81

The Company granted 38,653 and 33,587 RSU's in the years ended December 31, 2025 and 2024, respectively. The weighted-average grant date fair value of RSUs granted during the years ended December 31, 2025 and 2024 was $14.16 and $41.60, respectively.

As of December 31, 2025, there was approximately $0.7 million of unrecognized compensation cost related to unvested RSUs that the Company expects to recognize over a remaining weighted-average period of approximately 1.4 years.

Option repricing

On August 8, 2023, the board of directors approved a stock option repricing (the Option Repricing) effective on August 14, 2023 (the Effective Date) in accordance with the terms of the Company's 2015 Stock Incentive Plan (the 2015 Plan) and Second Amended and Restated 2018 Stock Option and Incentive Plan (the 2018 Plan, and together with the 2015 Plan, the Plans). Pursuant to the Option Repricing, the exercise price of each stock option previously granted under the Plans, totaling 401,994 options, was amended to reduce the exercise price of such options to $34.24 per share, the closing price of the Company's common stock on the Nasdaq Global Market on the Effective Date.

The repriced options otherwise retained their existing terms and conditions as set forth in the Plans and applicable award agreements. The stock option modification resulted in $4.6 million of incremental compensation cost, which was calculated using the Black-Scholes option-pricing model. Of the incremental compensation cost, $0.4 million and $2.3 million was

recognized in the twelve months ended December 31, 2025 and 2024, respectively. The remaining incremental compensation cost of $0.1 million, net of the reversal of expense related to employee terminations prior to August 14, 2024, will be recognized on the straight-line basis over the remaining vesting period of the repriced options. The incremental cost is included in general and administrative expense and research and development expense on the consolidated statements of operations.

Effective August 21, 2024, the board of directors approved a rescission of the Option Repricing for certain non-employee directors of the Company. All of the affected stock options have been reverted to their original exercise price as established at the time of the grant. The Company will continue to recognize the incremental fair value from the Option Repricing for the impacted options. The compensation expense associated with the Option Repricing for these options was not material.

13. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Twelve Months Ended December 31,	
	2025	2024
Net loss - basic and diluted	$ (116,803)	$ (117,122)
Weighted-average shares used in computing net loss per share, basic and diluted	6,891,336	5,491,652
Net loss per share, basic and diluted	$ (16.95)	$ (21.33)

The Company's potentially dilutive shares as of December 31, 2025 and 2024, which include outstanding stock options and unvested RSUs, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the period presented because including them would have been antidilutive:

	As of December 31,	
	2025	2024
Options to purchase common stock	763,464	935,329
Unvested restricted stock units	46,842	44,979
Total	810,306	980,308

14. Income Taxes

The components of the provision for (benefit from) income taxes are as follows (in thousands):

	December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision for (benefit from) income taxes	$ —	$ —

There was no income tax expense nor benefit for the years ended December 31, 2025 and 2024.

A reconciliation of the Company's effective tax rate to the statutory U.S. federal rate is as follows:

	Year Ended December 31, 2025	
	Amount	Percentage
U.S. federal taxes at statutory rate	$ (24,530)	21.0%
State tax, net of federal benefit	—	—
Tax credits	—	—
Change in valuation allowance	20,788	(17.8)%
Nondeductible items		
Stock based compensation	2,924	(2.5)%
Permanent differences	—	—
Other	103	(0.1)%
Worldwide changes in unrecognized tax benefits	—	—
Other	—	—
Foreign tax effects		
Foreign rate differential	715	(0.6)%
Provision for income taxes	$ —	(0.0)%

	2024
Federal statutory income tax rate	21.0%
State income taxes	0.1%
Change in valuation allowance	(17.5)%
Stock-based compensation	(3.3)%
Foreign rate differential	(0.2)%
Other permanent differences	(0.1)%
Provision for income taxes	(0.0)%

The tax effects of temporary differences and carryforwards of the deferred tax assets are presented below (in thousands):

