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

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2024**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**

**Commission File Number 001-41259**

# ARCELLX, INC.

**(Exact name of Registrant as specified in its Charter)**

| **Delaware** | **47-2855917** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **800 Bridge Parkway Redwood City, CA 94065** | **94065** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (240) 327-0630**

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, $0.001 par value per share | ACLX | The Nasdaq Global Select Market |

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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, a 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 Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, par value $0.001 per share, held by non-affiliates of the registrant on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $2.6 billion based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on that date. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

The number of shares of Registrant's Common Stock outstanding as of February 21, 2025 was 54,944,012.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Registrant's 2025 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2024. Except with respect to information specifically incorporated by reference, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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"Arcellx," "we," "us," "our," or "the Company" as used in this Annual Report on Form 10-K refer to Arcellx, Inc. and, where appropriate, our subsidiary, Subdomain, LLC.

**Special Note Regarding Forward-Looking Statements**

This Annual Report on Form 10-K (Annual Report) contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
- our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
- the timing, progress, and results of preclinical studies and clinical trials for our programs and product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to recruit and enroll suitable patients in our clinical trials;
- our ability to take advantage of expedited regulatory pathways for our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- our ability to maintain our collaborative relationship with Kite Pharma, Inc., a Gilead company (Kite), in connection with the development, manufacturing and commercialization of certain of our product candidates;
- the expected benefits of potential strategic collaborations with third parties, including our collaboration with Kite and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients who suffer from the diseases we are targeting and the number of participants that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to adequately secure our information technology systems and the regulated data stored therein, as required by law;
- the pricing and reimbursement of our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;

- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our reliance on third parties to conduct clinical trials of our product candidates and manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing cash and cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, military conflicts in Ukraine, Israel, and the Middle East, economic sanctions, political instability, pandemics, climate and/or public health emergencies and economic slowdowns or recessions that may result from such developments which could harm our people or business as well as the value of our common stock and our ability to access capital markets; and
- our anticipated use of our existing resources.

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory, and economic developments. In some cases, you can identify forward-looking statements by terms such as "may," "will," "intend," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," "continue," "likely," and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part I, Item 1A (Risk Factors) of this Annual Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report and the documents that we reference in this Annual Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the SEC) completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

# PART I

## Item 1. Business.

### Overview

We are a clinical-stage biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases. We believe cell therapies are one of the forward pillars of medicine, and our mission is to advance humanity by engineering cell therapies that are safer, more effective and more broadly accessible. Although cell therapies have shown benefits to date, cell therapies have primarily been constrained to existing biologic structures, which has limited their impact and opportunity. Our novel synthetic binding scaffold, the D-Domain, is designed to overcome the limitations of traditional Chimeric Antigen Receptor T-cells (CAR-Ts). Existing cell therapy solutions, most of which use a biologic-based, single chain variable fragment (scFv) binding domain, tend to be difficult to manufacture, beneficial to a limited segment of patients, often result in high toxicity, and have narrow applicability in treatable indications. We believe we can address these limitations by engineering a new class of D-Domain powered cell therapies, including classical single infusion CAR-Ts called "ddCARs" and dosable and controllable universal CAR-Ts called "ARC-SparX", to address hematologic cancers, solid tumors, and indications outside of oncology, such as autoimmune diseases.

Our lead program is a BCMA-targeting ddCAR product candidate called anitocabtagene autoleucel or "anito-cel" (formerly, CART-ddBCMA), which is currently being evaluated in our pivotal Phase 2 iMMagine-1 and the Phase 3 iMMagine-3 trials in patients with relapsed or refractory multiple myeloma (rrMM). We have partnered anito-cel with Kite Pharma Inc., a Gilead company (Kite), through our co-development/co-commercialization collaboration agreement, as described in more detail in "Licenses and Collaborations" below (the Kite Collaboration Agreement). Recently, Kite initiated a global Phase 3 randomized controlled clinical trial (iMMagine-3) of anito-cel in patients with second through fourth line rrMM. Kite will manufacture anito-cel for iMMagine-3. This followed the completion of the technical transfer to Kite, which was announced in May 2024, as well as the transfer of the Investigational New Drug (IND) application for anito-cel in rrMM, which has been cleared by the U.S. Food and Drug Administration (FDA).

Outside of our collaboration with Kite, we intend to evaluate anito-cel for the treatment of certain non-oncology indications, including some autoimmune disorders. We received FDA clearance of an IND application and have initiated a Phase 1 trial in generalized myasthenia gravis (gMG) in 2024.

We also are developing two clinical-stage ARC-SparX programs in Phase 1 trials: ACLX-001, which targets BCMA in rrMM; and our wholly-owned ACLX-002, which targets CD123 in relapsed or refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). In November 2023, Kite exercised its option under the Kite Collaboration Agreement to negotiate a license for ACLX-001.

In December 2024, at the Annual Meeting of the American Society of Hematology (ASH), we presented preliminary data from our pivotal Phase 2 iMMagine-1 trial evaluating anito-cel, in patients with rrMM. We believe these results, along with the data from our Phase 1 clinical trial evaluating anito-cel in rrMM, further demonstrate that our D-Domain technology can potentially provide meaningful clinical benefits. As of the October 31, 2024 data cutoff date for the iMMagine-1 ASH presentation, 86 patients were evaluable for efficacy based on a follow-up of at least two months after treatment with anito-cel, and 98 patients were evaluable for safety based on a follow-up of at least one month after treatment with anito-cel. Data were assessed using the 2016 International Myeloma Working Group (IMWG) uniform response criteria for MM. For more information regarding the IMWG uniform response criteria for MM, see the section entitled "Our Multiple Myeloma Program - anito-cel: Phase 1 Trial in rrMM" below. All patients in iMMagine-1 received a single infusion of anito-cel (target dose of $115\times10^6$ CAR+ T cells).

Key highlights from the preliminary data presented for iMMagine-1 as of the October 31, 2024 data cutoff date are as follows:

- For the 86 efficacy evaluable patients with median follow-up of 9.5 months, per IMWG criteria:
    - 97% (83 of 86) overall response rate (ORR) achieved;

- 53 of 86 (62%) patients achieved complete response (CR) or a stringent complete response (sCR); and
- 70 of 86 (81%) patients achieved very good partial response (VGPR) or higher.

- Of those evaluable for MRD testing (n=58), 54 (93%) were MRD-negative at a minimum of $10^{-5}$ sensitivity.
- Median progression free survival (PFS), and overall survival (OS) were not reached, as less than half of all dosed subjects had experienced an event of progression or death.
- Using the Kaplan-Meier analysis, which calculates the cumulative survival probability in any given length of time through analysis of subjects who have had an event (death or progression) within specified time intervals:
  - PFS rates, which reflect the percentage of patients who are alive and have not progressed, at 6 and 12 months were 93% and 79%, respectively;
  - OS rates, which reflect the percentage of patients who are alive at 6 and 12 months were 97% and 97%, respectively.
- For the 98 safety evaluable patients, anito-cel continues to be well-tolerated.
  - No delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome, have been observed in more than 150 patients dosed with anito-cel.
  - Cytopenias were the most common Grade ≥3 TEAEs; 53 patients (54%) had Grade ≥3 neutropenia, 20 (20%) had Grade ≥3 thrombocytopenia, and 22 (22%) had Grade ≥3 anemia.
  - 84 of 98 patients (86%) experienced Grade 1 or lower cytokine release syndrome (CRS), including 17 (17%) with no CRS. Any grade CRS was observed in 81 patients (83%) with 67 (68%) Grade 1, 13 (13%) Grade 2, and 1 (1%) Grade 5.
  - Any grade ICANS was observed in 9 patients (9%) with 4 (4%) Grade 1, 4 (4%) Grade 2, and 1 (1%) Grade 3. All cases of ICANS resolved.
  - Three deaths occurred in the 117 patients treated in iMMagine-1 due to treatment-emergent adverse events (TEAEs) (related or unrelated to anito-cel: retroperitoneal hemorrhage, CRS, and fungal infection).
- In the safety evaluable population, 85 of 98 patients (87%) were triple refractory, and 41 of 98 patients (42%) were penta refractory. Patients received a median of four prior lines of therapy, with 45 of 98 patients (46%) having received three prior lines.

Additionally, in December 2024, at the Annual Meeting of the ASH, we presented updated data from our ongoing Phase 1 clinical trial for anito-cel for the treatment of rrMM. As of the October 3, 2024, data cutoff date, 38 patients were evaluable for safety and efficacy analysis using IMWG uniform response criteria for MM. These evaluable patients comprised the dose escalation cohorts for the first dose level (DL1) (n=6), the second dose level (DL2) (n=6), and a dose expansion cohort of DL1 (n=26).

Key highlights from the data presented are as follows:

- For the 38 efficacy evaluable patients with median follow-up of 38.1 months, per IMWG criteria:
  - 100% ORR achieved;
  - 30 of 38 (79%) patients achieved CR or sCR; and
  - 35 of 38 (92%) patients achieved VGPR or higher.
- Of those evaluable for MRD testing (n=28), 25 (89%) were MRD-negative at a minimum of $10^{-5}$ sensitivity.

- With a median follow-up of 38.1 months, median OS was not reached and the estimated Kaplan-Meier median PFS for the study population was 30.2 months.

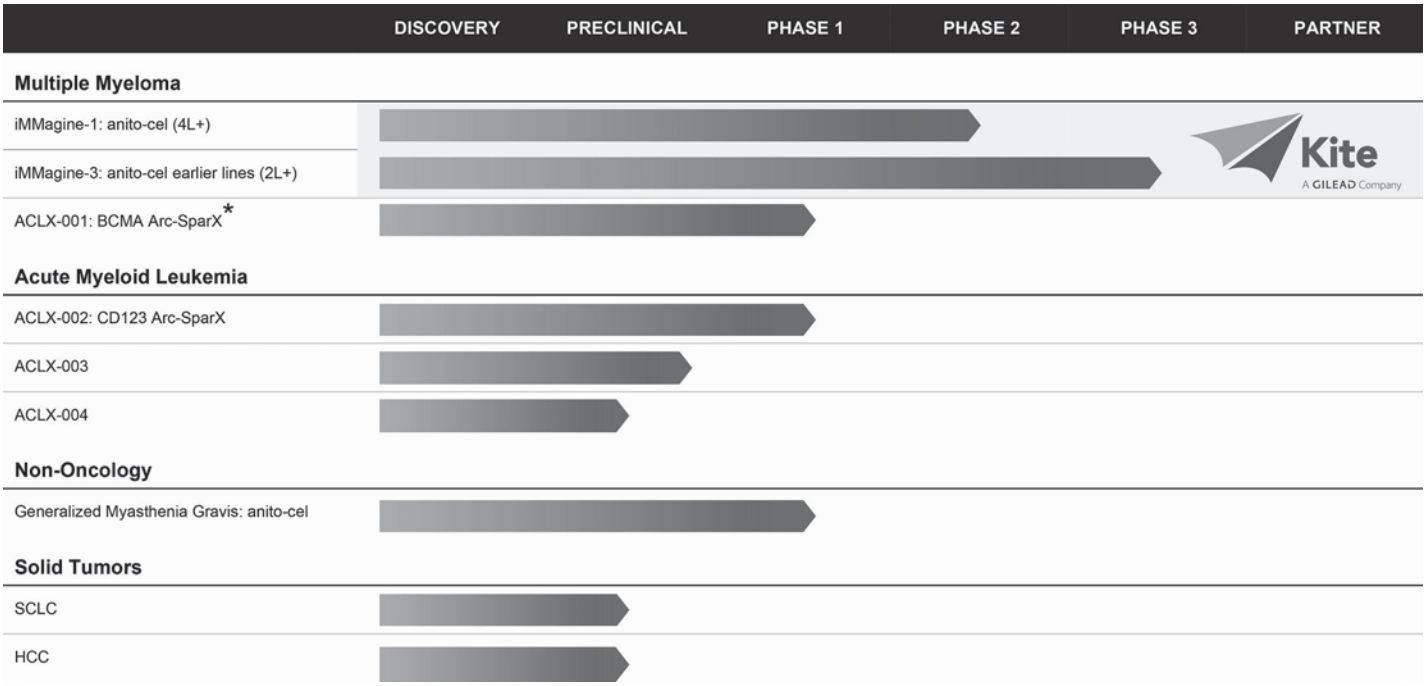
- The safety profile was manageable and consistent with prior data presentations, including no delayed or non-ICANS neurotoxicities observed, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome.

Overall, patients enrolled in the Phase 1 trial had poor prognostic factors with 26 of 38 (68%) patients being penta-refractory and all 38 patients being triple refractory, with a median of four prior lines of therapy. 20 of 38 (53%) patients were aged 65 or older at time of dosing. 26 of 38 (68%) patients had at least one high-risk prognostic feature, defined as a patient with extramedullary disease (EMD); International Staging System (ISS) Stage III (defined as serum ß2 micro globulin value that is greater than or equal to 5.5 mg/L); High Risk Cytogenetics (Del17p, t(14;16), or t(4;14)); or greater than or equal to 60% bone marrow plasma cells (BMPC). Patients with these high-risk prognostic features have been reported to experience lower CR rates and shorter duration of response (DOR) in clinical trials of other BCMA-targeting CAR-T therapies. All patients enrolled scored 0 or 1 on the Eastern Cooperative Oncology Group Performance Status Scale and the subtypes of MM were representative of the natural distribution of MM subtypes.

We believe the preliminary results from our pivotal Phase 2 iMMagine-1 trial along with the Phase 1 trial of anito-cel demonstrate the potential for anito-cel to become a best-in-class treatment for patients suffering from rrMM, including those considered high risk. MM is the third most common hematological malignancy in the United States and Europe, with approximately 35,000 new cases diagnosed per year in the United States. Although changes in the treatment landscape for MM have increased the rates of and depth of response (antitumor activity), MM is currently considered incurable; and patients typically have a life expectancy of just over five years. We estimate that the size of the global MM market was approximately $25 billion in 2024 and that the current total addressable global CAR-T market for rrMM to be $12 billion or more based on the number of patients who are receiving second line treatments and beyond.

Based on our recent discussions with the FDA, we believe that results from our iMMagine-1 Phase 2 clinical trial, if positive, together with the results from our Phase 1 trial could be sufficient to support the filing of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). We are also rapidly pursuing clinical development of anito-cel in earlier lines of therapy through our Phase 3 iMMagine-3 clinical trial in second through fourth line rrMM in collaboration with Kite. In November 2024, we announced the first patient dosed iMMagine-3, which is being manufactured by Kite, and followed the completion of the technical transfer of our cell manufacturing to Kite earlier in 2024. As described in more detail in “Licenses and Collaborations” below, we are collaborating with Kite to co-develop and co-commercialize anito-cel as well as other autologous and non-autologous CAR-T cell therapies that use the same D-domain BCMA binder for the treatment of MM, pursuant to the Kite Collaboration Agreement.

We have summarized our preclinical and clinical programs in the pipeline chart below and indicated where such programs are subject to the Kite Collaboration Agreement, which is described in “Licenses and Collaborations” below. Except for such partnered programs, we have worldwide rights to all our programs.



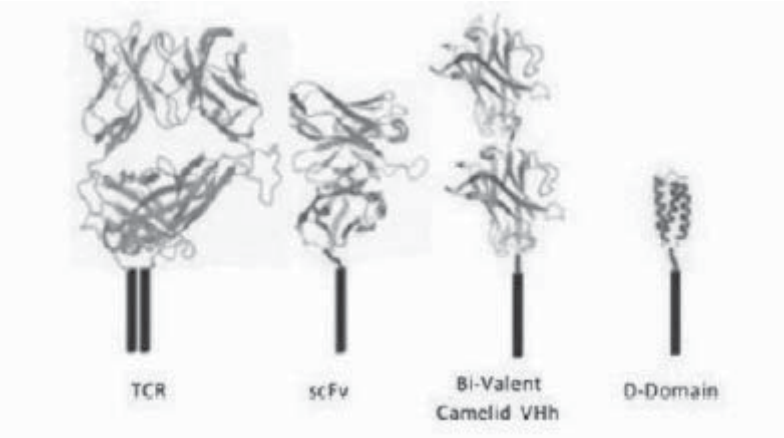

** Kite exercised its option to negotiate a license for ACLX-001 and retains one remaining option for a select ARC-SparX program in multiple myeloma and lymphoma*

Outside our collaboration with Kite, we are also advancing anito-cel into select autoimmune disorders. We recently initiated our Phase 1 clinical trial of anito-cel in generalized Myasthenia Gravis (gMG), a rare autoimmune disease characterized by severe muscle weakness. In gMG, the body's immune system mistakenly attacks proteins in the neuromuscular junction, disrupting neuromuscular signaling and preventing muscle contraction. We believe anito-cel's mechanism in targeting plasma cells through BCMA may be a relevant mechanism to address the underlying pathogenesis of disease. We estimate that gMG affects over 70,000 people in the United States and there is no known cure.

We are also advancing our novel ARC-SparX programs, including our clinical-stage programs, ACLX-001 in rrMM and wholly-owned ACLX-002 in relapsed or refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). ARC-SparX are adaptable versions of ddCARs where the antigen-targeting region is located on a SparX protein that can be dosed separately from the ARC-T cells, our proprietary D-Domain based universal CAR-T-cells that are designed to activate only when bound to a SparX protein that is bound to an antigen on a cell. We believe that controlling ARC-T activation with SparX protein effectively separates the antigen-recognition and killing functions, which allows for a more controlled, modular approach to CAR-T therapy, as SparX dosing may be modified over the course of treatment to reduce toxicities, multiple SparX proteins may be incorporated to address antigen heterogeneity, and additional functionality (i.e., logic-gating) may be designed to expand the utility of CAR-T therapy. Further, the approach has potential to simplify the manufacturing and the regulatory path of multiple CAR-T programs, as the ARC-T programs can utilize the same vector and express the same binding domain. Our preclinical studies of our ARC-SparX product candidates have demonstrated that ARC-T cells can be activated by different SparX proteins that target different antigens suggesting that ARC-SparX can potentially address antigen heterogeneity, and thereby address some harder to treat indications.

We initiated our Phase 1 clinical trial of ACLX-001, the first product candidate developed under our ARC-SparX platform, for the treatment of rrMM in the second quarter of 2022. ACLX-001 is an immunotherapeutic combination composed of our ARC-T-cells and SparX proteins that target BCMA. This trial is intended to establish an ARC-SparX dosing regimen and prepare for ARC-SparX trials in expanded indications. In November 2023, Kite exercised its option under the Kite Collaboration Agreement to negotiate a license for ACLX-001. Our lead ARC-SparX indication is AML/MDS, for which we have multiple SparX in development targeting different antigens. We initiated the Phase 1 clinical trial for ACLX-002, an ARC-SparX product candidate targeting CD123, for the treatment of AML/MDS in the fourth quarter of 2022.

We believe we have built a broad and scalable pipeline that positions us to capitalize on the potential of our proprietary platform technologies and potentially achieve long-term growth and sustainability within the field of cell therapy. We believe our therapeutic approaches, ddCAR and ARC-SparX, will enable us to select mechanisms that are most appropriate for each target and indication we may choose to pursue based on underlying disease biology and patient need, such as in solid tumors, including small cell lung cancer (SCLC) and hepatocellular carcinoma (HCC). We are also integrating AI-powered discovery and computational tools to expand the applicability of our platforms.




Our D-Domain platform has broad potential utility for additional cell modalities, targets, therapeutic areas and applications and we plan to expand our pipeline beyond hematologic and solid cancers to autoimmune disease, as well as to allogeneic and other cell types, including through our collaboration with Kite. We believe our preliminary clinical data for anito-cel have demonstrated that D-Domains can potentially provide meaningful clinical benefits. Our D-Domain platform consists of structurally unique binders that are small and stable, which can be consistently manufactured. They can also be modified to generate diverse libraries of proprietary target- binding domains. The small size and structure of our D-Domain binders compared to other antigen binding domains used in CAR constructs, such as scFvs, are illustrated above. In our preclinical studies, we have demonstrated that CARs with D-Domains exhibit higher transduction efficiency, higher surface expression, and lower tonic signaling than CARs with scFvs, which we believe can lead to cell therapies with improved therapeutic benefit and reduced toxicity. From our clinical trials of anito-cel, we reported preliminary data that we believe supports efficacy and safety benefits, as well as potential manufacturability advantages associated with our D-Domain technology.

The recent availability of cell therapy products, such as CAR-T-cells, introduced an unprecedented “living therapeutic” modality that offers benefits well beyond what previous oncology modalities offered. For the first time, these therapeutics directly harness the strength of the patient’s own immune system to significantly reduce, even potentially eradicate, tumors. While CAR-T and other genetically modified cell therapies have shown significant progress in extending or improving the lives of patients who often have no other treatment options, there remain limitations to their broader use, including variable long-term efficacy, significant adverse effects, narrow applicability, and limited access. Our mission is to advance humanity by engineering cell therapies that are safer, more effective, and broadly accessible. We plan to achieve this goal by maximizing the impact of our proprietary D-Domain binders, which may enable CAR-Ts to have distinct advantages that address these limitations, including achieving promising preliminary clinical data with high ORR and durable responses, potentially differentiated safety profile, opportunity to treat a broader group of patients, and potential manufacturability advantages through our D-Domain technology and the partnership with an experienced CAR-T company (see Kite Collaboration Agreement), as detailed in the section entitled “Cell Therapy Background & Current Limitations” below.

The foundation of our competitive advantage is our proprietary technology, clinical evidence, track record of execution, manufacturing success, and assembly of a proven management team. We believe these advantages, and our recent partnership around our lead program anito-cel with global cell therapy leader, Kite, position us to achieve significant market share in a large and attractive market and to ultimately transform the cell therapy market, contributing to a significant advancement in medicine.

## Our Strategy

Our strategy to achieve our mission is as follows:

- In collaboration with Kite, advance anito-cel to treat rrMM patients in the United States and abroad;
- Develop a comprehensive ARC-SparX AML/MDS program;
- Expand our pipeline, including to select solid tumor indications and indications outside of oncology;
- Evaluate anito-cel for the treatment of certain non-oncology indications, including selected autoimmune disorders;
- Apply our D-Domain technology outside of autologous CAR-T solutions, including through our collaboration with Kite;
- Enable greater access to CAR-T therapy through clinical trials in broader patient populations that support improved market access;
- Invest in building out infrastructure and technologies that lower customer friction, increase capacity and improve responsiveness;
- Leverage AI, machine learning, and other novel technologies to drive our discovery efforts; and
- Opportunistically pursue strategic partnerships and collaborations, such as our collaboration with Kite, to maximize the full potential of our platform.

## Our Team

Our team and culture are critical to realizing our vision of reimagining cell therapy as one of the future pillars of medicine.

We are led by a diverse team of executives with significant experience in business, discovery, development, manufacturing, and commercialization of differentiated and novel therapies specifically in the fields of oncology, cell therapy and rare diseases. Rami Elghandour, our Chairman and Chief Executive Officer, previously served as President and Chief Executive Officer at Nevro where he grew the company from a small private company to a publicly traded commercial organization with nearly $400 million in revenue. Prior to Nevro, Mr. Elghandour was an investor with Johnson & Johnson Development Corporation where he led several investments, including Nevro's Series B financing. Our Chief Medical Officer, Christopher Heery, M.D., an oncologist by training, was the former Head of Clinical Trials Group for the Laboratory of Tumor Immunology and Biology at the National Cancer Institute, and previously served as Chief Medical Officer at Precision Biosciences and Bavarian Nordic. Our Chief Financial Officer, Michelle Gilson, was previously a senior equity research analyst covering the biotechnology sector, most recently as a Managing Director at Canaccord Genuity.

We have attracted a diverse and talented group of innovators and company builders to help us execute our strategy and to build a transformative cell therapy platform company. Collectively, we are driven by our shared purpose and our values.

As of December 31, 2024, we had 163 full-time employees and we are committed to continuing to build and maintain a diverse and inclusive organization. We believe focusing on diversity and inclusion is not only the right thing to do but is also a competitive advantage. We also believe talent is equally distributed across gender, ethnicity and is not overly represented in any single group. As such, we believe focusing on building high performance teams naturally leads to building diverse teams. We are purposeful in our efforts to create a culture and environment that attracts and retains top talent, including talent from underrepresented groups as reflected in the diversity throughout our organization:

- Total Company: 54% female; 74% diverse (gender, racial & ethnic representation);
- Board of Directors: 43% female; 86% diverse;
- Executive Leadership: 60% female; 90% diverse;
- Directors roles: 41% female; 59% diverse;

- Managers and senior scientists with managerial responsibilities: 45% female; 63% diverse; and

- Technical and Scientific roles: 48% female; 67% diverse.

Demographics are self-reported and diversity numbers are representative of both gender and ethnic diversity. Our commitment to diversity does not stop within the walls of our organization. With our mission of advancing humanity, we believe in equitable access to healthcare. Inclusive research programs that encompass real-world patient populations can contribute to addressing racial inequality in healthcare. We are dedicated to expanding representation within our clinical trials. We also believe deeply in corporate social responsibility and being conscious stewards in our society. We are devoted to leveraging our science to make a positive impact for the patient and local communities we serve. As our organization expands, we intend to grow our community involvement and outreach efforts and establish our corporate brand as a force for good through corporate philanthropy, patient advocacy, and employee volunteerism.

## Cell Therapy Background & Current Limitations

### Background

T-cells are a key component of the immune system that can target diseased cells for elimination through the recognition of cell surface antigens. A growing understanding of the immune system over the years and advances in cell, gene and protein engineering have led to approved genetically modified cell therapy products.

Genetically modified cell therapy involves isolating immune cells, modifying them outside of the patient's body and then reintroducing them into the patient to destroy diseased cells. Such cell therapies have largely focused on using the patient's own T-cells (autologous approach) to express engineered antigen receptor complexes, such as TCRs or CARs. The extracellular binding domain of the TCR or CAR recognizes the antigen, and, after the T cell binds with the cell expressing the antigen, the intracellular signaling domain induces cell killing and activates pathways specific for the T cell's proliferation and survival.

The recent availability of cell therapy products introduced an unprecedented "living therapeutic" modality that offers benefits well beyond what previous oncology modalities offered. For the first time, these therapeutics directly harness the strength of the patient's own immune system to significantly reduce, even potentially eradicate, tumors. Initially evaluated in indications where patients were refractory to multiple lines of therapy and had generally exhausted their therapeutic options, adoptive cell therapies have shown response rates that exceed many other available modalities, and are now being evaluated in earlier line settings. Particularly striking is that these responses are achieved with a single, personalized administration of the cell therapy, generally achieving rapid and durable responses with toxicities resolving in days to weeks. This transformative therapy results in extended quality of life benefits without maintenance or additional treatment.

As of December 31, 2024, there are seven FDA approved CAR-T cell therapies:

- Carvykti (ciltacabtagene autoleucel), which has been approved by the FDA for treatment of adult patients with rrMM after four or more prior lines of therapy;

- Abecma (idecabtagene vicleucel), which has been approved by the FDA for treatment of adult patients with rrMM after four or more prior lines of therapy;

- Breyanzi (lisocabtagene maraleucel), which has been approved by the FDA for treatment of adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy within 12 months or are also ineligible for stem cell transplantation, and relapsed or refractory LBCL after two or more lines of systemic therapy;

- Kymriah (tisagenlecleucel), which has been approved by the FDA for treatment of patients up to 25 years of age with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, and adult patients with relapsed or refractory LBCL after two or more lines of systemic therapy, and adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy;

- Tecartus (brexucabtagene autoleucel), which has been approved by the FDA for treatment of adult patients with relapsed or refractory mantle cell lymphoma and adult patients with relapsed or refractory B-cell precursor ALL;

- Yescarta (axicabtagene ciloleucel), which has been approved by the FDA for treatment of adult patients with LBCL that is refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, and relapsed or refractory LBCL after two or more lines of systemic therapy, and adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy; and

- Aucatzyl (obecabtagene autoleucel), which has been approved by the FDA for treatment of adults with relapsed or refractory B-cell precursor ALL.

Hematologic cancers represent a robust and growing market opportunity for CAR-T cell therapies. These cancers, which include leukemia, lymphoma and myeloma, account for approximately 10% of all cancer incidence in 2020. Sales of CAR-T therapies in hematologic cancers exceeded $4.5 billion in 2024, representing year over year growth of 22%.

**Current Limitations**

While CAR-T and other genetically modified cell therapies have shown significant progress in extending the lives of patients who often have no other treatment options, there are limitations to their broader use, including:

- **Variable Long-Term Efficacy**: FDA-approved CAR-Ts may offer higher response rates compared to other available therapies, but efficacy as measured by the DOR is highly variable between different CAR-T programs and also within the same program for different patients. Further, unmet need remains for patients with high-risk prognostic features, such as EMD within rrMM, who experience worse outcomes in clinical trials of other BCMA-targeting CAR-T therapies than non-EMD patients, and often do not achieve deep, durable responses.

- **Significant Adverse Effects**: Some cell therapies also have the potential to cause several adverse effects. Uncontrolled cellular expansion and potentially related side effects such as non-ICANS/delayed neurotoxicities (Parkinsonism, cranial nerve palsies, and Guillain-Barré syndrome) as well as other potential off-tumor toxicities may stifle the broader use of these therapies in several key ways. Specifically, they may limit the number of patients that are eligible for treatment, complicate adoption into earlier lines of treatment, preclude the use of these therapies in the non-academic and outpatient settings, and increase costs to patients, payers and providers due to the need for intensive care unit access when they are used.

- **Narrow Applicability**: Currently, CAR-T and other genetically modified cell therapies are utilized in only a few hematological oncology indications. Their activity in most tumors is primarily driven by a limited number of tumor specific antigen targets. Their utility is further limited by secondary resistance mechanisms arising in the relapsed or refractory settings, as well as the antigen heterogeneity that is characteristic of some of these diseases.

- **Limited Access:** Due to the potential for severe toxicities, the limited number of safe and efficacious targets, supply constraints due to manufacturing complexity and scalability of processes, length of the regulatory process, and the substantial capital requirements for bringing cell therapies to market at scale, CAR-Ts are still not widely available for oncology patients. Supply constraints have been specifically cited as a limiting factor for access to FDA-approved BCMA CAR-Ts since their launches. Further, FDA-approved CAR-Ts are primarily administered and managed in authorized treatment centers, which represent approximately 7% of oncology/hematology practices in the United States.

**Our Solution**

Our mission is to advance humanity by engineering cell therapies that are safer, more effective, and broadly accessible. We plan to achieve this goal by maximizing the impact of our proprietary D-Domain binders, which enable CAR-Ts to have distinct advantages including:

- **Promising Clinical Data–High ORR and Durable Responses:** In our iMMagine-1 clinical trial of anito-cel in patients with rrMM, for the 86 patients evaluable for efficacy evaluation, we reported an ORR of 97%, a complete response/stringent complete response (CR/sCR) rate of 62%, and 12-month PFS rate of 79% with a median follow up of 9.5 months. In our Phase 1 trial of anito-cel in 38 patients with rrMM, we reported an ORR of 100%, a CR/sCR rate of 79%, and median PFS of 30 months with a median follow up of 38 months. We believe these results demonstrate the capability of D-Domains not only to effectively bind target antigens and drive CAR-T cell proliferation but also to enable efficient killing of a substantial proportion of tumor cells. High cell surface expression and low propensity for tonic signaling of D-Domains may enable more effective interactions between the CAR and the antigen as well as reduced T-cell exhaustion, which may explain the rapid and long-term responses currently observed in our Phase 1 and iMMagine-1 clinical trials.

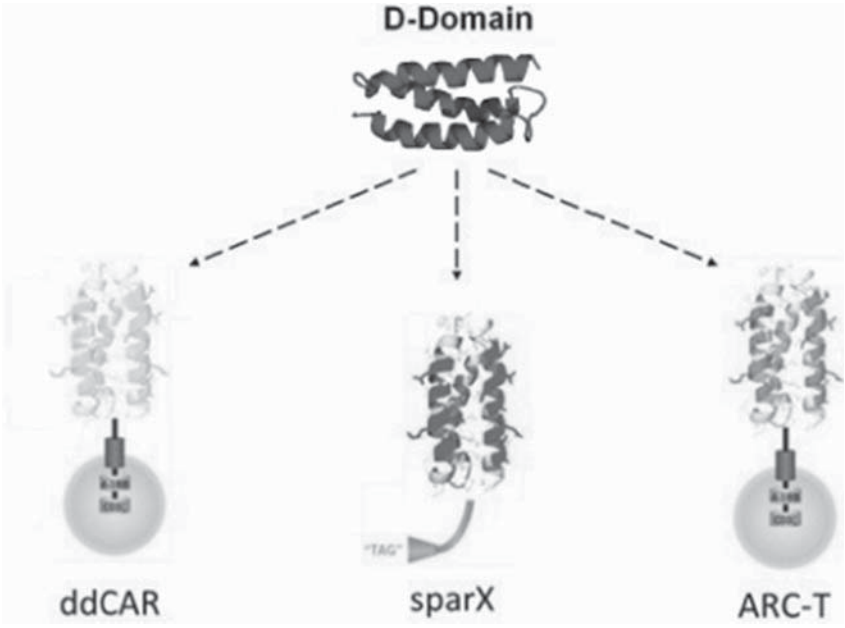
- **Potentially Differentiated Safety Profile:** We believe the small and stable structure of the D-Domain enables a high transduction rate, resulting in a high proportion of cells expressing the CAR construct on the cell surface (CAR+ cells), as we observed in our clinical trials of anito-cel. A high proportion of CAR+ cells lowers the total number of T-cells required to be administered which we believe may yield a therapy with an improved toxicity profile, consistent with currently available results of the clinical trials of anito-cel. In our clinical trials of anito-cel, we did not observe any non-ICANS/delayed neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome in the entire population through the follow-up period. Additionally, a 2022 cross-trial safety analysis on CAR-Ts by the FDA supports this concept, finding lower transduction frequency in the CAR-T product was significantly associated with higher rates of severe CRS.

- **Opportunity to Treat a Broader Group of Patients:** We believe the preliminary positive results of our clinical trials of anito-cel underscores the advantages conferred by our D-Domain binders. The potential safety profile may allow for increased access through outpatient dosing and ability to discharge patients sooner. Additionally, we plan to continue to expand our pipeline of D-Domain based CAR-Ts to a wider variety of indications in the future. Based on the differentiation of the D-Domain, and the breadth and depth of our D-Domain libraries, we believe we can expand to a broader group of patients, including those with heterogeneous tumor antigen expression and antigen targets that might be difficult to target. We are currently developing therapies within both our ddCAR and ARC-SparX platforms to treat a broad variety of indications, starting with rrMM, AML/MDS, gMG and, in the future, solid tumors.

- **Potential Advantages from D-Domain Manufacturability and Experienced CAR-T Partner:** We believe the manufacturing data from our clinical trials of anito-cel demonstrate the potential manufacturing advantages conferred by D-Domains vs. scFv and biologics-based constructs used in CAR-T therapies. Along with the experience and established CAR-T infrastructure offered by our Kite Collaboration Agreement, which has resulted in high success rates and reliability in delivering their currently marketed products, we are encouraged by our combined potential to mitigate the supply constraints which have limited BCMA CAR-T launches to date. Further, we believe the Kite Collaboration Agreement and the associated economic terms substantially limits our need for additional capital to build out commercial manufacturing infrastructure.

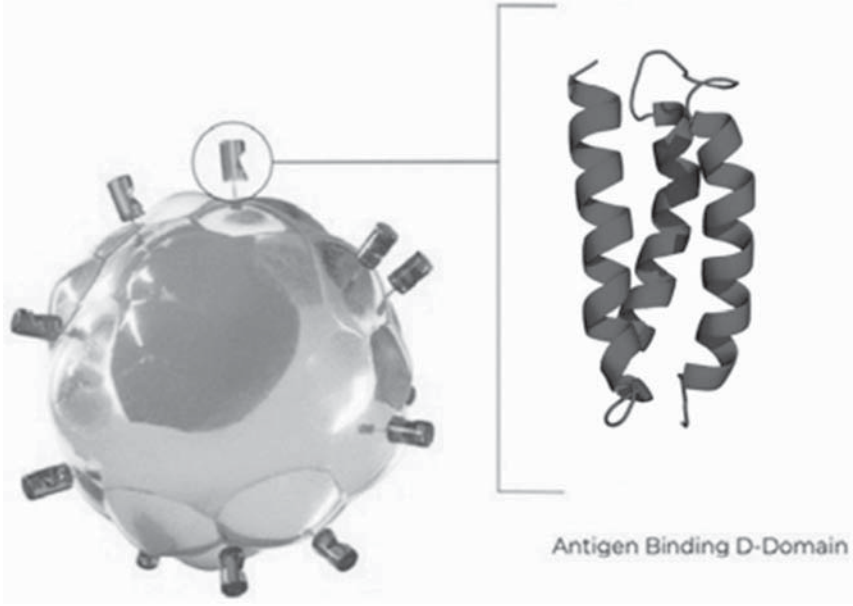
The foundation of our proprietary platform is our D-Domain technology, that has generated promising initial clinical data. We believe our D-Domain technology is a transformational platform that enables us to take the right approach for the right indication within cell therapy. The strengths of the D-Domains are its size, stability, and structure which make it a unique and essential building block for making next generation CAR-Ts to unlock the potential of this therapeutic category which is poised to be one of the forward pillars of medicine. Our method of generating D-Domains, and the individual binders themselves are protected in our patent portfolio, which as of December 31, 2024, includes 34 U.S. and foreign patents and over 90 U.S. and foreign pending applications.

We are generating D-Domains against multiple targets which can then be deployed to create a new class of D-Domain powered cell therapies, including ddCAR and ARC-SparX CAR-T therapies, to address hematologic cancers, solid tumors, and indications outside of oncology such as autoimmune diseases. ddCARs are single infusion CAR-Ts enhanced with our D-Domains as the antigen recognition motif. ARC-SparX are adaptable versions of ddCARs where the SparX protein is dosed separately from the ARC-T cell. Our ARC-T-cells are dosable, controllable, universal CAR-Ts designed to activate only when combined with a SparX protein that is bound to an antigen on a cell.




**ddCAR Platform**

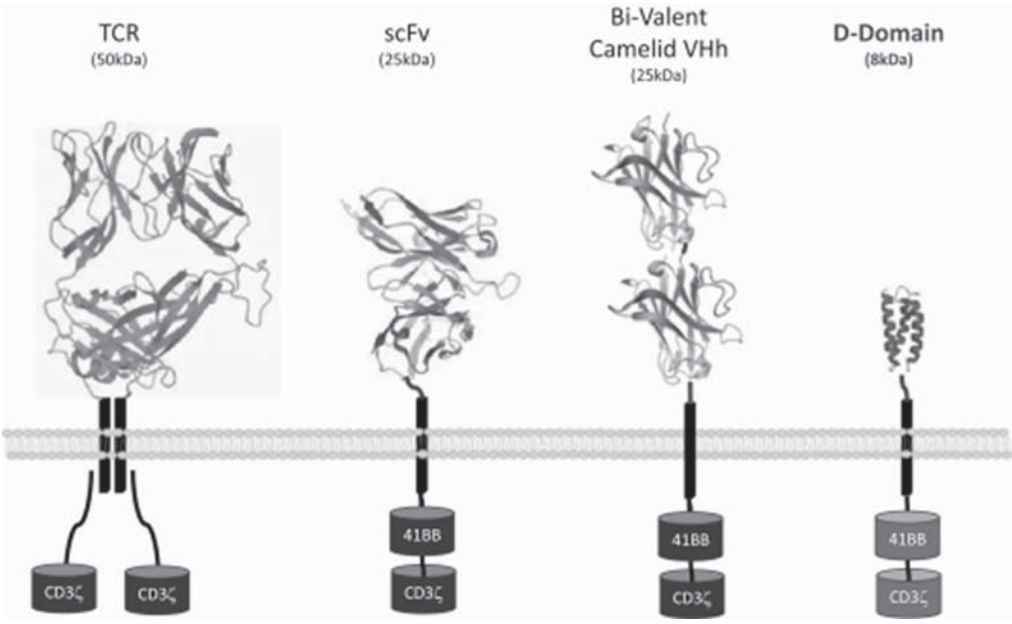
We use our ddCAR platform to generate single infusion therapies where our D-Domain binder replaces the scFvs. The ddCAR is composed of an intracellular T cell signaling domain similar to traditional CARs fused to our D-Domain, which functions as the extracellular antigen binding region. Upon engagement with the antigen on a target cell, the ddCAR signals to activate the T cell to kill the target cell.



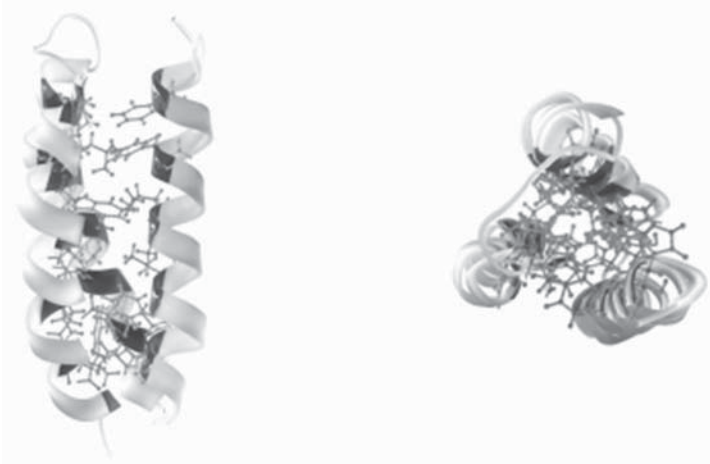

The D-Domain was developed to overcome limitations of existing CAR-T therapies by employing a novel synthetic binding domain as a replacement to the traditionally used antigen binding domains for conventional CAR-T therapies, known as scFvs. The result is a structurally unique binder that is small, stable, and can be modified to generate a diverse library of proprietary target-binding domains.

***Structurally Unique D-Domains***: The unique structural features of our D-Domain may confer the unique combination of properties we observe in our ddCAR product candidates, such as high cell surface expression, high proportion of CAR+ cells (high transduction rate), and low tonic signaling, which we believe have contributed to the efficacy, safety, and manufacturability profile observed in our clinical trials of our lead program anito-cel. D-Domains are short polypeptides that spontaneously fold into a stable triple alpha-helical structure. The D-Domain is derived from a 73 amino acid synthetic protein, α-3D, that has no known homolog in nature or apparent function as first described in a paper by Walsh, et al. that appeared in the Proceedings of the National Academy of Sciences in 1999. This domain is devoid of post-translational glycosylation or disulfide bonds leading to consistent manufacturability via microbial, fungal or mammalian protein expression. Additional key structural features of the D-Domain are as follows:

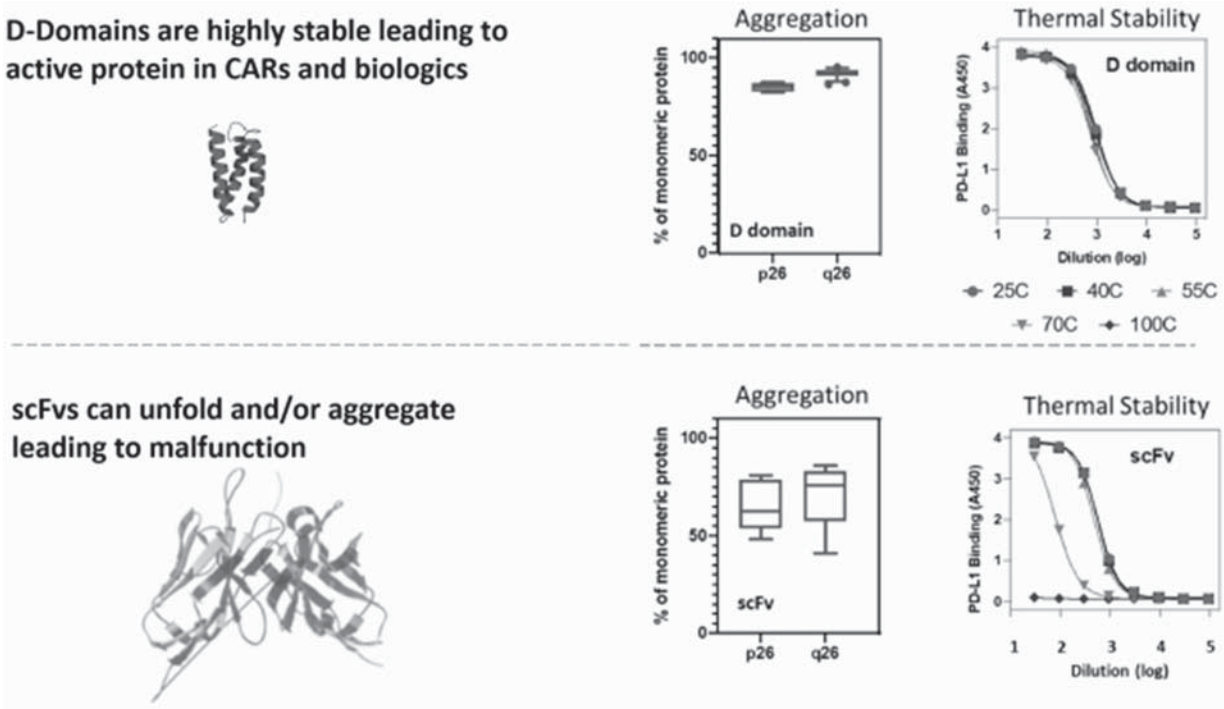
- ***Small Size:*** The figure below showcases the small size of the 8kDa D-Domain compared to other antigen binding domains used in CAR constructs such as the scFv and bi-valent camelid VHh structure of approximately 25kDa. A smaller antigen binding domain will decrease the overall lentiviral construct size which may improve transduction efficiency. The small antigen binding domain may also function to improve the immunological synapse formation and thus CAR-T cell killing.