	December 31,	
	2025	2024
Deferred Tax Assets:		
Net operating loss carryforwards	$ 103,031	$ 74,848
Operating lease liability	2,919	3,638
Finance lease liability	210	—
Stock-based compensation	3,043	3,009
Intangible assets	541	621
Fixed assets	1,489	1,032
Accruals and reserves	1,041	1,234
Sec 174 Capitalized R&D	30,834	37,888
Tax credits	26	26
Gross deferred tax assets	143,134	122,296
Less: Valuation allowance	(140,532)	(119,293)
Deferred tax assets, net of valuation allowance	2,602	3,003
Deferred tax liabilities:		
Operating lease right-of-use asset	(2,385)	(3,003)
Finance lease right-of-use asset	(217)	—
Net deferred tax assets	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. Because of the Company’s recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance increased by $21.2 million and by $20.2 million during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, the Company had net operating loss carryforwards of $472.7 million, $16.7 million, and $ 15.2 million to reduce future taxable income, if any, for federal, state and foreign income tax purposes, respectively. Of the federal net operating loss carryforwards, $7.5 million will begin to expire in 2036 if not utilized, and $465.2 million can be carried forward indefinitely. The state carryforwards will begin to expire in 2035.

The Company also had approximately $19.7 million of federal and $11.6 million of California research and development tax credit carryforwards available to offset future taxable income as of December 31, 2025. The federal credits begin to expire in 2041 and the California research credits can be carried forward indefinitely.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. If the Company has experienced an ownership change, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation. As of December 31, 2025, the ownership change analysis has not been completed. Any previous ownership changes may result in a limitation that will reduce the total amount of net operating loss and tax credit carryforwards disclosed that can be utilized. Subsequent ownership changes may affect the limitation in future years.

The Company files income tax returns in the United States federal jurisdiction, California, Massachusetts and Israel. The tax years 2016 to 2024 remains open to United States federal and state examination to the extent of the utilization of net operating loss and credit carryovers. Additionally, the Company is currently undergoing an audit with California's Franchise Tax Board (FTB) regarding the apportionment of revenue for the tax year 2017 and may be obligated to make future payments to the state related to this tax year, depending on the outcome of the examination. The Company is evaluating the FTB's proposal and assessing its course of action.

As of December 31, 2025, the Company had unrecognized tax benefits of $0.8 million related to the transfer of certain intellectual property from its Israeli subsidiary. In addition, as of December 31, 2025, the Company had unrecognized tax benefits of $31.3 million related to the federal and state research and development credits as a result of no formal research credit study performed.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Balance at the beginning of the year	$ 26,370	$ 18,462
Adjustment based on tax positions related to current year	5,734	7,908
Balance at the end of the year	$ 32,104	$ 26,370

The Company recognizes interest expense and penalties related to the above unrecognized tax benefits within income tax expense (benefit). Management determined that no accrual for interest and penalties was required as of December 31, 2025.

15. Related Party Transactions

As of December 31, 2025, Regeneron owned 60,511 shares of the Company's common stock. Regeneron became a related party in July 2019 as a result of Series B redeemable convertible preferred stock financing which was subsequently converted into common stock. For the year ended December 31, 2025, the Company recorded no revenue from the Regeneron Agreement. See Note 9 for a discussion of the Regeneron Agreement.

16. Defined Contribution Plan

The Company maintains a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time United States employees. Employee contributions are voluntary and are determined on an individual

basis subject to the maximum allowable under federal tax regulations. During the years ended December 31, 2025 and 2024, the Company made aggregate matching contributions of $1.1 million each year.

17. Segment Reporting

The Company's operations are organized and reported as a single reportable segment, which includes all activities related to the discovery, development, and commercialization of allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. This presentation is consistent with how the Company's CODM, its Chief Executive Officer, assesses the performance of the Company and makes operating decisions on a consolidated basis. The accounting policies of the consolidated segment are the same as those described in the summary of significant accounting policies (refer to Note 2). The CODM assesses performance and decides how to allocate resources based on consolidated net loss that also is reported on the consolidated statements of operations and comprehensive loss as net loss. The CODM uses consolidated net loss to monitor budget versus actual results, assess cash runway, and benchmark against the Company's competitors. The measure of segment assets is reported on the consolidated balance sheets as total assets. The Company's assets are primarily held in the United States.