- ***Hydrophobic Core***: The figure below depicts the three-dimensional structure of the D-Domain highlighting the triple alpha helical bundle with the tight hydrophobic core (in red). The hydrophobic core results in ultrafast folding kinetics of the D-Domain creating a stable structure when expressed in cells.

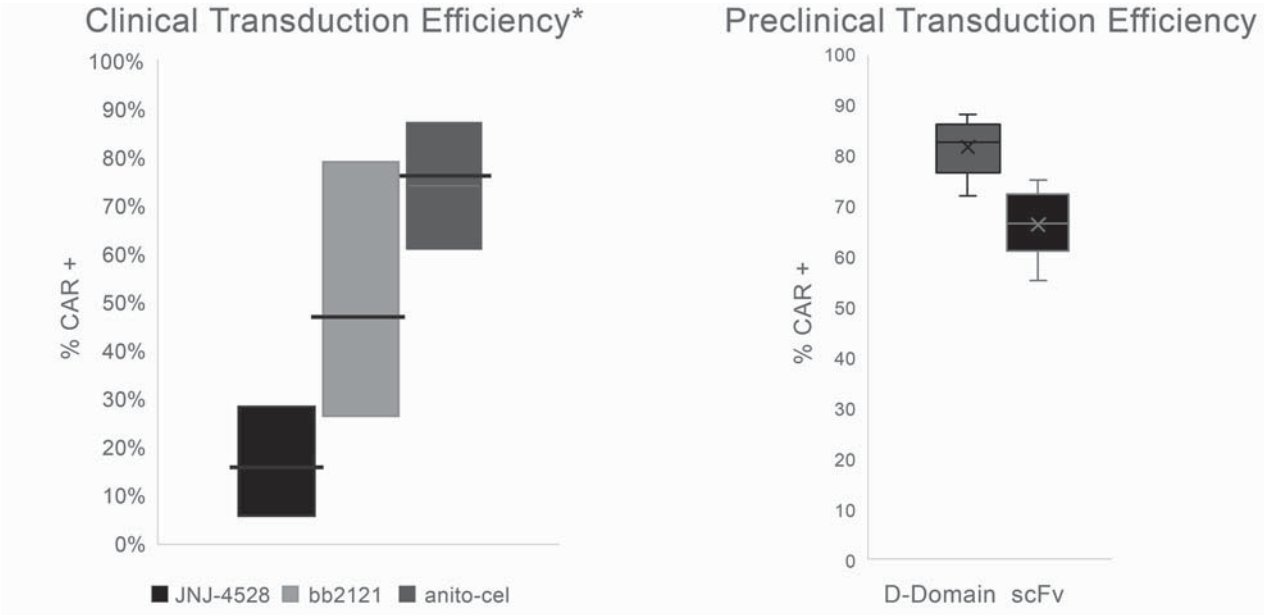


- ***Stability:*** D-Domains are highly stable proteins compared to scFvs which facilitates the high expression of CARs on T-cells and manufacturing of SparX proteins. As shown in the middle panels of the figure below, using size exclusion chromatography, we have demonstrated that a higher level of monomeric protein content can be purified from human embryonic kidney (HEK) 293 cells expressing D-Domain-based SparX proteins compared to scFv, indicating lower levels of aggregation of the D-Domain based SparX proteins and thus greater stability. In addition, we have tested the thermal stability of D-Domains as compared to a PD-L1 binding scFv by heating them to temperatures about 100 degrees Celsius and measuring the retention of PD-L1 binding. As shown in the panels on the far right, D-Domains that were heated to the indicated temperatures retained greater PD-L1 binding as compared to the PD-L1-binding scFv, demonstrating the thermal stability of the D-Domains.




When utilized in CARs, we believe the structural properties of the D-Domain translate into unique benefits of high transduction rates, high cell surface expression, and low tonic signaling. To modify the binding properties of the D-Domain, we can vary the amino acids on the D-Domain scaffold. In the context of ddCARs, we believe the D-Domain structure creates an efficient and scalable cell manufacturing process, as demonstrated by our high CAR+ rate, yield, and viability of cell product made to date. See "Manufacturing and Delivery—anito-cel Cell and ARC-T Cell."

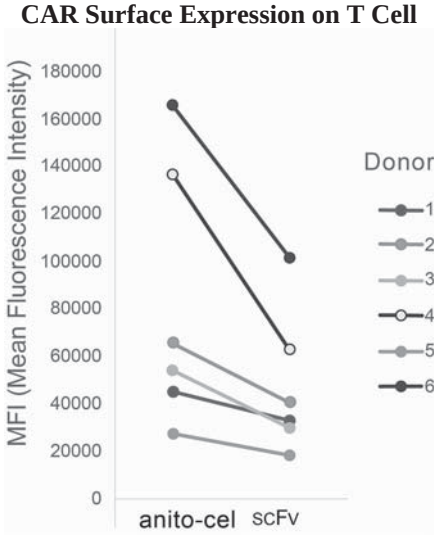
- ***High Transduction Rate*:** In the manufacturing of 38 lots of anito-cel in our Phase 1 clinical trial, the median transduction rate was 70%. In the manufacturing of 117 lots of anito-cel in iMMagine-1, the median transduction rate was 62%. We believe this high transduction efficiency may improve product consistency and reduce the number of untransduced T-cells administered to patients that do not contribute to efficacy but may contribute to toxicity. Our high transduction rate compares favorably with previously published Phase 1 data regarding the transduction rates for Abecma (then known as bb2121) and Carvykti (then known as JNJ-4528), as shown in the left panel of the figure below. While we believe these data suggest that anito-cel has a meaningful advantage in transduction efficiency over existing CAR-T therapies, these data are based on a cross-trial comparison and not a head-to-head clinical trial and may not be directly comparable due to differences in trial designs and methodologies. As manufacturing processes and vectors can also be vastly different across cell products, we also engineered a vector where the D-Domain was replaced by an scFv targeting BCMA while leaving all other conditions identical to isolate the effects on transduction from using a D-Domain as compared to scFv. As shown in the right panel of the figure below, our anito-cel transduced T-cells demonstrated superior transduction efficiency when compared to scFv transduced T-cells derived from multiple normal human donors.



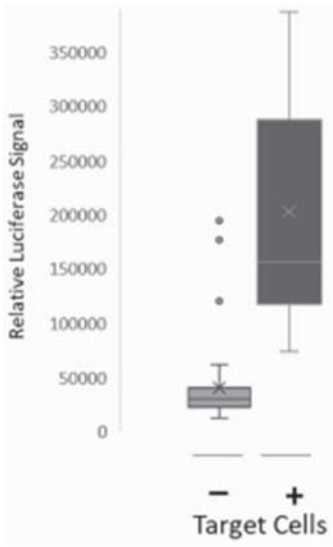

*JNJ-4528 data presented at ASH 2019; bb2121 data presented at ASH 2017; anito-cel Phase 1 data presented at ASH 2023

- ***High Cell Surface Expression*:** Coincident with higher transduction rates, the expression of the CAR on the surface of the T cell is higher with CARs employing a D-Domain compared with an scFv. As shown in the figure below, when transduced with different CAR constructs, the CAR expression on the surface of T-cells of six normal human donors was uniformly higher using a BCMA-binding D-Domain as compared to a BCMA-binding scFv. We believe that higher CAR cell surface density may help drive activation against low antigen-expressing target cells.

**CAR Surface Expression on T Cell**




- ***Low Tonic Signaling*:** Tonic signaling occurs in CAR-T-cells when the CAR construct signals without engaging an antigen on a target cell, which can exhaust a T cell prematurely. T cell exhaustion has been associated with suboptimal outcomes for CAR-T therapies. Tonic signaling has been described in the literature for several scFv-based CARs. To determine the percentage of D-Domains that induce tonic signaling, we examined 42 D-Domains isolated from two different screening campaigns for their ability to signal without antigen stimulation when incorporated into a CAR construct. Pooled data indicated that only 3 out of the 42 D-Domains exhibited a level of tonic signaling above background, as measured by relative luciferase units, a signal detecting CAR activation, as represented by the blue dots in the left-hand column of the figure below. In contrast, the 42 D-Domains exhibited a much higher level of CAR activation in the presence of the CAR antigen, as illustrated by the right hand column of the figure below. We believe the low propensity for tonic signaling of D-Domain-based CARs may lower T cell exhaustion.

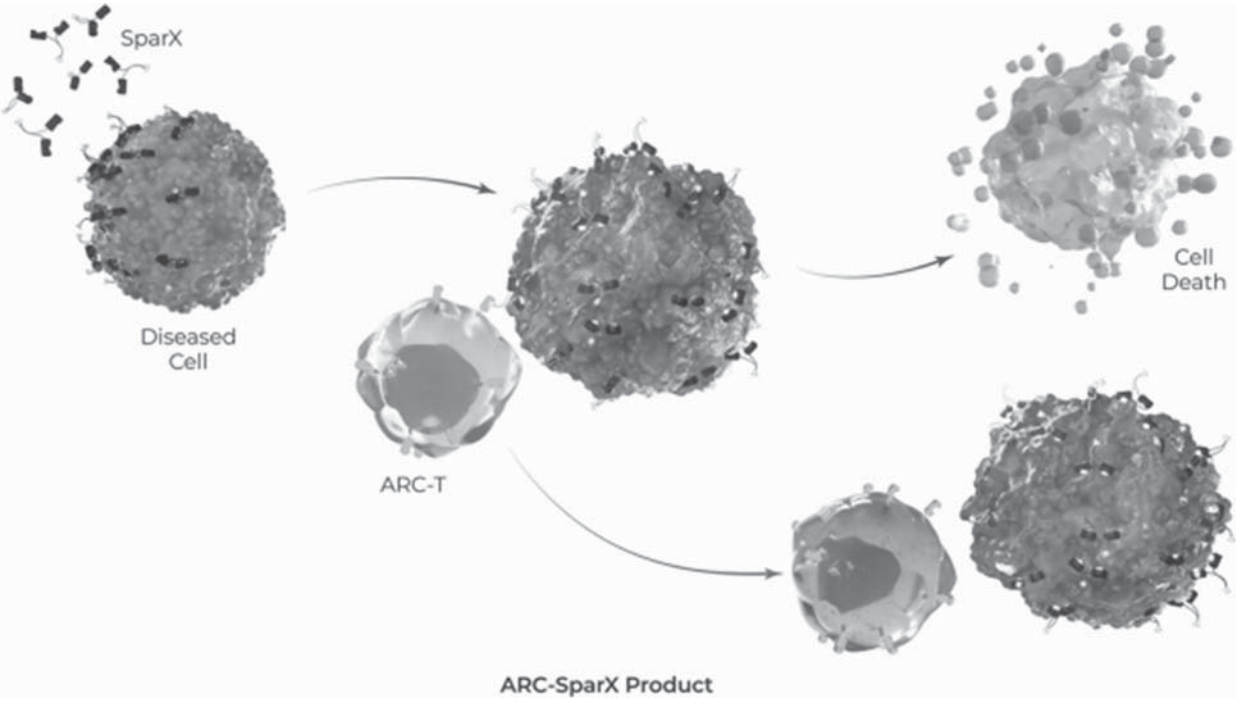



- ***Engineered D-Domain Scaffolds*:** The structural features of the D-Domain make it particularly well suited as a scaffold protein that can be modified by inserting selected amino acids to generate diverse libraries of proprietary target-binding domains. We create highly diverse libraries of variants of α-3D by randomly replacing 12-14 amino acid residues on the outward facing surface of α-3D with one of 18 amino acids.

We screen the resulting libraries for potential target-binding domains and engineer further variants with the appropriate target binding profiles to enhance target specificity, optimize binding affinity, and remove potentially immunogenic sequences, a process we refer to as "deimmunization". We use rigorous target selection criteria applied to genomic and proteomic datasets generated from public, collaborator, and internal sources. We internally validate expression profiles for all antigens under evaluation to select the best targets. At the same time, all the reagents needed to screen our proprietary D-Domain libraries for specific binders to the antigen are generated and qualified. D-Domain binders to a variety of tumor antigens have already been generated to date. We have also identified and characterized several target-binding domains for certain therapeutic targets, such as BCMA, CD123, CS1, HER2, and PD-L1, among others. AI-based approaches are employed to assist in optimization and continue to be developed to enhance our discovery process. Applying all these discovery methods, the engineered D-Domains are incorporated into our genetically modified T-cells in our ddCAR and ARC-SparX platform.

**ARC-SparX Platform**

Our ARC-SparX platform is a controllable and adaptable modular therapy that builds on our ddCARs platform by replacing the antigen binding domain of the T cell with a novel synthetic binding domain that recognizes only SparX proteins, which contain the antigen binding domain. When the SparX protein's antigen binding domain recognizes and binds to the antigen on a diseased cell, it recruits the ARC-T cell to kill the diseased cell.




Our ARC-T-cells are designed to remain in an inactive state, or silenced, and activate only when combined with a SparX protein that is bound to an antigen on a cell. We believe that controlling ARC-T activation with SparX protein effectively separates the antigen-recognition and killing functions. By separating these functions, our approach renders the killing function of the ARC-T cell dependent on the antigen specificity and dose of the SparX protein enabling a differentiated CAR-T expansion and proliferation profile as compared to conventional CAR-T therapy. The separation of the CAR-T from the antigen binding domain allows for a more controlled, modular approach to CAR-T therapy, as SparX dosing can be modified over the course of treatment, multiple SparX proteins may be incorporated, and additional functionality (i.e., logic-gating) may be designed to expand the utility of CAR-T therapy. Further, the approach may simplify the manufacturing of multiple CAR-T programs and the regulatory path, as the ARC-T programs can utilize the same vector to express binding domain. We also believe unregulated killing, which induces severe toxicities, may be mitigated with our approach by adjusting the dose and schedule of SparX protein administration, which may expand the antigens that can be targeted safely with CAR-T therapy. Additionally, stopping the dose of the SparX protein periodically can allow the ARC-T-cells to rest after activation lowering the risk of T-cell exhaustion, which is a common cause of rapid decline of genetically modified T-cells.

**Soluble Protein Antigen Receptor X-linkers (SparX protein)**

All SparX proteins are comprised of one or more antigen-specific binding domains from our D-Domain library, fused to a protein that we refer to as the "TAG". We believe the TAG we use in our SparX proteins offers unique properties that confer a competitive advantage for our program. The TAG is a protein designed to be recognized by our ARC-T-cells, which have a D-Domain-based binding moiety that is specific to the TAG, which we call the anti-TAG. This TAG/anti-TAG design is critical to the universality of our ARC-T-cells as it allows such cells to bind any SparX protein, because each SparX protein contains the same TAG. As SparX proteins bind their target antigen on diseased cells, they display the TAG thereby "tagging" such cell as one that should be killed by an ARC-T cell.

The TAG we have built into our SparX proteins is a ~26 kDa C-terminal fragment of human alpha fetoprotein (hAFP). We selected and engineered the TAG for our SparX proteins for the following reasons:

- Humans have a pre-established tolerance to hAFP from experiencing high levels in utero and as pregnant mothers. We believe that creating our TAG from a normal human protein will reduce the likelihood of immunogenicity of the TAG and by extension, the SparX protein containing the TAG.

- We believe the small size of the SparX protein will allow it to penetrate complex tumor microenvironments with a half-life short enough (estimated to be several hours in humans) that physicians could manage an emerging toxicity by withholding or decreasing the next SparX protein dose thereby causing the ARC-T-cells to deactivate. Such control is not possible with most mAb-based adapters due to their half-life of several weeks.

- The TAG can also be readily fused to multiple binding regions, enabling SparX proteins to be multi-valent or multi-specific.

Because the antigen-specific binding domains on the SparX protein differ by only 12-14 amino acids on the outer faces of the scaffold, the manufacturing process for each SparX protein is substantially similar regardless of specificity. SparX proteins can be readily produced in microbial, yeast and mammalian expression systems, and development is underway on subcutaneous formulations. We also expect the pharmacokinetics of all SparX proteins to be similar and believe that we can leverage the learnings from clinical trials of one SparX protein to inform the design of later trials for other SparX proteins.

**Antigen Receptor Complex (ARC)**

The ARC is similar to CARs in that both are engineered chimeric transmembrane receptors, where the engagement of the extracellular antigen binding domain induces activation of the intracellular domain resulting in the T cell's proliferative and cytolytic activity. However, in lieu of the scFv extracellular binding domain of conventional CAR-T therapies, the extracellular domain of the ARC is comprised of our proprietary binding D-Domain that is designed to exclusively bind the TAG and not hAFP or any other known proteins or antigens. Thus, the ARC-T remains in an inactive state, or silenced, in the absence of our proprietary SparX protein. The ARC signals through a similar mechanism as traditional second-generation CARs since they share the same intracellular signaling regions of 4-1BB and CD3-zeta with the only difference arising from when the T-cells are activated.

Additionally, because all ARC-T-cells are intended to express a TAG-specific binding domain rather than a cell surface antigen-specific binding domain, the manufacturing of ARC-T is more scalable than in conventional CAR-T therapies in that ARC-T's comprise the same drug product irrespective of clinical indication or target antigen. The same lentiviral vector comprising the universal ARC and a similar T-cell transduction process can be used for every patient regardless of disease or target antigen. With conventional CAR-T therapy, different viral vectors, each with a different T-cell transduction process, need to be used to make new CAR-T-cells when physicians want to target a new antigen. This represents a potentially significant manufacturing and regulatory advantage. In the longer term, engineering an allogeneic ARC-T cell presents the opportunity for a truly universal cell therapy that could be manufactured to be an "off-the-shelf" option that physicians can use regardless of disease or target antigen. Moreover, ARC-T-cells could be redirected to kill cells expressing different antigens just by changing the SparX protein. This universal nature of the ARC-T cell could provide substantial flexibility to the physician and allow for dynamic treatments that can respond quickly to the changing profile of a disease such as cancer, unlike a conventional CAR-T therapy.

**Benefits of the ARC-SparX Platform**

We believe the key benefits to our ARC-SparX platform are driven by the controllable and adaptable characteristics and present an opportunity in indications where toxicities, heterogeneity, or on-target off-tumor effects represent a challenge:

***Dose Regulation of SparX Protein.*** Our ARC-T-cells are activated only when combined with a SparX protein that is bound to an antigen on a cell. Our ARC-T-cells bind the SparX protein, but do not bind directly to the diseased cell. The SparX protein is designed to recognize and bind one or more specific antigens on the diseased cells and then flag such cells for destruction. Once the triple complex of ARC-T cell plus SparX protein plus antigen-expressing cell is formed, the ARC-T cell is activated to kill the antigen-expressing cell. The ARC-T cell remains in an inactive state, or silenced, in the absence of our proprietary SparX proteins. The dosability of our ARC-SparX platform potentially provides a new way for physicians to manage or prevent severe T cell-associated toxicities, while maintaining the objective to maximize efficacy.

We have conducted preclinical studies in which we have observed the ability of SparX proteins to control the killing function of ARC-T-cells in a dose-dependent manner.

***Adaptability of Treatment Regimen.*** Because ARC-T-cells are not antigen-specific, they can be adapted to changing disease conditions by the administration of additional SparX proteins with different target specificity. Due to tumor heterogeneity and downregulation or loss of the target antigen, relapsed or refractory disease remains a significant issue for CAR-T therapy. On our ARC-SparX platform, physicians can administer different SparX proteins to redirect the same ARC-T-cells to new antigens. This is particularly important in settings where tumors may be heterogeneous or downregulate expression of the antigen(s) targeted by the initial SparX proteins. We believe that our ARC-SparX platform can address refractory disease caused by tumor heterogeneity because the same ARC-T-cells can be redirected *in vivo* to target different antigens through the administration of different SparX proteins for personalized therapy tailored to the molecular profile for each patient's disease. This will be particularly important as we move beyond B cell malignancies into indications like AML/MDS or solid tumors. We believe our *in vivo* preclinical studies support the ability of ARC-T-cells to kill heterogeneous tumors through sequential administration of SparX proteins with different target specificity.

***Custom Logic-Gated Therapeutics to Enable Selectivity and Improve Targeting.*** The unique properties of D-Domains, and our ability to engineer them, allow us to create mono-valent, multi-valent, or multi-specific SparX to optimize antigen binding affinity and improve efficacy. Bi-specific SparX proteins can be designed as an 'OR' gate to target two different antigens for broader tumor cell recognition when faced with antigen heterogeneity or an 'AND' gate to more specifically identify diseased cells that uniquely co-express two antigens but spare healthy cells that express only one antigen. Through affinity engineering and controlled dosing, the AND-gated bispecific SparX proteins can drive greater specificity for dual-antigen expressing tumor cells over single antigen expressing normal cells to avoid the typical on-target off-tumor related toxicities observed with so many conventional CAR-T products targeting solid tumor antigens.

***Streamlined Manufacturing Across All Programs.*** ARC-T-cells are genetically modified to express the same anti-TAG binding receptor to be used in every patient, regardless of disease or the target-specificity of the SparX protein. We believe this feature may enable use of the same lentiviral vector and similar cell processing, resulting in a scalable manufacturing process that is applicable to every patient across all programs. We have also established manufacturing processes for SparX proteins utilizing a cost-effective microbial-based expression system and purification process. Because each SparX protein is substantially similar regardless of specificity, the manufacturing and purification processes for each SparX protein is substantially similar regardless of specificity. For more details, see "—Manufacturing and Delivery."

***Efficient Regulatory Process.*** Because the ARC-T cell manufacturing process is identical across all ARC-SparX programs, the regulatory requirements will be shared across the platform. This may provide advantages that will span global regulatory filings from IND through post BLA requirements.

## Our Pipeline Approach

We are leveraging the full breadth of our platform by matching ddCARs and ARC-SparX with the indications in which they would be most effective based on the biology, patients, and market dynamics.

In MM, we plan to:

- Evaluate the efficacy of our lead product candidate, anito-cel, in our pivotal Phase 2 iMMagine-1 and Phase 3 iMMagine-3 trials in rrMM and seek regulatory approval in collaboration with Kite;
- In collaboration with Kite, pursue expanded access to anito-cel through other label expansion clinical trials, including iMMagine-3 and others;
- Through our ex-U.S. partner, Kite, pursue clinical development of anito-cel in other key geographies, such as Europe and Asia; and
- Evaluate the potential of our ARC-SparX technology through our ongoing Phase 1 clinical trial of ACLX-001 in rrMM.

In AML/MDS, we plan to:

- Pursue AML/MDS with a library of SparX proteins beginning with our wholly-owned ACLX-002 program, which is currently in a Phase 1 clinical trial; and
- Explore trials that evaluate the use of a single administration of ARC-T-cells together with a combination of SparX proteins engineered to target different AML and MDS antigens, to extend the power of the platform.

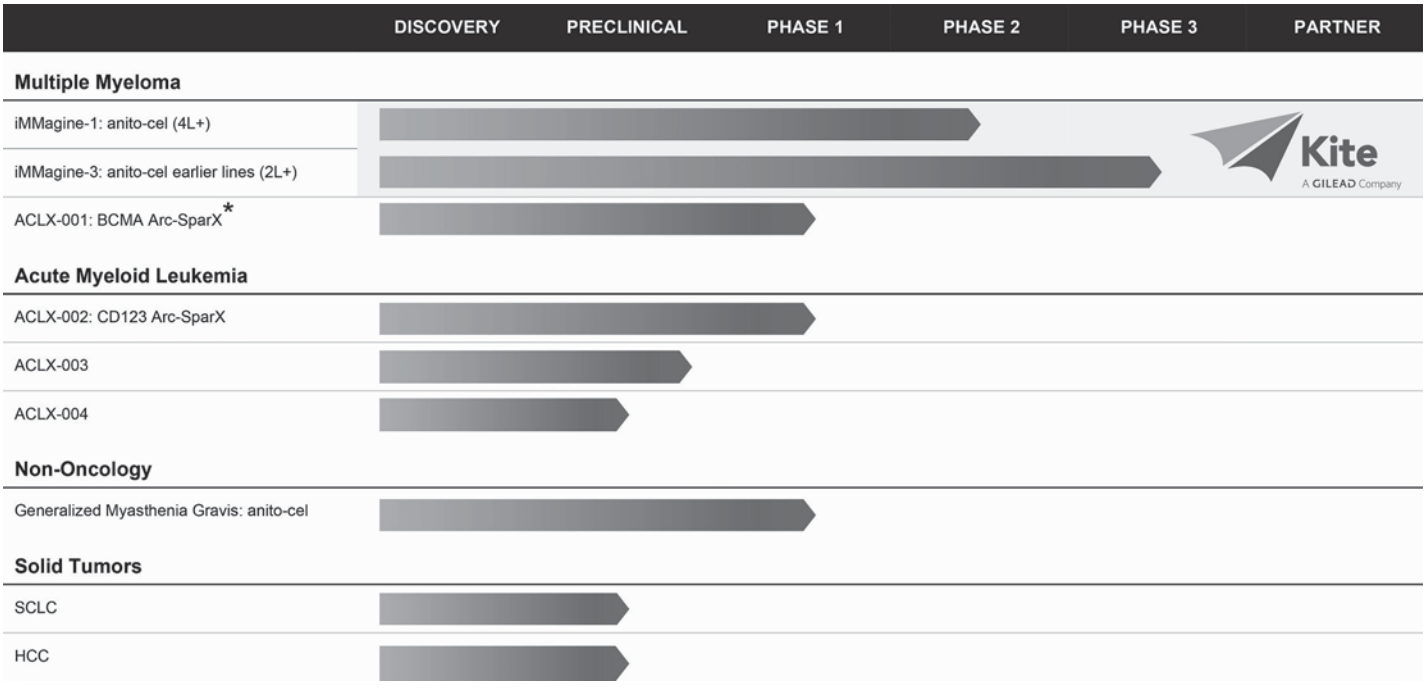
In additional indications, we plan to:

- Evaluate the efficacy of anito-cel in indications outside of oncology, including in some autoimmune indications such as gMG.

- Extend benefits of our D-Domain platform by applying ddCARs and ARC-SparXs to additional hematological and solid tumor indications, including SCLC and HCC.

**Our Pipeline**

We have built a broad and scalable pipeline that has positioned us to capitalize on the potential of our proprietary platform technologies and achieve long-term growth and sustainability within the field of cell therapy. We have summarized our preclinical and clinical programs in the pipeline chart below and indicated where such programs are subject to the Kite Collaboration Agreement, which is described in "Licenses and Collaborations" below. Except for such partnered programs, we have worldwide rights to all of our programs:




** Kite exercised its option to negotiate a license for ACLX-001 and retains an option for additional select ARC-SparX programs in multiple myeloma and lymphoma*

**Our Multiple Myeloma Program**

Our MM program is led by our anito-cel product candidate, which is an autologous cell therapy comprised of D-Domain powered T-cells that have been genetically modified to recognize and kill specific cells expressing BCMA, a target antigen for multiple myeloma. In collaboration with Kite, we are advancing our anito-cel product through our pivotal Phase 2 iMMagine-1 trial in patients with rrMM, which we initiated in the fourth quarter of 2022 and thereafter plan to pursue U.S. regulatory approval. We and Kite are also evaluating anito-cel in our global Phase 3 iMMagine-3 trial in second through fourth line patients with rrMM which began dosing patients in the fourth quarter of 2024. Anito-cel has been granted Fast Track and Orphan Drug by the FDA. In May 2021, we also received Regenerative Medicine Advanced Therapy (RMAT) designation for anito-cel for the treatment of multiple myeloma. In collaboration with Kite, we plan to continue to enroll more patients into additional clinical trials, to support label expansion to enter into earlier lines of therapy and include patients who have had prior BCMA-targeted therapies. Additionally, pursuant to the Kite Collaboration Agreement, as further described in "Licenses and Collaborations" below, Kite will pursue international clinical trials to expand into geographic locations in Europe and Asia-Pacific. We are also advancing our initial ARC-SparX program, ACLX-001, an immunotherapeutic combination composed of ARC-T-cells and bi-valent SparX proteins targeting BCMA, to treat rrMM. This program is designed to lay the foundation for our ARC-SparX platform. In December 2023, Kite exercised its option under the Kite Collaboration Agreement to negotiate a license for ACLX-001.

**Market Opportunity**

MM is a type of hematological cancer in which diseased plasma cells proliferate and accumulate in the bone marrow, crowding out healthy blood cells and causing bone lesions, loss of bone density and bone fractures. These abnormal plasma cells also produce excessive quantities of an abnormal immunoglobulin fragment called a myeloma protein (M protein) causing kidney damage and impairing the patient's immune function.

MM is the third most common hematological malignancy in the United States and Europe, representing approximately 10% of all hematological cancer cases, 20% of deaths due to hematological malignancies and, by our estimate, impacting over 175,000 patients globally each year. The Surveillance, Epidemiology, and End Results (SEER) Program database projects that approximately 35,000 new cases of MM in the United States and over 35,000 new cases in six select markets within Europe and Asia.

The median age of MM patients at diagnosis is 69 years with one-third of patients diagnosed at an age of at least 75 years. Because MM tends to afflict patients at an advanced stage of life, patients often have multiple co-morbidities and toxicities that can quickly escalate and become life-endangering. Despite the development and use of multiple new therapies, including second generation proteasome inhibitors (PI) and immunomodulatory drugs (IMiD), stem cell transplantation and CD38-binding monoclonal antibodies, the five-year survival rate is still approximately 60% and MM remains incurable in most patients.

Currently, multiple BCMA-targeting therapies are approved, in development or under regulatory review, including T cell engagers (TCEs), antibody drug conjugates (ADCs) and other CAR-T therapies.

We estimate that the size of the global MM market was approximately $25 billion in 2024 and that the current total addressable CAR-T market for rrMM to be $12 billion or more based on the number of patients who are receiving second line treatments and beyond.

As of December 31, 2024, the two CAR-T therapies targeting BCMA that have been approved by the FDA are Abecma and Carvykti, developed and marketed by 2seventy bio/Bristol Myers Squibb and Legend/Johnson & Johnson, respectively. Currently, Abecma is approved for the treatment of adult patients with rrMM after two or more prior lines of therapy including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody. Carvykti is approved for the treatment of adult patients with rrMM who have received at least 1 prior line of therapy, including a PI and an IMiD and are refractory to lenalidomide. In addition to its current approval in rrMM, Carvykti is currently enrolling additional clinical trials to expand into front-line multiple myeloma treatment.

Carvykti, developed by Legend/Johnson & Johnson, has demonstrated an ORR of 97.9%, a CR/sCR rate of 82% and an estimated median progression-free survival (mPFS) of 34.9 months in the Phase 1b/2 CARTITUDE-1 trial in patients with rrMM that had received 3 or more prior lines of therapy. Abecma developed by 2seventy bio/Bristol Myers Squibb, has demonstrated an ORR of 73.4%, and an sCR/CR rate of 33% with an estimated mPFS of 8.8 months in the Phase 2 KarMMa trial in patients with rrMM that had received 3 or more prior lines of therapy.

Although approved BCMA-targeting CAR-T therapies represent a step forward, there remains a need for improved overall response, durability, safety, and accessibility, especially in difficult to treat patient populations. For example, across the clinical trials of Abecma and Carvykti, several poor prognostic factors have been identified including the presence of extra-medullary disease (EMD) and more broadly plasmacytomas, ISS stage 3, high tumor burden, and high-risk cytogenetics. In clinical trials in rrMM, these patients demonstrated shorter PFS rates. For example, in the Phase 1b/2 trial of Carvykti (CARTITUDE-1), patients with plasmacytomas (of which ~2/3 had EMD) demonstrated a mPFS of 13.8 months, patients with ISS stage 3 disease demonstrated a mPFS of 15.0 months, patients with BMPC ≥60% demonstrated a mPFS of 24.1 months, and patients with high risk cytogenetics demonstrated a mPFS of 21.1 months. Additionally, Carvykti has a Black Box warning for Parkinsonism and Guillain-Barré syndrome, and its label contains Warnings and Precautions for Neurologic Toxicities, including those not considered ICANS such as Parkinsonism, Guillain-Barré Syndrome, Immune Mediated Myelitis, Peripheral Neuropathy, and Cranial Nerve Palsies.

In addition to the FDA-approved CAR-T therapies targeting BCMA, several other BCMA-targeting therapies have been approved by the FDA for treatment of rrMM, these include BCMA-targeting TCEs and ADCs.

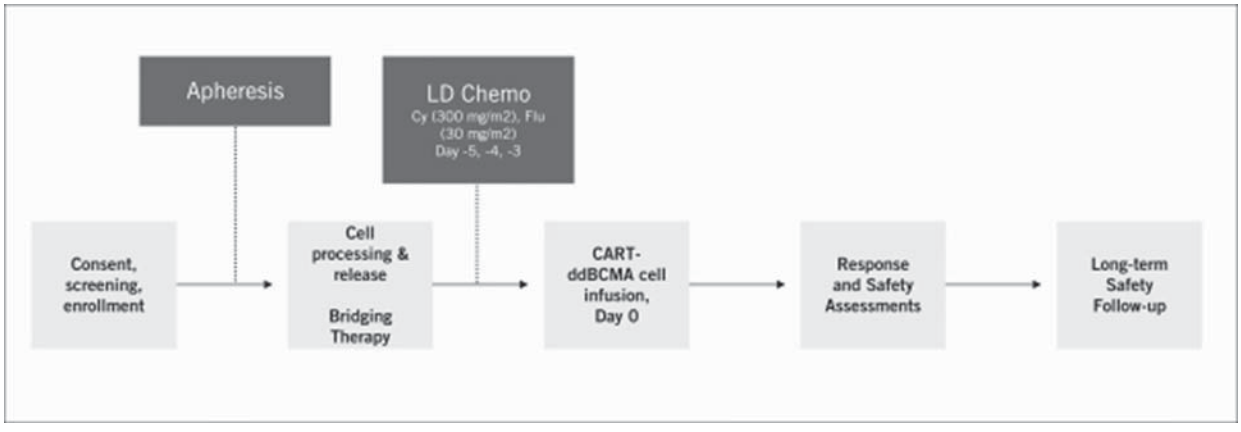
- In October 2022, the BCMA-targeting bispecific antibody, Tecvayli developed by Johnson & Johnson, received accelerated approval for treatment of adults with rrMM who have received at least four prior lines of therapy. Tecvayli has reported an ORR of 63% and a CR/sCR rate of 46%, with a mPFS of 11.4 months. However, Tecvayli is dosed weekly or biweekly, and is administered under a Risk Evaluation and Mitigation Strategy (REMS) program and requires hospitalization through the initial titration period.

- In August 2023, the BCMA-targeting bispecific antibody, Elrexfio, developed by Pfizer, received accelerated approval for treatment of adults with rrMM who have received at least four prior lines of therapy. Elrexfio has reported an ORR of 61% and a CR/sCR rate of 37%, with a mPFS of 17.2 months. However, Elrexfio is dosed weekly or biweekly, and is administered under a REMS, and requires hospitalization following administration of the initial doses.

- The BCMA-targeting ADC, Blenrep was an approved product, but the manufacturer, GSK, began the withdrawal of the U.S. marketing authorization in November 2022, at the request of the FDA. In November 2023, GSK announced positive results from the Phase 3 DREAMM-7 trial of Blenrep in rrMM, which were presented in February 2024. DREAMM-7 evaluated belantamab mafodotin (belamaf) + bortezomib, and dexamethasone (BVd) vs daratumumab, bortezomib, and dexamethasone (DVd) in rrMM patients with at least one line of prior therapy and reported an ORR of 83%, CR/sCR of 34% and mPFS of 37 months which was deemed as a clinically meaningful improvement over comparator arm. GSK is also evaluating the Phase 3 DREAMM-8 trial of Blenrep in rrMM. DREAMM-8 is a randomized, open-label trial that evaluated belantamab mafodotin, pomalidomide, and dexamethasone (BPd), as compared with pomalidomide, bortezomib, and dexamethasone (PVd), in lenalidomide-exposed rrMM patients after at least one line of therapy. BPd reported an ORR of 77% and CR/sCR of 40%. mPFS was not reached for the BPd cohort after a median follow-up of 22 months. The FDA has assigned a Prescription Drug User Fee Act action date of July 23, 2025 for both BVd and BPd combinations.

**anito-cel: Phase 1 Trial in rrMM**

The anito-cel Phase 1 multi-center, open label, trial is the first involving one of our proprietary D-Domains and was designed to test anito-cel in rrMM patients to evaluate the safety profile of escalating dose levels (DL) and to expand enrollment at a selected dose to further characterize the efficacy and safety profile of that dose. To be eligible, patients must have had at least 3 prior lines of treatment, which had to include an immunomodulatory drug (IMiD), a proteosome inhibitor (PI), and an anti-CD38 antibody, be refractory to the most recent line of therapy, have an ECOG performance status of 0 or 1, have measurable disease, and have adequate function of vital organs. If eligible, patients were enrolled, underwent leukapheresis (apheresis), and could receive bridging therapy while cell manufacturing occurred. When anito-cel cell manufacturing was complete, patients received lymphodepleting (LD) chemotherapy with fludarabine (Flu) and cyclophosphamide (Cy) on days -5, -4, and -3. On day 0, patients received an intravenous infusion of anito-cel. After infusion, patients were evaluated at fixed intervals for assessment of AEs and evidence of objective response using PET/CT scan, serum measurement of M-protein (including heavy or light chain measurement), and measurement of number of malignant plasma cells in bone marrow aspirates. Safety data are assessed for dose limiting toxicity in the first 28 days following infusion and will be collected throughout the trial. Long-term safety data will be collected for up to 15 years per health authority guidelines. Efficacy data are assessed pursuant to the IMWG criteria on a monthly basis for the first 6 months and then quarterly for up to two years, or upon symptomatic relapse.




The IMWG uniform response criteria have been utilized in registration trials of approved myeloma drugs. The IMWG uniform response criteria assess efficacy of treatment options for myeloma and allow for a comparison of efficacy between treatment strategies in clinical trials, strict definitions for responses, as shown in the table below, and classifications to improve detail and clarify inconsistent interpretations across clinical trials. The IMWG criteria for sCR, CR, VGPR, and PR are summarized below.

- ***stringent Complete Response (sCR)***: Complete Response (as defined below) plus normal free light chain (FLC) ratio and absence of clonal cells in bone marrow biopsy by immunohistochemistry (kappa to lambda light chain ratio (κ/λ) ≤4:1 or ≥1:2 for κ or λ patients, respectively, after counting ≥100 plasma cells).

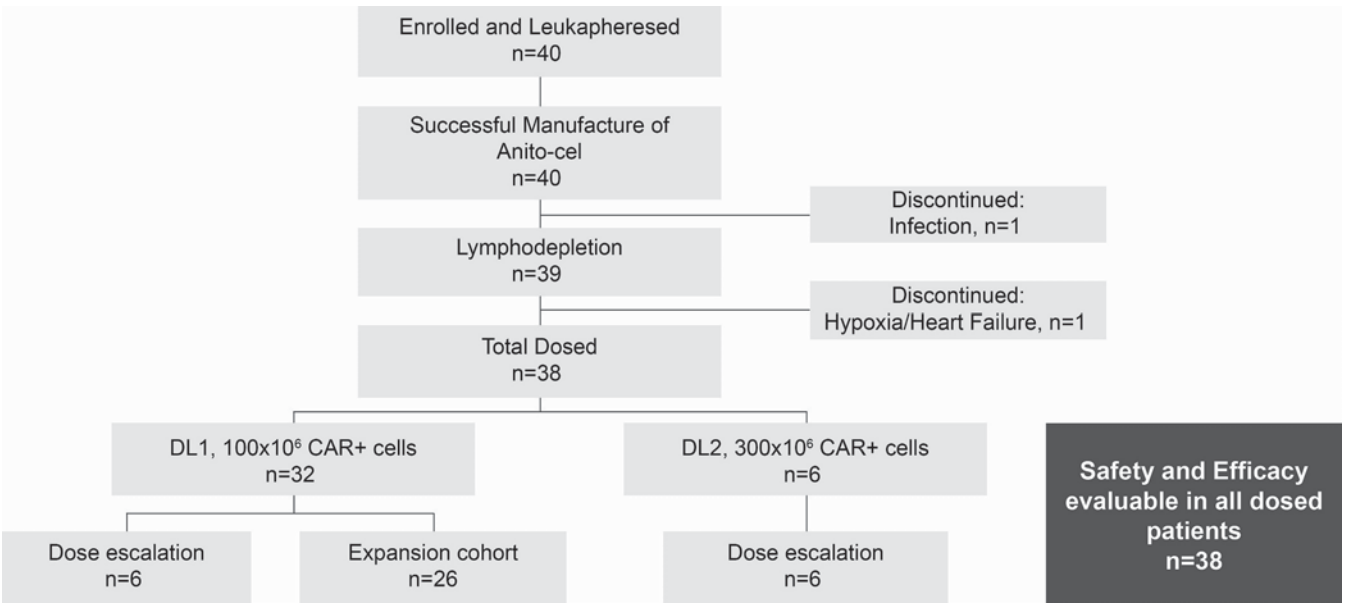
- ***Complete Response (CR)***: Negative immunofixation in the serum and urine; and disappearance of any soft tissue plasmacytomas; and <5% plasma cells in bone marrow aspirates.

- ***Very Good Partial Response (VGPR)***: Serum and urine M protein, detectable by immunofixation but not on electrophoresis; or ≥90% reduction in serum M protein plus urine M protein level <100 mg/24 hr.

- ***Partial Response (PR)***: ≥50% reduction of serum M protein plus reduction in 24-hour urinary M protein by ≥90% or to <200 mg/24 h; or if the serum and urine M protein are unmeasurable, a ≥50% decrease in the difference between involved and uninvolved FLC levels is required in place of the M protein criteria and if serum-free light assay is also unmeasurable, ≥50% reduction in plasma cells is required in place of M protein, provided baseline BMPC percentage was ≥30%. In addition to these criteria, if present at baseline, a ≥50% reduction in the size (SPD) of soft tissue plasmacytomas is also required.

Overall Response Rate (ORR) includes patients that achieved sCR, CR, VGPR or PR. sCR and CR do not indicate that the patient was cured of the condition, as multiple myeloma is currently considered incurable.

The clinical trial began enrollment in December 2019 and the first patient was dosed in February 2020. Four clinical trial sites participated in the Phase 1 trial. We completed the dose escalation component with 6 patients each enrolled in DL1 (100 (+/-20%) x $10^6$ cells) and DL2 (300 (+/- 20%) x $10^6$ cells) and enrolled additional patients (n=26) at DL1 for further characterization of safety and preliminary efficacy. The median dose administered in DL1 was 115 million cells (range, 112-120 million cells), and the recommended Phase 2 dose (RP2D) is 115 (+/- 10) x $10^6$ CAR+ cells. The data from the dose escalation and expansion were most recently presented at the 2024 Annual Meeting of the ASH. In the safety and efficacy analysis, 38 patients were evaluable, 32 in the DL1 and 6 in DL2.