The following table sets forth the Company's segment information (in thousands):

	Twelve Months Ended December 31,	
	2025	2024
External program expenses for product candidates		
Prula-cel	$ 17,038	$ 17,756
ADI-270	9,440	4,474
ADI-212	2,181	—
Other programs[1]	—	1,191
Total external program expenses for product candidates	28,659	23,421
Non-program specific expenses[2]	11,300	12,085
Personnel-related expenses (including non-cash stock-based compensation)[3]	53,194	62,163
Depreciation	6,381	6,468
Professional services and consulting fees	8,050	7,339
Facilities and infrastructure expenses	8,154	8,560
Other segment expense[4]	6,376	7,579
Interest income	(5,777)	(10,714)
Other expense, net	466	221
Income tax provision	—	—
Segment net loss	$ 116,803	$ 117,122

(1) Relates to programs that have been discontinued or are currently in the research stage.

(2) Relates to platform research and development expenses which are not attributed to specific programs.

(3) Relates to personnel-related expenses, including non-cash stock-based compensation for the years ended December 31, 2025 and 2024 of $14.3 million and $22.2 million, respectively.

(4) Relates to other expenses primarily for software subscriptions and licenses, office expenses, travel and entertainment, director compensation and recruiting fees.

18. Restricted Cash

As of December 31, 2025 and December 31, 2024, the Company maintained letters of credit of $2.9 million, which are collateralized with bank accounts at financial institutions for letters of credit issued in connection with real estate leases and a letter of credit issued in connection with corporate credit card services. The letters of credit are included within restricted cash on the Company's consolidated balance sheets. Total restricted cash as of December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Redwood City, CA lease[(1)]	$ 2,306	$ 2,337
Boston, MA lease	266	266
Corporate credit card services	300	300
Total	$ 2,872	$ 2,903

(1) Includes the Company's lease at 1000 Bridge Parkway and 1200 Bridge Parkway.

Adicet Bio, Inc.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1*	Restated Certificate of Incorporation, as amended (as currently in effect)
3.2	Amended and Restated Bylaws of the Registrant (as currently in effect) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on January 30, 2018).
4.1*	Description of Securities
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2022).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on January 24, 2024).
10.1	Second Amendment to Lease, dated as of June 16, 2022, between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC, as Landlord (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on June 21, 2022).
10.2+	Antibody Discovery Agreement, dated as of March 23, 2021, by and between the Registrant and Twist Bioscience Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on November 8, 2022).
10.3+	First Amendment to Antibody Discovery Agreement, dated as of November 8, 2022, by and between the Registrant and Twist Bioscience Corporation (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2023).
10.4#	Second Amended and Restated 2018 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on June 5, 2023).
10.5#	2017 Stock Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended, (File No. 333-222373) filed with the SEC on January 16, 2018).
10.6#	2015 Stock Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.13 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).
10.7#	Amended and Restated 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2022).
10.8#	Second Amended and Restated 2018 Stock Option and Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on June 7, 2024).
10.9#	2022 Inducement Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2022).
10.10#	First Amendment to the 2022 Inducement Plan (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2023).
10.11#	Second Amendment to the 2022 Inducement Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 6, 2025).
10.12#	Form of Employment Agreement (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2022).
10.13	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 15, 2022).
10.14#	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.18 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on May 9, 2023).