Median administered dose at DL1, 115 million cells (range, 112-120 million cells)

Patient and Disease Characteristics are demonstrated in the table below. Taken together, these demographic data indicate the patient population enrolled in this trial had poor prognosis with expected median OS in the range of 6-8 months based on published analyses of patients with similar characteristics.

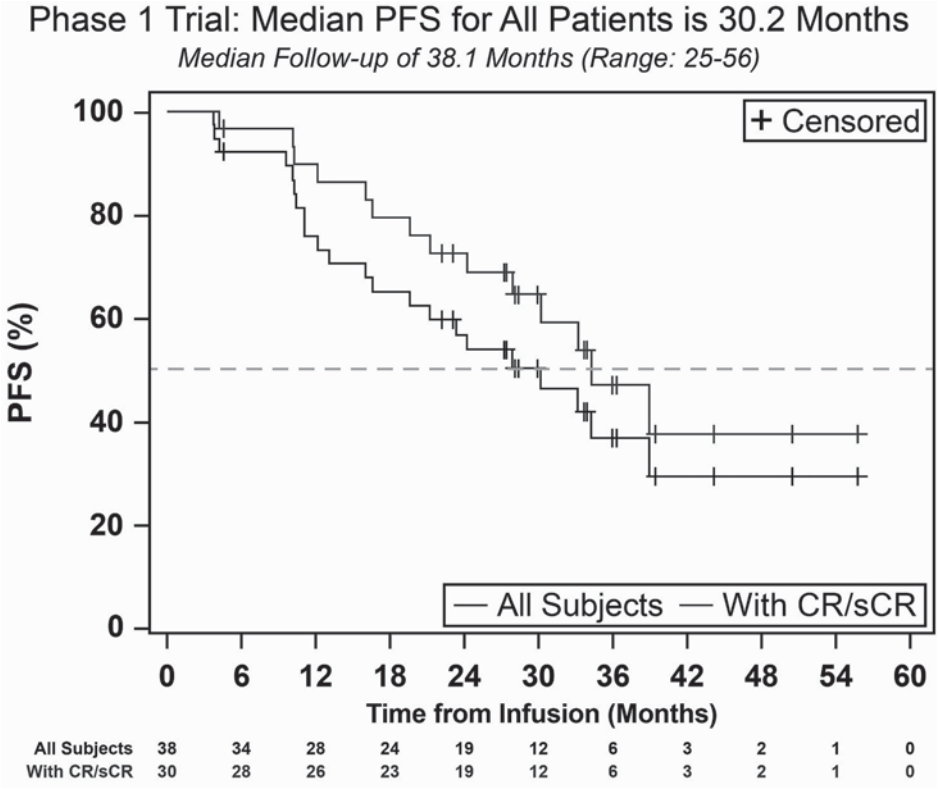
**Phase 1 Trial: Patient and Disease Characteristics**

| Characteristics | DL1: 100 x $10^6$ CAR+ T cells (n=32) | DL2: 300 x $10^6$ CAR+ T cells (n=6) | Total (n=38) |
|---|---|---|---|
| Age, median (min - max) | 66 (44 - 76) | 60 (52 - 65) | 66 (44 - 76) |
| Age ≥ 65 | 19 (59%) | 1 (17%) | 20 (53%) |
| Gender, male / female | 18 (56%) / 14 (44%) | 5 (83%) / 1 (17%) | 23 (61%) / 15 (39%) |
| Race | | | |
| White | 28 (88%) | 4 (67%) | 32 (84%) |
| Black / African American | 3 (9%) | 1 (17%) | 4 (11%) |
| Asian | 1 (3%) | 0 (0%) | 1 (3%) |
| Other | 0 (0%) | 1 (17%) | 1 (3%) |
| ECOG PS[a] 0 / 1 | 9 (28%) / 23 (72%) | 3 (50%) / 3 (50%) | 12 (32%) / 26 (68%) |
| High Risk Prognostic Feature[b] | 20 (63%) | 6 (100%) | 26 (68%) |
| Prior Lines of Therapy, median (min - max) | 5 (3 - 7) | 4 (3 - 16) | 4 (3 - 16) |
| Triple refractory | 32 (100%) | 6 (100%) | 38 (100%) |
| Penta refractory | 21 (66%) | 5 (83%) | 26 (68%) |
| Prior ASCT | 25 (78%) | 4 (67%) | 29 (76%) |
| Time since diagnosis, median (min - max) | 6.5 years (1.5 - 14.9 years) | 6.9 years (1.7 - 11.0 years) | 6.5 years (1.5 - 14.9 years) |
| Bridging therapy[c] | 20 (63%) | 6 (100%) | 26 (68%) |

a) Eastern Cooperative Oncology Group Performance Status Scale; b) Defined as a patient with EMD, ISS Stage III (B2M ≥ 5.5), High Risk Cytogenetics (Del17p, t(14:16), or t(4;14)), or BMPC ≥60%; c) Bridging agents were limited only to those previously received

As of the October 3, 2024 data cutoff date, the ORR was 100%, the CR/sCR rate was 79%, the VGPR rate was 13%, and the PR rate was 8%. As previously presented (ASH Presentation 2022), the likelihood of achieving CR/sCR increased with longer follow-up. This observation is consistent with other rrMM studies, especially in BCMA-targeted CAR-T cell trials, primarily related to the IMWG criteria for CR/sCR. Additionally, 89% (n=25 of 28) of all subjects who are evaluable for minimal residual disease testing (MRD) were negative at the depth of $10^{-5}$. Evaluable patients had identifiable malignant clone in the baseline bone marrow aspirate.

As of the October 3, 2024 data cutoff date, with a median follow up of 38.1 months, the mPFS for all patients (N=38) was 30.2 months. For those subjects with CR/sCR (n=30), the mPFS was 34.3 months. Median OS was Not Reached.




A Kaplan-Meier analysis of all subjects demonstrated a PFS rate at 6, 12, 18, 24, and 30 months of 92%, 76%, 65%, 57%, and 50%, respectively. A subgroup analysis of subjects with high risk clinical features (defined as presence of EMD, BMPC ≥ 60%, High Risk Cytogenetics or ISS Stage III) indicated similar PFS rates at 12, 24, and 30 months of 72%, 60%, and 60%, respectively.

Phase 1 Trial: Kaplan-Meier Estimated PFS Rates

| | All Patients | High Risk Features* | Age ≥65 years |
|---|---|---|---|
| **Patients n (%)** | 38 (100) | 26 (68.4) | 20 (52.6) |
| **12-month PFS % (95% CI)** | 75.9 (58.7, 86.6) | 72.2 (50.4, 85.7) | 85.0 (60.4, 94.9) |
| **24-month PFS % (95% CI)** | 56.6 (39.2, 70.8) | 60.2 (38.7, 76.3) | 65.0 (40.3, 81.5) |
| **30-month PFS % (95% CI)** | 50.3 (33.0, 65.3) | 60.2 (38.7, 76.3) | 53.6 (29.5, 72.7) |

**The estimated median PFS has not been reached at 30 months for high-risk subgroups**

*High Risk Features defined as a patient with EMD, ISS Stage III (B2M ≥ 5.5), High Risk Cytogenetics (Del17p, t(14:16), or t(4:14)), or BMPC ≥60%

Of the 38 patients dosed in our Phase 1 trial of anito-cel, all (100%) were evaluable for safety analysis. No delayed or non-ICANS neurotoxicities were observed, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome in the entire population through the follow-up period. The rate of AEs of grade 3 or higher CRS and ICANS are of special interest (AESIs). A potential difference was observed in the incidence of AESIs in DL2 compared with DL1. Specifically, in DL2 (n=6), 1 patient had a grade 3 CRS event and another had a grade 3 ICANS event, while no events of grade 3 or higher CRS or ICANS occurred in the 6-patient dose escalation cohort of DL1. After dose expansion at the RP2D, no events of grade 3 or higher CRS were observed in a total of 32 subjects. and only 1 (3%) out of 32 patients had a grade 3 ICANS event. In combined analysis of all patients in DL1, 30 (94%) had a grade 1 or 2 CRS event but 0% had grade 3 or higher CRS. The median time to onset of CRS was 2 (range 1-12) days and median duration was 8 (range 2-14) days. The median time to ICANS onset was 4.5 days (range 3-6 days) with a median duration of 7.5 days (4-11 days). All cases of ICANS and CRS resolved with standard interventions, such as tocilizumab and dexamethasone. Additional AEs, regardless of attribution, were presented at the ASH 2024 Annual Meeting and are presented in the figures below. The observed AEs are consistent with those of other autologous CAR-T-cells in clinical trials and in commercial use.

Phase 1 Trial: Grade 3/4 AEs (non-CRS/ICANS) per CTCAE v5.0 ≥5% after cell infusion

| Hematologic | n (%) | Non-hematologic | n (%) |
|---|---|---|---|
| Neutropenia[a] | 33 (86.8%) | Hypertension | 3 (7.9%) |
| Anemia | 21 (55.3%) | Pneumonia | 3 (7.9%) |
| Thrombocytopenia[a] | 17 (44.7%) | AST[b] increased | 2 (5.3%) |
| Lymphopenia[a] | 16 (42.1%) | Cardiac arrest | 2 (5.3%) |
| Leukopenia[a] | 8 (21.1%) | Cellulitis | 2 (5.3%) |
| Febrile neutropenia | 6 (15.8%) | Hypokalemia | 2 (5.3%) |
| | | Hyponatraemia | 2 (5.3%) |
| | | Hypophosphatemia | 2 (5.3%) |
| | | Pain in extremity | 2 (5.3%) |
| | | Sepsis[a] | 2 (5.3%) |
| | | Urinary tract infection | 2 (5.3%) |

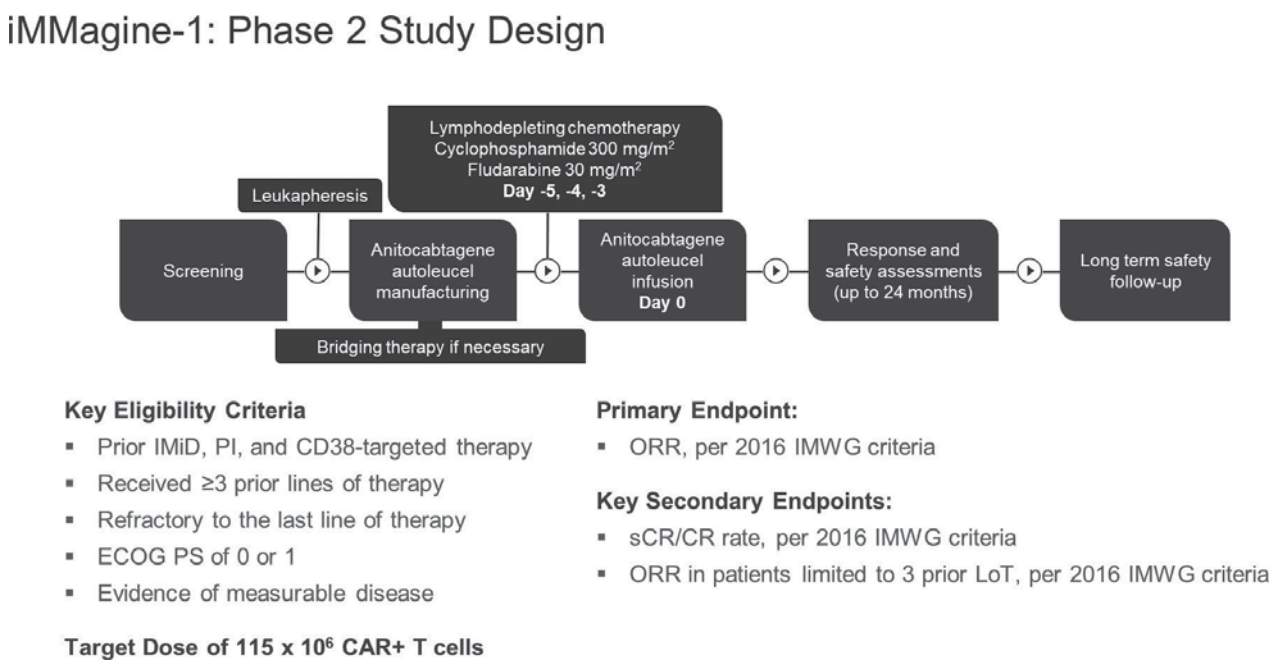
a) Grouped category for each of the following: neutropenia, thrombocytopenia, lymphopenia, leukopenia, and sepsis;
b) Aspartate Aminotransferase Test

Phase 1 Trial: CAR-T Associated AEs of CRS and ICANS per ASTCT Criteria

| CAR T-associated AEs Per ASTCT Criteria | DL1: 100 x $10^6$ CAR+ T cells (n=32) | | | | DL2: 300 x $10^6$ CAR+ T cells (n=6) | | | | Total (N=38) |
|---|---|---|---|---|---|---|---|---|---|
| **CRS** | **Gr1** | **Gr2** | **Gr3** | **Gr4** | **Gr1** | **Gr2** | **Gr3** | **Gr4** | **Any Gr** |
| **Max grade, n (%)** | 15 (47%) | 15 (47%) | 0 (0%) | 0 (0%) | 3 (50%) | 2 (33%) | 1 (17%) | 0 (0%) | 36 (95%) |
| Median onset (min - max) | 2 days (1 - 12 days) | | | | 2 days (1 - 2 days) | | | | |
| Median duration* (min - max) | 5 days (1 - 9 days) | | | | 5 days (3 - 9 days) | | | | |
| **ICANS** | **Gr1** | **Gr2** | **Gr3** | **Gr4** | **Gr1** | **Gr2** | **Gr3** | **Gr4** | **Any Gr** |
| **Max grade, n (%)** | 3 (9%) | 2 (6%) | 1 (3%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (17%) | 0 (0%) | 7 (18%) |
| Median onset (min - max) | 4.5 days (3 - 6 days) | | | | 7 days | | | | |
| Median duration (min - max) | 3.5 days (1- 9 days) | | | | 17 days | | | | |
| **Toxicity Management** | | | | | | | | | |
| Tocilizumab | 27 (84%) | | | | 5 (83%) | | | | 32 (84%) |
| Dexamethasone | 20 (63%) | | | | 2 (33%) | | | | 22 (58%) |

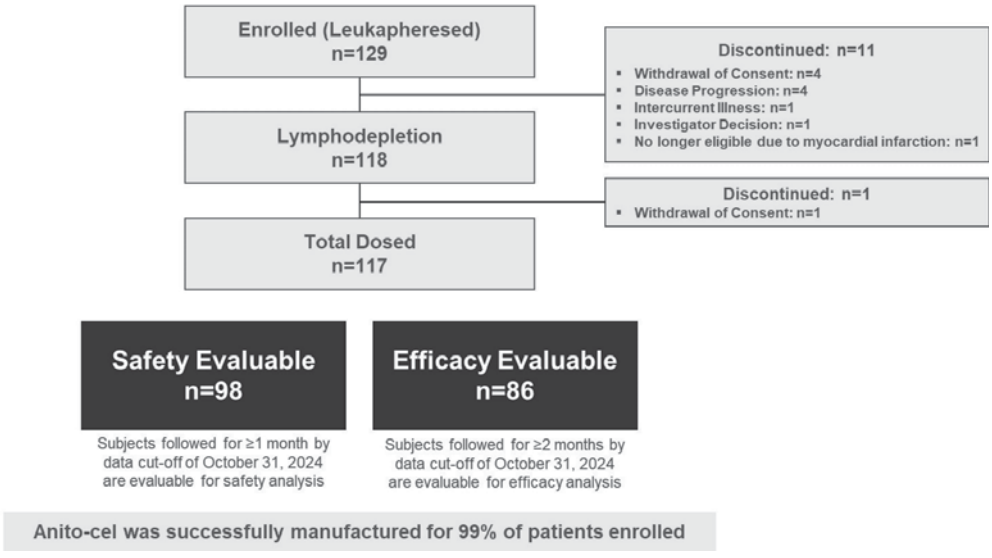
**anito-cel: Phase 2 Pivotal Trial in rrMM (iMMagine-1)**

Our Phase 2 pivotal trial of anito-cel in rrMM, the iMMagine-1 trial is a single-arm, open-label, evaluation of the efficacy of anito-cel, as measured by the primary endpoint of ORR. Key secondary endpoints include sCR/CR rate and duration of response of a single infusion of anito-cel after lymphodepleting chemotherapy. The primary endpoint was selected based on historical precedent of the primary endpoint used in other CAR-T pivotal trials and the selection of this primary endpoint has been reviewed and agreed with the FDA. Based upon feedback from regulatory authorities, we plan to include the 117 patients in the pivotal iMMagine-1 trial as the primary analysis used for review for consideration of approval. To be eligible, patients must have had at least 3 prior lines of treatment, which had to include an IMiD, PI and an anti-CD38 antibody, be refractory to the most recent line of therapy, have an ECOG performance status of 0 or 1, have measurable disease, and have adequate function of vital organs. This trial is being conducted at institutions in the United States only. Other secondary and/or exploratory endpoints will include progression free survival (PFS), OS, assessment of minimal residual disease, further characterization of the safety profile of anito-cel in a larger patient population, and confirmatory correlative biomarker analysis for pharmacology, predictive biomarkers of depth and duration of response, and manufactured anito-cel cell phenotyping. Based on continued positive data from this clinical trial, we plan to file a BLA in collaboration with Kite.




The iMMagine-1 trial was initiated in the fourth quarter of 2022 and completed dosing patient in the fourth quarter of 2024. Twenty clinical trial sites participated in the iMMagine-1 trial. Patients (N=117) were administered a single infusion of anito-cel at a dose level of 115 million cells 115 (+/- 10) x $10^6$ viable CAR+ cells. The preliminary data from iMMagine-1 were presented at the 2024 Annual Meeting of the ASH. As of the October 31, 2024 data cutoff date used for the ASH presentation, 86 patients were evaluable for efficacy based on a follow-up of at least two months after treatment with anito-cel, and 98 patients were evaluable for safety based on a follow-up of at least one month after treatment with anito-cel.

## iMMagine-1: Overall Patient Disposition and Evaluable Populations



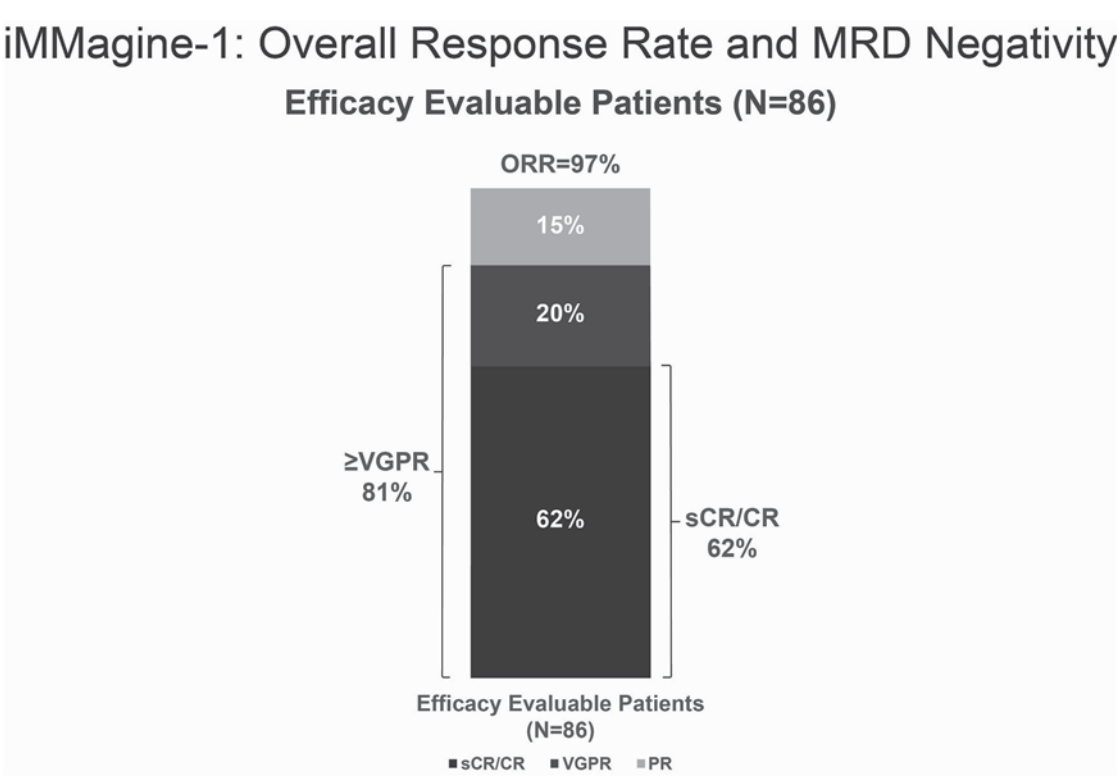

In the safety evaluable population, 85 of 98 patients (87%) were triple refractory, and 41 of 98 patients (42%) were penta refractory. Patients received a median of four prior lines of therapy, with 45 of 98 patients (46%) having received three prior lines. Patient and Disease Characteristics are demonstrated in the table below.

## iMMagine-1: Patient and Disease Characteristics

| Characteristics | Safety Evaluable (n=98) | Efficacy Evaluable (n=86) |
|---|---|---|
| Age (yrs), median (min - max)<br>Age ≥ 65<br>Age ≥ 70<br>Age ≥ 75 | 65 (38 – 78)<br>51 (52%)<br>30 (31%)<br>10 (10%) | 65 (38 – 78)<br>47 (55%)<br>28 (33%)<br>10 (12%) |
| Gender (male / female) | 55 (56%) / 43 (44%) | 48 (56%) / 38 (44%) |
| Race<br>White<br>Black / African American<br>Asian / Other | <br>79 (81%)<br>9 (9%)<br>10 (10%) | <br>70 (81%)<br>8 (9%)<br>8 (9%) |
| ECOG PS 0 / 1 | 45 (46%) / 53 (54%) | 39 (45%) / 47 (55%) |
| Extramedullary disease[a] | 16 (16%) | 13 (15%) |
| High Risk Cytogenetics[b] | 39 (40%) | 33 (38%) |
| Refractory to last line of therapy | 98 (100%) | 86 (100%) |
| Triple refractory | 85 (87%) | 74 (86%) |
| Penta refractory | 41 (42%) | 37 (43%) |
| Prior Lines of Therapy, median (min - max)<br>3 Prior LoT | 4 (3 – 8)<br>45 (46%) | 4 (3 – 8)<br>37 (43%) |
| Time since diagnosis (yrs), median (min-max) | 7.2 (1 – 23) | 7.5 (1 – 23) |
| Prior ASCT | 73 (75%) | 64 (74%) |
| Bridging therapy | 65 (66%) | 61 (71%) |
| Outpatient administration | 8 (8%) | 5 (6%) |

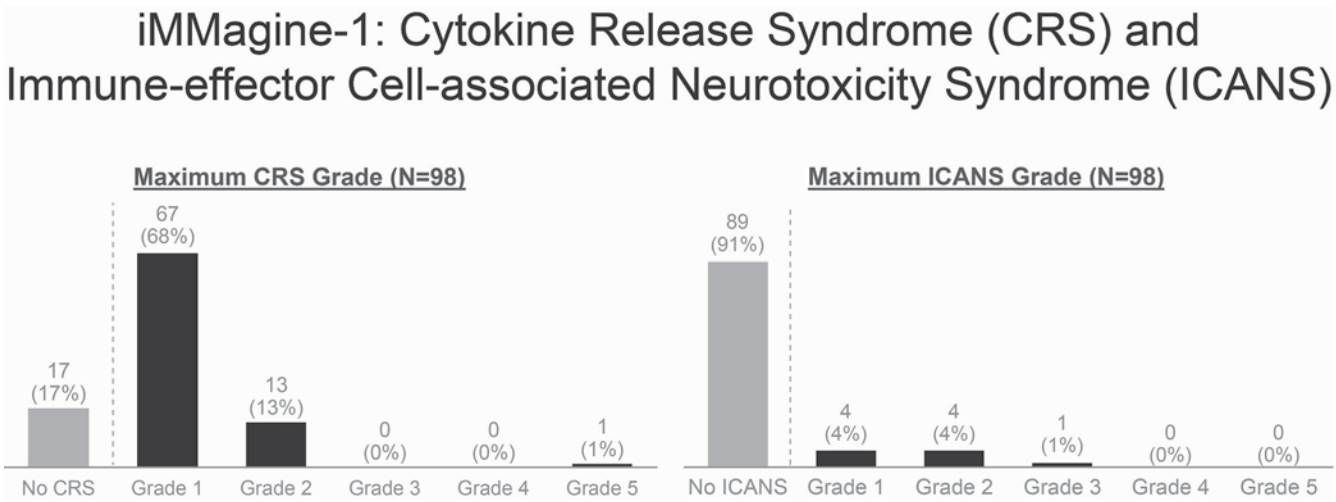
*a) Presence of a non-bone based plasmacytoma; b) Defined as the presence of Del 17p, t(14;16), or t(4;14).*
*ASCT, autologous stem cell transplant; ECOG PS, Eastern Cooperative Oncology Group Performance Status; LoT, line of therapy*

As of the October 31, 2024 data cutoff date, 86 patients were evaluable for efficacy based on a follow-up of at least two months after treatment with anito-cel. With a median follow up of 9.5 months, ORR was 97%, the CR/sCR rate was 62%, the VGPR rate was 20%, and the PR rate was 15%. Data were investigator assessed per IMWG criteria, for more information see the section entitled "Our Multiple Myeloma Program - anito-cel: Phase 1 Trial in rrMM" above. Additionally, 93% (n=54 of 58) of all subjects who are evaluable for minimal residual disease testing (MRD) were negative at the depth of $10^{-5}$. MRD evaluable patients had identifiable malignant clone in the baseline bone marrow aspirate and had a post-treatment bone marrow sample sufficient to assess MRD negativity.




With a median follow-up of 9.5 months, PFS and OS were not reached at the time of the October 31, 2024 data cutoff date, as less than half of all dosed subjects had experienced an event of progression or death. A Kaplan-Meier analysis of efficacy evaluable subjects demonstrated a PFS rate, which reflect the percentage of patients who are alive and have not progressed, at 6 and 12 of 93% and 79%, respectively. Additionally, OS rates by Kaplan-Meier analysis, at 6 and 12 months were 97% and 97%, respectively.

For the 98 patient in the safety evaluable population, anito-cel demonstrated a predictable manageable safety profile. No delayed or non-ICANS neurotoxicities were reported, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome. 84 of 98 patients (86%) experienced Grade 1 or lower cytokine release syndrome (CRS), including 17 (17%) with no CRS. The median time to onset of CRS was 4 days with a median duration of 3 days. 98% of patients had CRS that either resolved within 14 days of anito-cel infusion or did not experience any CRS. Any grade ICANS was observed in 9 patients (9%) with 4 (4%) Grade 1, 4 (4%) Grade 2, and 1 (1%) Grade 3. All cases of ICANS resolved. Three deaths occurred in the 117 patients treated in iMMagine-1 due to treatment-emergent adverse events (TEAEs) (related or unrelated to anito-cel: retroperitoneal hemorrhage, CRS, and fungal infection). Cytopenias were the most common Grade ≥3 TEAEs; 53 patients (54%) had Grade ≥3 neutropenia, 20 (20%) had Grade ≥3 thrombocytopenia, and 22 (22%) had Grade ≥3 anemia.



## iMMagine-1: Treatment-Emergent Adverse Events (Non-CRS/Non-ICANS)

| | Any Grade AEs ≥20% after cell infusion (N=98) | Grade 3/4 AEs after cell infusion (N=98) |
|---|---|---|
| **Hematologic** | | |
| Neutropenia | 56 (57%) | 53 (54%) |
| Anemia | 24 (25%) | 22 (22%) |
| Thrombocytopenia | 20 (20%) | 20 (20%) |
| | | |
| **Non-hematologic** | | |
| Fatigue | 34 (35%) | 2 (2%) |
| Hypophosphatemia | 29 (30%) | 2 (2%) |
| Nausea | 28 (29%) | 1 (1%) |
| Headache | 27 (28%) | 2 (2%) |
| Diarrhea | 26 (27%) | 1 (1%) |
| Hypogammaglobulinemia | 23 (24%) | 1 (1%) |
| Hypokalemia | 21 (21%) | 2 (2%) |
| | | |
| **Infections** | 44 (45%) | 10 (10%) |
| Upper respiratory tract infection | 9 (9%) | 2 (2%) |
| Urinary tract infection | 8 (8%) | 2 (2%) |
| COVID-19 | 5 (5%) | 1 (1%) |

*TEAE is defined as, 1) any AE with onset date on or after the first anito-cel infusion, until 90 days after the first anito-cel infusion regardless of causality assessment, or until start of subsequent anti-myeloma therapy, whichever is earlier; or 2) any AE occurring at any time assessed by the investigator as related to anito-cel*

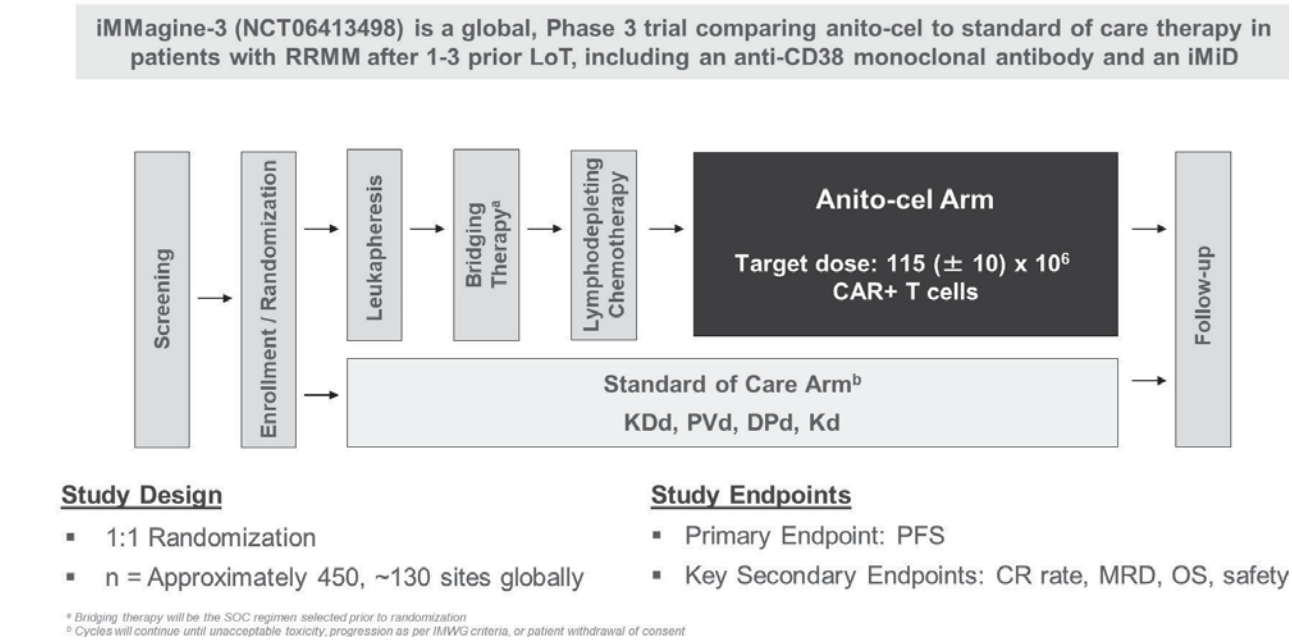
**anito-cel: Global Phase 3 Trial (iMMagine-3)**

Pursuant to the Kite Collaboration Agreement, as further described in "Licenses and Collaborations" below, Kite initiated iMMagine-3, a global Phase 3 randomized controlled study designed to compare the efficacy and safety of anito-cel with standard of care in patients with rrMM who have received one to three prior lines of therapy, including an immunomodulatory drug (lMiD) and an anti-CD38 monoclonal antibody.

iMMagine-3 will enroll approximately 450 adult patients. Prior to randomization, an investigator's choice of standard of care (SOC) regimen will be selected, which include either: pomalidomide, bortezomib, and dexamethasone (PVd); daratumumab, pomalidomide, and dexamethasone (DPd); carfilzomib, daratumumab, and dexamethasone (KDd); or carfilzomib and dexamethasone (Kd). Patients in the anito-cel arm will undergo leukapheresis and bridging therapy (with the SOC regimen selected by the investigator prior to randomization) followed by lymphodepleting chemotherapy (fludarabine 30 mg/m2/d and cyclophosphamide 300 mg/m2/d for 3 days) and one infusion of anito-cel ($115\times10^6$ CAR+ T cells) on Day 1. Patients in the control arm will continue to receive the selected SOC regimen.

The primary endpoint is progression-free survival (PFS) per blinded independent review according to the IMWG uniform response criteria for multiple myeloma (MM) with the hypothesis that anito-cel will prolong PFS compared to SOC. Key secondary endpoints include complete response rate (CR/sCR), minimal residual disease negativity, OS, and safety.

The iMMagine-3 study was initiated in the second half of 2024 and is planned to enroll across approximately 130 study sites in North America, Europe, and the rest of the world.




**anito-cel: Future Clinical Plans**

Pursuant to the Kite Collaboration Agreement, as further described in "Licenses and Collaborations" below, Kite will initiate clinical trials of anito-cel in additional key geographies, such as Europe and Asia, which may also serve to further expand the label into additional myeloma or lymphoma populations in the United States.

**ACLX-001 (BCMA): Phase 1 Trial**

Our first ARC-SparX program is ACLX-001, an immunotherapeutic combination composed of ARC-T-cells and bi-valent SparX proteins targeting BCMA, or SPRX001, for the treatment of rrMM. In ACLX-001, we use our ARC-T-cells for the first time in combination with SPRX001, which utilizes the same antigen binding domain as anito-cel. We initiated our Phase 1 dose-escalation clinical trial of ACLX-001 in the second quarter of 2022. This trial is intended to serve as clinical validation of our ARC-SparX platform as we seek to understand PK, safety profile, and dosing strategy for future clinical development. The clinical trial is designed to allow dose escalation and flexibility in the frequency of SPRX001 administration based on observed pharmacokinetics of SPRX001 and ARC-T cell expansion kinetics.

The primary objective of the trial is to provide clinical validation of our ARC-SparX platform as we seek to understand PK, safety profile, and dosing strategy for future clinical development programs. We intend to also demonstrate clinical benefit in patients with rrMM that can support the potential of ACLX-001 and the ARC-SparX platform. The primary endpoint of the trial is to determine the incidence of treatment-emergent adverse events (TEAEs), including dose limiting toxicities (DLTs). Upon completion of the Phase 1 trial, we will leverage the learnings from this trial to advance our AML/MDS programs utilizing ARC-SparX and consider developing additional SparX for rrMM for a broader pipeline in this disease area. Additionally, in December 2023, Kite exercised its option under the Kite Collaboration Agreement to negotiate a license for ACLX-001. Upon successful negotiation of such license, we will collaborate with Kite on the further development of ACLX-001.

**Our AML/MDS Programs**

With the ARC-SparX platform we are developing a comprehensive solution for personalized therapy tailored to the molecular profile of an AML/MDS patient's disease.

Diseased cells from AML and high risk MDS patients often have a complex cytogenetic profile that leads to significant clonal heterogeneity. This heterogeneity exists not only between patients but also within an individual's disease. Traditional targeted therapies including CAR-Ts have struggled to drive deep and durable responses because they target only a fraction of the patient's diseased cells. In addition, traditional CAR-T targets in AML/MDS such as CD33, CD123 and CLL1 are expressed on normal myeloid cells, including progenitor cell populations, which may lead to prolonged myelosuppression.

We intend to utilize SparX proteins targeting different AML and MDS antigens that can be used in combination to combat disease heterogeneity. Furthermore, we believe the controllability of the ARC-SparX platform will give physicians the ability to turn off the therapy once disease is controlled to allow for faster recovery of the normal myeloid compartment and thus less toxicity. We initiated the Phase 1 clinical trial for ACLX-002, our lead ARC-SparX program for AML/MDS in the fourth quarter of 2022 and continue to develop preclinical SparX proteins for other AML/MDS antigens.

**Background, Current Treatments and Limitations**

**Acute myeloid leukemia (AML)**, also referred to as acute myelogenous leukemia, arises from healthy bone marrow stem cells that have accumulated multiple genetic mutations causing the mutated stem cells to grow uncontrollably. The aggressive growth of AML cells in the bone marrow disrupts the development of healthy blood cells including white cells, red cells and platelets. The net result is that AML patients often present with anemia (too few red blood cells), infections (caused by too few functioning white blood cells) or frequent bleeding and bruising (caused by too few platelets). The aggressive growth of AML in the bone marrow and blood, its disruption of normal blood cell production and the lack of durable treatments leave AML patients with an estimated 35% five-year survival rate.

According to the National Cancer Institute SEER database, there were estimated to be 73,168 people living with AML in the USA in 2020. New cases were estimated to have been approximately 19,940, with 11,180 deaths in 2020. The disease accounts for approximately 1.1% of all new cancers, but is the most common acute leukemia affecting adults. AML also represents approximately 20% of childhood leukemia.

The standard of care for the majority of AML patients consists of induction chemotherapy (cytarabine and anthracycline) followed by additional rounds of chemotherapy with or without stem cell transplant. Although approximately two-thirds of patients achieve remission, relapse often occurs within the first 18 months following treatment. The high relapse rate points to the need for new therapies capable of extending disease free survival. We believe there is a critical need to develop new therapeutic modalities with greater safety and efficacy, especially for patients with relapsed or refractory AML.

Currently, new therapies for AML have many limitations. The lead candidates of small molecule inhibitors of proteins that are over-expressed or otherwise dysregulated in AML show only modest efficacy with short duration of response. Antibody-based therapeutics, including antibody-drug conjugates and bispecifics, have thus far shown limited efficacy and in some cases, significant toxicities. Additionally, cell therapies are being deployed with specificity for various targets including CD33, CD123, FLT3, CLL1, CD19, IL1RAP and NKG2DL. Many of these therapies are in the early stages of clinical development. The common theme across the various therapeutic modalities described above is the need for new therapies with enhanced efficacy and improved safety.

**Myelodysplastic syndrome (MDS)** is a closely related disease in which a population of abnormal myeloid stem cells develop in the bone marrow. Depending on the type of abnormal, or dysplastic cell that emerges, patients may experience a specific decrease in red blood cells, or one of the disease-fighting cell populations referred to as monocytes, neutrophils and dendritic cells. Like AML, MDS impacts the elderly with patients often diagnosed in their 70s. The incidence of MDS has been estimated to be as low as 10,000 new cases per year in the United States. MDS is considered to be a type of cancer because about one-third of MDS patients progress to AML. Standard therapy for MDS is cytarabine alone or in combination with idarubicin or daunorubicin. Stem cell transplant can cure MDS but the advanced age of onset and co-morbidities often limit MDS patient transplant eligibility due to the toxicity of typical transplant conditioning regimens, especially for those patients characterized with high risk MDS. Thus, new therapies are needed for MDS patients as well.

**ACLX-002 (CD123): Phase 1 Trial**

Our first AML/MDS product candidate is ACLX-002, which is an immunotherapeutic combination agent composed of the same ARC-T-cells used in ACLX-001, together with mono-valent SparX proteins that each contain a binding domain directed at CD123. We began clinical development of ACLX-002 in the fourth quarter of 2022 with initiation of a Phase 1, dose escalation trial of both ARC-T-cells and SPRX002 in relapsed or refractory AML and/or high-risk MDS. The primary objective of the trial is to identify a recommended Phase 2 dose (RP2D) that does not exceed the MTD and achieves evidence of clear clinical benefit. The primary endpoint of the trial will be to determine the incidence of TEAEs, including DLTs. The clinical trial is designed to allow dose escalation and flexibility in the frequency of SPRX002 administration based on observed pharmacokinetics of SPRX002 and ARC-T cell expansion kinetics.

**Preclinical AML/MDS Product Candidates**

We have also identified a group of high priority antigen targets associated with AML/MDS through internal analyses and conversations with key opinion leaders and are developing additional SparX proteins against such target antigens. We have isolated D-Domain binders to several of these high value AML/MDS targets and plan to progress them in our pipeline. In several of our preclinical and discovery projects, we have engineered D-Domains into SparX proteins that bind to these targets, including for ACLX-003, which continues to progress towards IND filing. Additionally, we are building a map of target expression in primary AML patient tumors to understand how our targets may eventually be combined to combat the inherent heterogeneity of the disease.

**Our Autoimmune Program**

We intend to evaluate the efficacy of anito-cel outside of our collaboration with Kite in indications outside of oncology, which remain wholly-owned, including in some autoimmune indications. Initially, we are focusing our efforts on anito-cel in settings where elimination of plasma cells may be relevant for patients with severe autoimmune diseases. For example, published scientific studies have shown that clearance of plasma cells within patients that have antibody-mediated autoimmune diseases have resulted in improvement in clinical symptoms. In the future, we may develop additional assets and technology to expand on the opportunity for D-Domain based therapies in autoimmune diseases.

We recently initiated our Phase 1 clinical trial of anito-cel in generalized Myasthenia Gravis (gMG), a rare autoimmune disease characterized by severe muscle weakness. In gMG, the body’s immune system mistakenly attacks proteins in the neuromuscular junction, disrupting neuromuscular signaling and preventing muscle contraction. We believe anito-cel's mechanism in targeting plasma cells through BCMA may be a relevant mechanism to address the underlying pathogenesis of disease. We estimate that gMG affects over 70,000 people in the United States and there is no known cure.

**Our Solid Tumor Program**

We intend to develop multiple assets and novel technology to combat a variety of solid tumor indications while leveraging the strengths of each of our existing therapeutic platforms.

ddCARs may be best suited for targets that have highly homogeneous tumor cell expression with little to no normal cell expression with potential for a wide therapeutic window. We are continuing to build ddCARs where the target biology supports this approach. To this end, we have selected D-Domain binders to an attractive target that we are evaluating as a ddCAR to potentially treat patients with HCC.

Some solid tumors have been shown to contain a high level of heterogeneity within an individual’s tumor. Where this heterogeneity exists, we believe a library of SparX proteins targeting a specific solid tumor patient population has the potential to drive deep and durable responses beyond those produced by any single targeting therapeutic. We currently have engineered novel SparX proteins for various solid tumor-associated antigens, some with overlapping expression in specific patient populations such as SCLC, that together may allow ARC-SparX product candidates to overcome antigen heterogeneity of the disease.

Targeting solid tumors with cellular therapy presents additional hurdles such as on-target off-tumor toxicity as well as physical and immunological barriers. We intend to use a multi-pronged approach employing innovative technological solutions such as AND-gated SparX proteins as well as technologies designed to enhance the persistence and function of ddCAR or ARC-T-cells in the tumor environment. We also intend to employ clinical and translational strategies such as combinations with checkpoint inhibitors to boost activity of ddCAR or ARC-T-cells to further overcome some common immunological barriers to successful CAR-T therapy.

## Additional Indications and Applications of Our Technology

We believe our platform technologies lend themselves to a broad array of potential applications, including:

***Novel Targets.*** We believe our platforms are well suited to safely and rapidly explore targeting of novel antigens that would be otherwise challenging to target with a conventional CAR-Ts. We have successfully generated D-Domain binders to many tumor antigens and are employing sophisticated tools, such as AI and ML, to optimize these assets. We employ AI-based approaches to assist in the optimization of D-Domain properties and continue to develop AI-based approaches to enhance our discovery process. We currently use an in-silico immunogenicity risk assessment and deimmunization platform using an ML algorithm for predicting potential immunogenic epitopes. We also use AI-based protein structure determination programs to analyze the surface chemistry of our D-Domains to better determine aspects such as library design and hit optimization. We believe further implementation of AI and ML can assist in other areas of the discovery process such as D-Domain affinity optimization from deep learning of analysis of thousands of D-Domain sequences from our panning and screening campaigns.