10.15#	Amended and Restated Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2022).
10.16	Lease Agreement, dated as of October 31, 2018, by and between Adicet Bio, Inc. as Tenant, and Westport Office Park, LLC as Landlord (incorporated by reference to Exhibit 10.23 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).
10.17	First Amendment to Lease, dated as of December 30, 2020, by and between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC as Landlord (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on January 5, 2021).
10.18	Third Amendment to Lease, dated as of January 9, 2023, by and between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC as Landlord (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2023).
10.19	Office Lease Agreement, dated as of January 8, 2018, by and between resTORbio, Inc. and 500 Boylston and 222 Berkeley Owner (DE) LLC (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended, (File No. 333-222373) filed with the SEC on January 16, 2018).
10.20	First Amendment to Office Lease, dated as of April 1, 2019, by and between resTORbio, Inc. and 500 Boylston and 222 Berkeley Owner (DE) LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on May 15, 2019).
10.21	Sublease Agreement, dated as of July 19, 2021, by and between Adicet Bio, Inc. and RFS Opco LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on July 23, 2021).
10.22+	License and Collaboration Agreement, dated as of July 29, 2016, by and between Adicet Bio, Inc. and Regeneron Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.30 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).
10.23+	Amendment No. 1 to License and Collaboration Agreement, dated as of April 4, 2019, by and between Adicet Bio, Inc. and Regeneron Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.31 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).
10.24	Fourth Amendment to Lease, dated as of August 7, 2023, by and between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC as Landlord (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on August 9, 2023).
10.25+	Membership Agreements, dated January 19, 2024 and March 12, 2024, by and between the Registrant and Industrious Bos 131 Dartmouth Street LLC (incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 19, 2024).
10.26#	Form of Stock Option Cancellation Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on November 6, 2024).
10.27+	License and Collaboration Agreement, dated May 16, 2023, by and between the Registrant and CRISPR Therapeutics AG (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on August 7, 2025).
10.28+	Non Exclusive License Agreement, dated July 9, 2024, by and between the Registrant and City of Hope (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on August 7, 2025).
10.29*	Fifth Amendment to Lease, dated as of November 19, 2025, by and between Adicet Therapeutics, Inc. as Tenant and Westport Office Park, LLC as Landlord.
19.1	Adicet Bio, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 19, 2024).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 12, 2021).

23.1*	Consent of KPMG LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1#	Adicet Bio, Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 19, 2024).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File

* Filed herewith.
+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.
# Indicates a management contract or any compensatory plan, contract or arrangement.
** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

Item 16. 10-K Summary

Not applicable.

SIGNATURES

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

Adicet Bio, Inc.

Date: March 12, 2026

By: /s/ Chen Schor
Chen Schor
President, Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Chen Schor and Nick Harvey, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Chen Schor Chen Schor	President, Chief Executive Officer and Director (principal executive officer)	March 12, 2026
/s/ Nick Harvey Nick Harvey	Chief Financial Officer (principal financial officer and principal accounting officer)	March 12, 2026
/s/ Jeffrey Chodakewitz Jeffrey Chodakewitz, M.D.	Director	March 12, 2026
/s/ Steve Dubin Steve Dubin	Director	March 12, 2026
/s/ Michael Grissinger Michael Grissinger	Director	March 12, 2026
/s/Lloyd Klickstein, M.D., Ph.D. Lloyd Klickstein, M.D., Ph.D.	Director	March 12, 2026
/s/ Katie Peng Katie Peng	Director	March 12, 2026
/s/ Andrew Sinclair Andrew Sinclair, Ph.D.	Director	March 12, 2026

ADICET BIO, INC.
CORPORATE AND OTHER INFORMATION

Board of Directors

Jeffrey Chodakewitz, M.D.
Entrepreneur-in-Residence, Yale University Ventures; Advisory Partner, Ascenta Capital Management LLC

Steve Dubin, J.D.
Principal, SDA Ventures LLC

Michael Grissinger
Former Vice President M&A Operations, Divestitures, and Immunology Business Development, Johnson & Johnson

Katie Peng
Chief Commercial Officer, Denali Therapeutics, Inc.

Chen Schor
President, Chief Executive Officer and Director, Adicet Bio, Inc.

Andrew Sinclair, Ph.D., *Lead Director*
Partner, Abingworth LLP

Lloyd Klickstein, M.D., Ph.D.
President and Chief Executive Officer, Koslapp Therapeutics, Inc.

Executive Officers

Blake Aftab, Ph.D.
Chief Scientific Officer

Nick Harvey
Chief Financial Officer

Donald Healey, Ph.D.
Chief Technology Officer

Chen Schor
President, Chief Executive Officer and Director

Julia Maltzman, M.D.
Chief Medical Officer

Investor Relations

For additional information, please contact:
Anne Bowdidge, Head of IR
IR@adicetbio.com

Annual Meeting of Stockholders

The Company's 2026 Annual Meeting of Stockholders will be held virtually on the day and at time as set forth in the notice of the meeting, proxy statement and form of proxy that will be mailed to Company's stockholders in advance of the meeting.

Principal Executive Offices

131 Dartmouth Street, 3rd Floor
Boston, Massachusetts 02116

Transfer Agent

Computershare Trust Company, N.A.
150 Royall Street
Canton, MA 02021

Independent Registered Public Accounting Firm

KPMG LLP