***Next-Generation Cell Therapy Products, such as Allogeneic and Other Immune Cell Therapies.*** We believe it may be important for patients to have both autologous and allogeneic/off-the-shelf cell therapy options in certain settings as both therapeutic options mature, including therapies derived from T-cells and NK cells. Under the Kite Collaboration Agreement, as further described in "Licenses and Collaborations" below, Kite will develop allogeneic/off-the-shelf cell therapies for the treatment of myeloma as another tool in our fight against cancer that includes our autologous ddCARs and ARC-SparX.

***Indications Beyond Oncology.*** As the field of adoptive cell therapy looks to apply the technology beyond oncology, including transplantation, autoimmune, cardiac, infectious and neurological diseases, so too do we seek to explore such opportunities. We envision expanding into treatments for antibody-mediated autoimmune diseases. For example, published scientific studies have shown that clearance of plasma cells within patients that have antibody-mediated autoimmune diseases have resulted in improvement in clinical symptoms. We may evaluate anito-cel or ACLX-001 in settings where elimination of plasma cells may be relevant for patients with severe autoimmune diseases and have advanced anito-cel into a Phase 1 trial in generalized myasthenia gravis (gMG).

***Diagnostics.*** Our D-Domains or SparX proteins may be used in various diagnostic settings much like monoclonal antibodies or antibody fragments. As an example, we can envision labeling SparX proteins with a radiotracer for imaging tumors in patients as a patient selection tool prior to starting therapy with that same SparX together with ARC-T-cells.

***Antibody Alternatives.*** Our binding domains have many positive attributes over scFv binding domains that we believe could allow them to be used as an scFv alternative in non-cell therapy applications and serve as the foundation to creating a new class of therapeutic antibody alternatives.

## Manufacturing and Delivery

Our manufacturing process is consistent across anito-cel cells and ARC-T-cells. This consistent process enables flexibility of cell product production within a site using the same equipment and consistent protocols, utilizing product specific viral vector input. In our iMMagine-1 trial, anito-cel was successfully manufactured for 99% of patients enrolled. In May 2024, we announced the completion of technical transfer of our cell manufacturing process to Kite, which was initiated in 2023, and Kite is responsible pursuant to the Kite Collaboration Agreement for manufacturing activities for future clinical trials, including the ongoing iMMagine-3 trial, and for commercial supply of anito-cel.

### anito-cel Cell and ARC-T Cell

We currently rely on third parties for the manufacture and release testing of viral vectors and product candidates for clinical testing. We also currently rely on third parties for patient apheresis material logistics, as well as to package, label, store and distribute our product candidates. As we progress through development to commercialization, we will leverage our best-in-class vendors and collaboration with Kite, and evaluate other options as needed, to secure commercial-scale capacity.

In 2024, we completed the technology transfer activities and submitted IND amendments for the manufacturing of anito-cel at Kite for the manufacturing of our cell product. As we scale within our clinical trials and prepare for commercialization, we plan to increase capacity with our current suppliers and expand through our collaboration with Kite. Per the Kite Collaboration Agreement, Kite will manufacture anito-cel and Kite will bear the CMC commercial readiness costs and associated capital expenses. The parties will continue to split manufacturing costs for clinical material. Through our Kite Collaboration Agreement, we continue to invest in process improvements to reduce the overall process time and improve costs. Our D-Domain, due to its stability, has demonstrated a high transduction rate resulting in a more efficient manufacturing process. We believe this will translate to improved processes that will reduce the time to intervention for patients.

We have established partnerships with experienced cell therapy contract manufacturers to supply clinical materials and manufacturing services for our clinical trials outside of the Kite Collaboration Agreement. As we scale within our clinical trials and prepare for commercialization, we plan to increase capacity with our current suppliers and expand through our collaboration with Kite. Per the Kite Collaboration Agreement, Kite will manufacture anito-cel following completion of the technical transfer of our manufacturing process to Kite, which was completed in 2024, and Kite will bear the CMC commercial readiness costs and associated capital expenses. The parties will continue to split manufacturing costs for clinical material. The manufacturing process for our ARC-T-cells is consistent with the anito-cel process. However, cells are transduced with a lentiviral vector encoding our universal ARC, which is a CAR with an anti-TAG binding domain, in lieu of a lentiviral vector encoding the CAR construct with an anti-BCMA binding domain. Because our ARC-T-cells are designed to express the same TAG-specific binding domain rather than a cell surface antigen-specific binding domain, the same lentiviral vector encoding the universal ARC can be used across ARC-SparX programs regardless of disease or target antigen.

**SparX Protein**

We manufacture SparX proteins in-house for most research activities, but we use a third-party CMO for most preclinical studies, and all clinical trials. We produce research SparX proteins in mammalian and microbial systems using fermentation and protein purification strategies that we believe can be scaled for commercial purposes. The purified SparX protein is formulated to the desired concentration and then put into the desired formulation buffer. Every SparX protein is monitored throughout the purification process and afterwards using an array of analytical tests that assess SparX protein size, binding activity and potential biophysical changes in the SparX protein. We anticipate the process will evolve over time to improve yields, quality and quantity of recovered SparX protein.

## Competition

The biotechnology and pharmaceutical industries, including the oncology subsector, are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Any candidate that we successfully develop and commercialize will have to compete with existing therapies as well as therapies that may be developed in the future. While we believe our D-Domain, ddCAR and ARC-SparX platforms and scientific expertise provide us with a number of key advantages, we face substantial competition from many different sources, including large pharmaceutical companies and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions.

We anticipate substantial direct competition from other organizations developing advanced CAR-Ts, other types of genetically modified cell therapies, or other anti-BCMA biologics due to their promising clinical therapeutic effect in clinical trials including: 2seventy bio, Abbvie, Allogene, Amgen, AstraZeneca, Autolus, Bristol Myers Squibb, CARSgen, Cartesian, Cellular Biomedicine Group, Gilead, Gracell, GSK, Immix, Innovent, Johnson & Johnson, Legend, Novartis, Nanjing IASO Biotherapeutics Ltd, Pfizer, Poseida Therapeutics, Precision BioSciences, Pregene, Regeneron and Roche. In addition, some companies, such as Allogene, Caribou Biosciences, Cellectis, Celyad, and Crispr, are developing allogeneic cell therapies that could compete with our product candidate.

We cannot predict whether other types of therapies including CAR-T or other genetically modified cell therapies may be developed and demonstrate greater efficacy, and we may have direct and substantial competition from such therapies in the future. Further, despite the novel approach that we have developed to address the limitations of CAR-T and other types of genetically modified cell therapies, we expect to face increasing competition as new, more effective treatments for cancer enter the market and further advancements in technologies are made. We expect market adoption of any treatments that we develop and commercialize to be dependent on, among other things, efficacy, safety, delivery, price and the availability of reimbursement from government and other third-party payors.

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

## Commercialization

In light of our current stage of development, we are in the early phases of establishing a commercial organization and distribution capabilities. Prior to approval of any of our product candidates, we intend to establish a commercialization infrastructure for those products. Additionally, pursuant to the Kite Collaboration Agreement, we and Kite will be jointly responsible for commercialization of anito-cel and certain other MM cell therapy products, if approved by the FDA, in the United States and plan to leverage Kite's commercialization infrastructure, including sales and marketing and commercial distribution. Kite will be responsible for commercialization of anito-cel and such other MM products outside the United States, to the extent they are approved by the applicable regulatory authorities.

## Licenses and Collaborations

***Collaboration and License Agreement with Kite Pharma, Inc.***

In December 2022, we entered into a Collaboration and License Agreement (the Kite Collaboration Agreement) with Kite Pharma, Inc., a Gilead company (Kite), to co-develop and co-commercialize anito-cel and next-generation autologous and non-autologous CAR-T cell therapy products that use the same D-domain BCMA binder used in anito-cel, in each case for the treatment of MM. We also granted Kite an option to include autologous CAR-T-cell therapy products that utilize our ARC-SparX platform that are directed to BCMA, such as ACLX-001, as well as ARC-SparX products directed to CS1. In December 2023, we amended the Kite Collaboration Agreement, expanding the scope of the collaboration to include lymphomas. Kite also exercised its option to negotiate a license for ACLX-001.

In connection with the initial Kite Collaboration Agreement, we received a $225 million upfront cash payment in February 2023 and will be eligible to receive up to approximately $3.9 billion in clinical, regulatory, and commercial milestone payments. In connection with the amendment to the Kite Collaboration Agreement, we received a $85 million upfront cash payment in December 2023 and are eligible for additional potential milestone payments, including for the advancement of lymphoma and the license for ACLX-001, as well as additional milestone payments, to offset prespecified development costs over a limited period of time. During the year ended December 31, 2024, we achieved a clinical milestone for anito-cel and received $68.3 million from Kite relating to enrollment in the iMMagine-1 trial.

In the United States, we and Kite will equally share profits and losses from the commercialization of the anito-cel and any next-generation autologous CAR-T cell therapy product for which we may exercise our option to co-promote with Kite (collectively, the Co-Promote Products). For Co-Promote Products outside of the United States and for any other products we may license to Kite that are not a Co-Promote Product (Non-Co-Promote Products), we will be eligible for tiered royalties in the low to mid teen percentages.

We and Kite will jointly develop the Co-Promote Products in accordance with mutually agreed development plans and development budgets. We will conduct the iMMagine-1 trial for anito-cel and Kite will conduct all other development of the other Co-Promote Products. Other than certain items expressly set forth in the Kite Collaboration Agreement and amendment, the out-of-pocket development costs for activities conducted in the United States for Co-Promote Products will be shared equally by us and Kite, and the out-of-pocket development costs for activities conducted outside the United States as part of a global clinical trial for Co-Promote Products will be borne 60% by Kite and 40% by us, however Kite will be solely responsible for the costs for country-specific clinical trials and CMC commercial readiness. Kite will be solely responsible for the conduct of development of the Non-Co-Promote Products at its sole cost. In the United States, we and Kite will be jointly responsible for commercialization of the Co-Promote Products. Kite will be responsible, at its sole cost, for commercialization of the Co-Promote Products outside the United States and the Non-Co-Promote Products worldwide. Kite will manufacture the licensed products and bear the CMC commercial readiness costs and capital expenses, except that we are responsible for manufacturing anito-cel prior to transferring the manufacturing process to Kite and the parties share associated out-of-pocket costs.

Unless earlier terminated, the Kite Collaboration Agreement will continue in effect until no licensed products are being developed or commercialized. The Kite Collaboration Agreement is subject to customary termination provisions including termination by a party for the other party's uncured, material breach. In the event of certain terminations of the Kite Collaboration Agreement, we are entitled to certain reversionary rights with respect to the terminated products.

The Kite Collaboration Agreement contains customary representations, warranties, covenants, and terms governing the prosecution and enforcement of intellectual property.

In connection with the Kite Collaboration Agreement, we also entered into a common stock purchase agreement (the Purchase Agreement) and a standstill and stock restriction agreement (the Standstill Agreement) with Gilead Sciences (Gilead) in December 2022, pursuant to which, upon closing in January 2023, we issued and sold to Gilead 3,478,261 shares of our common stock for an aggregate purchase price of approximately $100.0 million and Gilead agreed to certain transfer and standstill restrictions and received certain registration rights. In connection with the amendment to the Kite Collaboration Agreement, in December 2023, we entered into a second common stock purchase agreement with Gilead and amended and restated the standstill and stock restriction agreement (the Amended Standstill Agreement), pursuant to which we issued and sold to Gilead 3,242,542 shares of our common stock for an aggregate purchase price of $200.0 million which shares are also subject to certain transfer and standstill restrictions and registration rights.

## Intellectual Property

Developing intellectual property is a vital component of our business plan for maximizing return on our investments. We actively develop intellectual property that we believe is important to our business, including seeking, maintaining, enforcing and defending United States and international patent rights for our product candidates, processes, and our discovery, development, and therapeutic platforms. We pursue, maintain and defend patent rights in strategic areas to protect the technology, inventions and improvements that are important to the commercial development of our business and our competitive position. We also rely on trade secrets to protect aspects of the technology, inventions and improvements that cannot be patented but are important to the development of our business and competitive position. We have spent considerable effort securing intellectual property rights, including patent rights related to our proprietary D-Domain binding domain, ARC and SparX protein technologies and to our product candidates.

As of December 31, 2024, our patent portfolio includes four patent families directed to the proprietary D-Domain binding domain technology.

- The first patent family broadly covers libraries of our proprietary D-Domain binding domains, compositions comprising our proprietary D-Domain binding domains and methods of using our proprietary D-Domain binding domains. This family includes 21 issued patents (including 3 issued U.S. patents) and 20 pending applications. Specifically, issued/granted claims encompass anito-cel and universal ARC-T-cells, ACLX-001: BCMA and ACLX-002: CD123 SparXs, and methods of use thereof in the treatment of cancer. Patents in this first family are expected to expire in 2036, not including any patent term adjustment and patent term extension.

- The second patent family is directed to proprietary D-Domain binding domains that bind commercially relevant target antigens and fusion polypeptides containing these domains. The second family includes 6 issued patents (including 3 issued U.S. patents) and 24 pending applications. The issued/granted claims encompass anito-cel, ARC-T-cells, ACLX-001: BCMA and ACLX-002: CD123 SparXs. Issued patents from the second family are expected to expire in 2038, not including any patent term adjustment and patent term extension.

- The third patent family is directed to proprietary D-Domain binding domains that bind commercially relevant target antigens and fusion polypeptides containing these domains. The patent family includes an issued U.S. patent, and 18 pending applications (both domestic and foreign). Any patent issuing from the family is expected to expire in 2042, not including any patent term adjustment and patent term extension.

- The fourth patent family is directed to proprietary D-Domain binding domains that bind commercially relevant target antigens and fusion polypeptides containing these domains. The family includes a pending international patent application. Any patent issuing from the family is expected to expire in 2042, not including any patent term adjustment and patent term extension.

As of December 31, 2024, our patent portfolio also includes two patent families directed to the proprietary ARC-SparX platform technology.

- One patent family is directed to our ARC construct and SparX protein technologies, and to methods of using them in T cell-based and other therapeutic applications. This family includes 6 issued patents and 21 pending applications. Any patent issuing from the family is expected to expire in 2038, not including any patent term adjustment and patent term extension.

- A second patent family is directed to dosing regimens for employing the proprietary ARC-SparX platform technology in therapeutic methods. The family includes pending applications in the U.S. and in 15 foreign jurisdictions. Any patent issuing from the family is expected to expire in 2042, not including any patent term adjustment and patent term extension.

In addition to patent protection, we also rely on trademark registration, trade secrets, know-how, other proprietary information and continuing technological innovation to develop and maintain our competitive position.

As of December 31, 2024, our trademark portfolio contains U.S. and foreign trademark registrations for the ARCELLX and ARCELLX logo, trademarks, and certain foreign trademark registrations for the marks ARC-SPARX and ARC-T.

We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Therefore, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specified circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach.

The patent and other intellectual property positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development, commercial strategies, drugs or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

For more information on these risks and other comprehensive risks related to our intellectual property, see "Risks Relating to Our Intellectual Property" under Item 1A. Risk Factors.

## Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products. Generally, before a new biopharmaceutical product can be marketed, considerable data demonstrating its quality, safety, purity and potency must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Potency is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

### U.S. Biopharmaceutical Development

In the United States, the FDA regulates biopharmaceuticals under the Food, Drug and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA). Biopharmaceuticals also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biologics must be licensed by the FDA under the PHSA through the submission of a BLA before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice (GLP) requirements;

- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board (IRB), or ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations to establish the potency, purity and safety of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of a FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- Potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the BLA;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States; and
- Compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

The data required to support a BLA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources.

**Preclinical Studies and IND**

Preclinical studies include laboratory evaluation of product biochemistry, formulation and stability, as well as *in vitro* and animal studies to assess the potential for toxicity and to establish a rationale for therapeutic use for supporting subsequent clinical testing. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

**Clinical Trials**

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the investigational product, findings from animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the investigational product has been associated with unexpected serious harm to patients.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board (DSMB) or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the biochemical and physical characteristics of the investigational product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

**Compliance with cGMP and GTP Requirements**

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

The FDA also will not approve the product if the manufacturer is not in compliance with GTP. These standards are found in FDA regulations and guidances that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements 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.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspection that follow a "risk based schedule" may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of biologic 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 requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

**BLA Review Process**

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, biochemistry and manufacturing information to ensure product quality, identity, purity and other relevant data. In short, the BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's FY 2025 fee schedule, effective through September 30, 2025, the user fee for an application requiring clinical data, such as a BLA, is approximately $4.3 million. PDUFA also imposes an annual program fee for each marketed human biologic ($403,889 in FY 2025) and an annual establishment fee on facilities used to manufacture prescription biologics. 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.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which 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.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes physicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

**Orphan Drugs**

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

For biologic drug products, an orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than the indication for which it is designated, it may not be entitled to orphan drug exclusivity.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of clinical superiority.

In view of the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), which challenged FDA's longstanding position, the FDA published a notice in the Federal Register in January 2023 to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. Further, in June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the current presidential administration may lead to new policies and changes in the regulations that may impact our clinical development plans.

**Expedited Development and Review Programs**

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drug products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For biologics, the sponsor can request the FDA to designate the product for fast track status any time before receiving a BLA approval, but ideally no later than the pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a biologic shown to be potent can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. In December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Additionally, a drug product may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drug products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

**RMAT Designation**

As part of the 21st Century Cures Act, Congress created the Regenerative Medicine Advanced Therapy (RMAT) designation to facilitate an efficient development program for, and expedite review of, a product candidate 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. A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like some of FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process.

**Abbreviated Licensure Pathway of Biological Products as Biosimilars or Interchangeable Biosimilars**

The Patient Protection and Affordable Care Act (ACA), signed into law in 2010, includes the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments. An application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- Analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- Animal studies (including the assessment of toxicity); and
- A clinical trial or trials (including the assessment of immunogenicity and pharmacokinetic or pharmacodynamic) sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference product is licensed and intended to be used.

In addition, an application must include information demonstrating that:

- The proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- The condition or conditions of use prescribed, recommended or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;
- The route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and
- The facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure and potent.

Biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. In addition, the law provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- The proposed product is biosimilar to the reference product;
- The proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- For a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the law that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical and/or clinical—required to demonstrate biosimilarity to a licensed biological product.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an orphan drug) may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under the biosimilarity statute or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block biosimilarity applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

**Post-Approval Requirements**

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse experiences and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label use," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new application or supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- Warning letters, or holds on post-approval clinical studies;
- Refusal of the FDA to approve pending applications or supplements to approved applications;
- Applications, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

**Other U.S. Regulatory Matters**

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services (CMS), other divisions of the Department of Health and Human Services (HHS), the Department of Justice (DOJ), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments.

For example, in the United States, sales, marketing and scientific and educational programs must also comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of biologic and 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, 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: changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

**U.S. Patent-Term Restoration and Marketing Exclusivity**

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, 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, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

**Government Regulation Outside of the United States**

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions where we seek to commercialize any of our product candidates, including countries in Europe and Asia. Such foreign regulations govern, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our product candidates. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of a clinical trial or marketing of a product in those countries. Certain countries outside of the United States have a similar approval process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted for each clinical trial to each country's national health authority and an independent ethics committee, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical trial may proceed. 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 requirements, applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

***European Union Drug Development***

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the E.U. Clinical Trials Directive 2001/20/EC has sought to harmonize the E.U. clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the E.U. Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the E.U. countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The E.U. clinical trials legislation currently is undergoing a transition process, In particular, the EU Clinical Trials Regulation (CTR) became applicable on January 31, 2022, repealing the EU Clinical Trials Directive. The implementation of the CTR also included the implementation of the Clinical Trials Information System (CTIS), a new clinical trial portal and database that will be maintained by the EMA in collaboration with the European Commission and the EU Member States. From January 31, 2025, any ongoing trials approved under the Clinical Trials Directive must comply with the Clinical Trials Regulation and their sponsors must have recorded information on them in CTIS. Complying with changes in regulatory requirements can incur additional costs, delay our clinical development plans, or expose us to greater liability if we are slow or unable to adapt to changes in existing requirements or new requirements or policies governing our business operations, including our clinical trials.

***E.U. Drug Review and Approval***

In the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of Marketing Authorizations:

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP), of the European Medicines Agency (EMA), and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or for products that are in the interest of public health in the European Union.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SPC) and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

***PRIME Designation in the E.U.***

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority Medicines (PRIME) scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from CHMP or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

***Orphan Drug Designation and Exclusivity***

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, 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 drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

**Coverage and Reimbursement**

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. The CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs, or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 drug products. For example, under the American Rescue Plan Act of 2021 provided that Medicaid statutory rebates will no longer be capped at 100% of average manufacturer price. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. The impact of these regulations and any future healthcare measures and agency rules implemented by the current presidential administration on us and the pharmaceutical industry as a whole is currently unknown. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization. These and other health reform measures that are implemented may have a material adverse effect on our operations.

As noted above, the marketability of any products 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. There is an increasing emphasis on cost containment measures in the United States with respect to healthcare costs and prescription drug prices and we expect it will continue to increase and exert greater pressure on pharmaceutical 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.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework could reduce our ability to generate revenue in the future or increase our costs, either of which could have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services and medical products to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if approved, and our ability to achieve or maintain profitability.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement, in order to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product in the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally, prices tend to be significantly lower.

## Employees and Human Capital

As of December 31, 2024, we had 163 full-time employees, 112 of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

## Corporate Information

We were incorporated in Delaware in December 2014 under the name "Encarta Therapeutics, Inc." and subsequently changed our name to "Arcellx, Inc." Our principal executive offices are located at 800 Bridge Parkway, Redwood City, California 94065. Our telephone number is (240) 327-0630. Our website address is www.arcellx.com.

## Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, and all amendments to these filings, can be obtained free of charge from our website at www.arcellx.com following our filing of any of these reports with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these and other websites referenced throughout the filing are not incorporated and do not constitute a part of this filing. Further, the Company's references to the URLs for these websites are intended to be inactive textual references only.

We have used, and intend to continue to use, our investor relations website, press releases, public conference calls, and webcasts to disclose material non-public information and to comply with our disclosure obligations under Regulation FD.

**Item 1A. Risk Factors.**

*Our business and industry are subject to significant risks. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Part II, Item 7, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described in the following risk factors and the risks described elsewhere in this report could seriously harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. The risks described below are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

**Risk Factor Summary**

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section immediately following this summary. These risks include, among others:

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

- We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

- We will need substantial additional funding. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs, future commercialization efforts or employee headcount.

**Risks Related to Development of Our Product Candidates**

- Although the FDA has previously issued and lifted one partial clinical hold on anito-cel, there is no assurance that the safety measures included in our clinical protocols will be effective at mitigating the risk of future serious adverse events or that the FDA or DSMB will not issue another clinical hold in the future.

- We have no products approved for commercial sale and have only recently begun clinical trials to test our first product candidates in humans, which may make it difficult for you to evaluate our current business and predict our future success and viability.

- Our ddCAR and ARC-SparX platforms represent novel and unproven approaches to treatment, which makes it difficult to predict the timing, results and costs of product candidate development and the likelihood of obtaining regulatory approval. In addition, we may experience difficulty in identifying appropriate target binding domains.

- Our ARC-SparX platform is highly dependent on the success of both ACLX-001 and ACLX-002.

- Clinical development is a lengthy, expensive and uncertain process. Our clinical trials may fail to demonstrate adequate safety and/or efficacy of any of our product candidates.

- We may encounter substantial delays, including difficulties enrolling patients, in our clinical trials.

- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

- Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available.

- Manufacturing genetically engineered products is complex and subject to both human and systemic risks. We or our third-party manufacturers may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of key components. Modifications in manufacturing may require additional studies and regulatory filings, resulting in additional costs or delay.

- We are subject to regulatory standards and requirements imposed by FDA in the regulatory approval process, which can be lengthy, time-consuming and inherently unpredictable, and may result in significant delays in clinical development or inability to commercialize our product candidates.

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

**Risks Related to Our Business**

- 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 expect to grow the size of our organization, and we may experience difficulties in managing this growth.

- We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

- Our business may be significantly adversely affected if events out of our control such as global pandemics, changes implemented by the new administration in the U.S., or geopolitical uncertainty and political instability disrupt our business, impact our people, or that of our third-party providers.

**Risks Related to Reliance on Third Parties**

- We rely and expect to continue to rely on third parties to conduct our clinical trials. If these third parties do not properly and 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 rely and expect to continue to rely on third parties to manufacture our clinical product supplies and clinical candidates, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates or fail to do so at acceptable quality levels or prices or if we terminate our relationship for any reason including due to a change in ownership, operating strategy or financial standing.

- We depend on Kite for certain development, manufacturing and commercialization activities with respect to certain of our product candidates pursuant to our collaboration with Kite. If such collaboration is not successful, we may not be able to realize the market potential of those product candidates.

**Risks Related to Our Intellectual Property**

- If we are unable to obtain and maintain sufficient intellectual property protection for our platforms and our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

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

**Risks Related to Government Regulation**

- We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

- We will face increasing regulation as we advance our product candidates through clinical trials and pursue commercialization, if approved.

**Risks Related to Commercialization of Our Product Candidates**

- 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.

**Risks Related to Ownership of our Common Stock**

- The price of shares of our common stock may be volatile and may be adversely impacted by future events, and you could lose all or part of your investment.

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

**We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.**

We are a clinical-stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing and protecting our intellectual property portfolio, developing our D-Domain, ddCAR and ARC-SparX technologies, identifying potential new target antigens, developing product candidates and undertaking research and development, including preclinical studies and clinical trials of our product candidates, all of which are biologics or biopharmaceuticals and require approval under a Biologics License Application (BLA). We have not yet demonstrated our ability to successfully complete any large-scale or pivotal clinical trials, obtain marketing approvals, manufacture commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history or were closer to commercialization. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges that may adversely affect our business.

We have no products approved for commercial sale and have not generated any revenue from product sales, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have incurred losses in each period since our inception in December 2014. Our net losses were $107.3 million, $70.7 million and $188.7 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, we had an accumulated deficit of $496.8 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we advance our product candidates through preclinical studies and clinical trials; continue to discover and develop additional product candidates and expand our pipeline; continue to develop our D-Domain, ddCAR and ARC-SparX platforms; maintain, expand, protect and enforce our intellectual property portfolio; and hire additional personnel. 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 meaningful revenue from product sales, which we do not expect will occur in the foreseeable future, as our product candidates are in preclinical or clinical development. Our prior and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

**We will need to obtain substantial additional funding as we continue to advance anito-cel through clinical development, the regulatory approval process and, if approved, commercial launch activities, initiate or continue to advance our ARC-SparX product candidates; and continue to discover and develop additional product candidates.**

Investment in biopharmaceutical product development is highly risky 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. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities, whether internally or with third-party partners and collaborators, and advance our product candidates through preclinical studies and clinical trials in order to obtain marketing approval. If we obtain marketing approval for any of our product candidates, we also expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we will continue to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our planned operations for at least the next twelve months, but our assumptions could prove to be wrong, and we could consume capital significantly faster than we expect, requiring us to seek additional funding sources sooner than planned, through public or private financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, the imposition of burdensome debt covenants and repayment obligations or other restrictions that may affect our business. Our future capital requirements will depend on many factors, including:

- The scope, progress, timing, results and costs of developing and manufacturing our product candidates, and their components, and conducting preclinical studies and clinical trials and other testing of our product candidates;
- Our ability to continue our business operations and product candidate research and development, and to adapt to any changes in the regulatory approval process, manufacturing supply, or clinical trial requirements and timing;
- The costs, timing and outcome of regulatory review of any of our product candidates;
- The costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- Our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- The costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- The extent to which our product candidates, if approved, can be offered by prescribers in various clinical settings, including academic hospitals and community practices, the acceptance of our products, if and when approved, by patients, the medical community and third-party payors, and the revenue received from commercial sale of any products for which we receive marketing approval;
- The effect of competing technologies and market developments; and
- The extent to which we acquire or invest in other businesses, products and technologies and any other licensing or collaboration arrangements for any of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all (as further described under Risks Related to Our Business). If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to decrease headcount and/or significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. 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 to us 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. Any of the foregoing events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

In addition, we may seek additional capital due to strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

**Risks Related to Development of Our Product Candidates**

**We have no products approved for commercial sale and have only recently begun clinical trials to test our first product candidates in humans, which may make it difficult for you to evaluate our current business and predict our future success and viability.**

We are still developing our D-Domain, ddCAR and ARC-SparX platforms, and conducting drug discovery and preclinical studies for a number of product candidates while advancing our ongoing clinical trials for anito-cel, ACLX-001 and ACLX-002. We have treated a small number of patients as of the date hereof and our clinical experience with our initial product candidates is limited. Because our product candidates are in the development stage, there is a high risk of failure and we may never succeed in developing marketable products. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy and/or feedback during the period of product development.

There is a high failure rate for biopharmaceutical products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. For example, a large percentage of the patients enrolled in the Phase 1 anito-cel trial had poor prognostic factors associated with increased tumor burden and may have impacted our rates of response. We therefore believe that the pivotal trial may yield improved PFS rates and retain a comparable safety profile to the Phase 1 trial as the pivotal trial enrolled a population with fewer poor prognostic features. However, the resulting enrolled patient population of the pivotal trial could be different than expected, these prognostic factors may not have as significant of an impact as we had expected, or there may be other factors that have greater impact on the rate of response, among other risks.

Although the FDA has previously issued and lifted one partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future. To the extent the FDA issues another clinical hold, addressing a clinical hold takes considerable time and expense and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of anito-cel would be materially harmed.

Because of the clinical stage of development of our product candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- Identification of additional target antigens for desired indications;
- Identification and development of D-Domain-based binding regions that bind to the desired target antigens;
- Successful completion of preclinical studies;
- Submission of INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical trials;
- Successful enrollment in, and completion of, clinical trials;
- Achieving favorable results from clinical trials;
- Receipt of marketing approvals from applicable regulatory authorities;
- Establishing and maintaining sufficient manufacturing capabilities, whether internally or with third parties, for clinical and commercial supply, including procurement of raw materials;
- Establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with other products;
- Sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials and commercialization activities;
- Effectively competing with other therapies;
- Developing and implementing successful marketing and reimbursement strategies;

- Obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and

- Maintaining a continued acceptable safety profile of any product following approval, if any.

If we do not achieve one or more of these requirements in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

We cannot be certain that our clinical trials will be initiated and completed on time, if at all, or whether our planned clinical strategy will be acceptable to the FDA or foreign health authorities.

To become and remain profitable, we must develop, obtain approval for and eventually commercialize products, if approved, that generate significant revenue. We do not expect to receive approval of any product candidates for many years and may never succeed in these activities. In addition, it is not uncommon for product candidates to exhibit unforeseen safety issues or inadequate efficacy when tested in humans despite promising results in preclinical animal models or earlier trials, and we may ultimately be unable to demonstrate adequate safety and efficacy of our product candidates to obtain marketing approval. Even if we obtain approval and begin commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development, manufacturing and other expenditures to develop and market additional product candidates. Our failure to become or remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

**Our ddCAR and ARC-SparX platforms represent novel and unproven approaches to treatment, which makes it difficult to predict the timing, results and costs of product candidate development and the likelihood of obtaining regulatory approval. In addition, we may experience difficulty in identifying appropriate target binding domains.**

We have concentrated our research and development efforts on our ddCAR and ARC-SparX platforms, and our future success depends on the successful development of these platforms. Although there are other cell therapies and adapter platforms in clinical development, our platform technologies, including our D-Domain technology, have not been extensively tested over any significant period of time. In addition, while we believe that our platforms may be capable of overcoming certain challenges faced by conventional CAR-T therapies, we cannot be certain that our approach will result in the intended benefits or will not result in unforeseen negative consequences over time. As an example, we may not be able to identify D-Domain binders that can recognize certain antigen targets that we would like to pursue, or the development of the applicable D-Domain, ddCAR or SparX protein targeting such antigens may be too challenging or expensive to be commercially viable. We do not currently have any approved or commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to re-engineer or abandon a particular product candidate. There can be no assurance that any problems we experience in the future related to preclinical and clinical development of our novel platforms and our product candidates will not cause significant delays or unanticipated costs or that such problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring those processes to manufacturing partners or developing our own internal manufacturing capabilities, which may prevent us from completing our clinical trials or successfully commercializing our product candidates on a timely or profitable basis, if at all.

Because cell therapies represent a relatively new field of cellular immunotherapy for treatment of cancer as well as autoimmune and other disorders, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- Developing and deploying consistent and reliable processes for procuring a patient's apheresis material, engineering a patient's T-cells ex vivo and infusing the engineered T-cells back into the patient;

- Developing protocols for the safe administration of our product candidates, including identifying appropriate patients and setting sufficient risk mitigation and adverse event management measures and safeguards;

- Establishing integrated solutions in collaboration with specialty treatment centers and other clinical settings in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;

- Conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our product candidates;

- Educating medical personnel about the administration of our product candidates, particularly if our clinical trials permit expansion of participating physicians to those in various clinical settings;

- Educating medical personnel regarding the potential efficacy and safety profiles of our product candidates, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens;

- Sourcing supplies for the materials used to manufacture and process our product candidates for clinical trials and, in the future, commercial sale, if our product candidates are approved;

- Developing reliable and scalable manufacturing processes;

- Establishing adequate manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical trials and our projected commercial requirements;

- Achieving cost efficiencies in the scale-up of our manufacturing capacity;

- Obtaining and maintaining regulatory approval from the FDA or other health authorities;

- Establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of novel therapies if we receive approval; and

- Obtaining coverage and adequate reimbursement from third-party payors for our novel therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our product candidates, our technology or our other product candidates in a manner that will yield products that are safe, effective, scalable or profitable. Additionally, because our technology involves the genetic modification of patient T-cells *ex vivo*, we are subject to additional regulatory challenges and risks, including:

- Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;

- Genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells;

- Although our viral vectors are not able to replicate, there is a risk with the use of lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and

- The FDA recommends a 15-year follow-up observation period for all patients who receive treatment using gene therapies, and we may need to adopt such an observation period for our product candidates.

Moreover, public perception and awareness of cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR-T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Additionally, in developing our product candidates, we have not exhaustively explored different options in the design and method for manufacturing ddCARs, ARC-T-cells and SparX proteins. Although we do not currently plan to change the structure of our ddCARs, ARC-T-cells or SparX proteins in the near term, we may in the future find our ddCARs, ARC-T-cells or SparX proteins, or any manufacturing process thereof, may be substantially improved with future design or process changes. Changes in product design and changes in the manufacturing process, equipment, or facilities may require further comparability analysis and approval by FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety, identity, purity and efficacy. For example, we have used a lentiviral vector to transduce the gene for the ddCAR and ARC constructs into patient T-cells. In the future, we may find that another type of vector or other means of genetically modifying T-cells may offer advantages, particularly as we consider inserting our ddCARs and ARC-T-cells into other immune cells. Changing how we genetically modify the immune cells would necessitate additional process development, comparability studies, regulatory filings and clinical testing and delay existing product candidates.

In addition, the clinical trial requirements of the FDA and foreign health authorities and the criteria these regulators use to determine whether a product candidate is acceptable for approval, can vary substantially according to the type, complexity, novelty and intended use and market of the potential products. While CAR-T and other cell therapy products have made progress in recent years, only a small number of products have been approved in the United States or other markets, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates.

**Our ARC-SparX platform is highly dependent on the success of both ACLX-001 and ACLX-002.**

Our ARC-SparX platform, including our AML/MDS program, is highly dependent on the success of ACLX-001 and ACLX-002, the first two product candidates based on our ARC-SparX platform. ACLX-001 is an immunotherapeutic combination composed of ARC-T-cells and bi-valent SparX proteins targeting BCMA, or SPRX001, for the treatment of rrMM. ACLX-002 is an immunotherapeutic combination composed of ARC-T-cells and monovalent SparX proteins targeting CD123, or SPRX002, for the treatment of relapsed or refractory AML and high-risk MDS. The ARC-T-cells and the SparX proteins comprising ACLX-001 and ACLX-002 are entirely novel and neither had been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. All SparX proteins are comprised of one or more antigen-specific binding domains fused to a protein that we refer to as the TAG. The TAG is a novel protein sequence derived from the 26kDA C-terminal fragment of human alpha fetoprotein (hAFP) and also had never been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. The ARC-T-cells are designed to have a binding domain that recognizes the TAG, which we refer to as anti-TAG. The anti-TAG had also never been previously tested in humans prior to the initiation of our Phase 1 trial of ACLX-001. There can be no assurance that the ARC-T-cells, the SparX proteins, the TAG, anti-TAG and other parts of ACLX-001 and ACLX-002 will not trigger an adverse response, cause unintended off-target recognition, limit the expected activity of the product candidates or result in other negative outcomes.

Additionally, because all product candidates in our ARC-SparX platform use the ARC-T-cells, a failure with ACLX-001 or ACLX-002 will increase the actual or perceived likelihood that our other product candidates in the ARC-SparX platform will experience similar failures.

Our Phase 1 trials of ACLX-001 and ACLX-002 are intended to serve as clinical validation of our ARC-SparX platform as we seek to understand the pharmacokinetics, safety profile, and dosing strategy for future clinical development. Upon completion of the Phase 1 trials, we will leverage knowledge gained from these trials to further advance our AML/MDS programs utilizing ARC-SparX for a broader pipeline in this disease area. If we do not successfully complete the Phase 1 trials for ACLX-001 and ACLX-002 in a timely manner or fail to achieve favorable results from the trial, we may experience significant delays or other issues in advancing our other ARC-SparX product candidates, and our other discovery projects in AML/MDS and other tumor settings.

**Clinical development is a lengthy, expensive and uncertain process. Our clinical trials may fail to demonstrate adequate safety and/or efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization and potentially impact the development of our other product candidates.**

Before obtaining regulatory approvals for the commercial sale of our product candidates, including anito-cel, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates have adequate safety and efficacy profiles, and the manufactured drug product has quality attributes that are appropriate for use in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during clinical development, and, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies and earlier clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, particularly because earlier trials have smaller numbers of subjects tested. In addition, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues, such as immunogenicity, when tested in humans despite promising results in preclinical animal models.

Any clinical trials that we may conduct may not demonstrate the safety and efficacy profiles necessary to obtain regulatory approval to market our product candidates. As we continue developing our product candidates, additional serious adverse events, undesirable side effects, or unexpected characteristics may cause us to make further protocol amendments, or change our clinical trial design. In some cases, we may be required to limit their development to more narrow uses or subpopulations in which the risk-benefit ratio is more acceptable, or abandon these product candidates or their development altogether.

Treatment with our product candidates may cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of patients with significant co-morbidities in our clinical trials may result in deaths or other adverse medical events due to an underlying condition or other therapies or medications that such patients may be using. As described above, any of these events could lead to another clinical hold, and/or prevent us from obtaining regulatory approval or achieving or maintaining market acceptance and impair our ability to commercialize our product candidates. Because the product candidates in our platforms share similar components, such as the D-Domain, a failure of one of our clinical trials may also increase the actual or perceived likelihood that our other product candidates will experience similar failures. Similarly, lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials for one indication that may adversely affect our development of the same product candidate in another indication.

Although the FDA has previously issued and lifted one partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future. To the extent the FDA issues another clinical hold, addressing a clinical hold takes considerable time and expense and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of anito-cel would be materially harmed.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to a variety of factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including but not limited to disease-stage or even indication(s) being tested, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If our ongoing or future clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, or if we encounter safety concerns associated with our product candidates, we may:

- Incur unplanned costs;
- Be delayed in or prevented from obtaining marketing approval for our product candidates;
- Obtain approval for indications or patient populations that are not as broad as intended or desired;
- Obtain approval with labeling that includes significant restrictions on use or distribution or safety warnings including boxed warnings, including the warnings regarding T cell malignancies required by the FDA as of January 2024 for all approved CAR-T therapies;
- Be subject to changes in the way the product is administered;
- Be required to perform additional clinical trials to support approval or be subject to additional post- marketing requirements;
- Have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy (REMS);
- Be subject to the addition of labeling statements, such as warnings or contraindications;
- Be sued; and/or
- Experience damage to our reputation.

In addition, even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or foreign health authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or foreign health authorities will view any of our product candidates as having adequate safety and efficacy profiles even if favorable results are observed in these clinical trials, and we may receive unexpected or unfavorable feedback from the FDA or foreign health authorities regarding satisfaction of safety, purity and potency (including clinical efficacy), amongst other factors. To the extent that the results of the trials are not satisfactory to the FDA or foreign health 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.

**We may encounter substantial delays in our clinical trials.**

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Events that may prevent successful or timely completion of clinical development include:

- Delays associated with events out of our control such as global pandemics or geopolitical uncertainty and instability, as further described under Risks Related to Our Business;

- Delays in reaching a consensus with regulatory agencies on trial design;

- Delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites and obtaining required institutional review board (IRB), approval at each clinical trial site;

- Delays in recruiting and enrolling suitable patients to participate in our clinical trials;

- Failure to collect sufficiently viable white blood cells from patients, adequately expand or successfully transduce sufficient number of patient T-cells for infusion or otherwise manufacture product candidates, or infuse patients in a timely manner with product candidate;

- Failure by our CROs, other third parties or us to adhere the trial protocol or the FDA's good clinical practices (GCPs) or applicable regulatory guidelines in other countries;

- Third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or foreign health authorities for violations of applicable regulatory requirements;

- Delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical trial sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or foreign health authorities to temporarily or permanently shut down due to violations of current good manufacturing practices (cGMPs) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- Delays in the technology transfer and scale up of our manufacturing process to support late-stage clinical trials;

- Delays in having patients complete their participation in a trial or return for post-treatment follow-up visits;

- Clinical trial sites or patients dropping out of a trial or experiencing changing health or other conditions that require removing them from the trial;

- Discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics;

- To the extent that we conduct clinical trials in foreign countries, the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries;

- Receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;

- Suspensions or terminations by IRBs or Data Safety Monitoring Boards (DSMBs) or internal clinical holds and/or clinical holds from or by regulatory authorities;

- Lack of adequate funding to continue operations; or

- Changes in regulatory requirements and guidance that require amending or submitting new clinical protocols and/or amendments to INDs.

In June 2023, the FDA issued a partial clinical hold on our IND for anito-cel following a patient death, which involved one clinical trial site treating a patient who was not eligible for anito-cel infusion and subsequently managing the patient in a manner conflicting with our trial protocol. Although we aligned with the FDA on modifications to the trial protocol and retrained our clinical trial sites in iMMagine-1 to enhance protocol adherence, there is no assurance that a site or another third party will not deviate from the trial protocol in the future. There is no assurance that the FDA will not issue another clinical hold in the future.

Any inability to successfully complete our clinical trials could result in additional costs to us or impair our ability to raise capital, generate revenues from product sales and enter into or maintain collaboration arrangements. In addition, if we make material manufacturing changes to our product candidates or change manufacturers, we may need to conduct additional bridging or comparability studies. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or 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.

**If we encounter delays or difficulties enrolling patients in our clinical trials and/or retention of patients in 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 their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until completion of treatment and adequate follow-up. The enrollment of patients depends on many factors, including:

- Inability to enroll, or delay in enrollment of, patients due to outbreaks and public health crises or other events out of our control, such as the COVID-19 global pandemic, as further described under Risks Related to Our Business;

- The patient eligibility criteria defined in the protocol;

- The perceived risks and benefits of the product candidate being studied;

- The size of the patient population required for analysis of the trial's primary endpoints;

- The proximity of patients to trial sites;

- The design of the trial;

- The availability of manufacturing slots;

- Our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- Our ability to obtain and maintain patient consent;

- Reporting of the preliminary results of any of our clinical trials; and

- The risk that patients enrolled in clinical trials will drop out of the trials before completion of treatment and adequate follow-up.

Although the FDA has previously issued and lifted one partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future, which could further delay clinical development.

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 will 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 investigation sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, and acts of war (including, for example, ongoing geopolitical tensions related to the Russia and Ukraine conflict, resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions), relevant to such foreign countries.

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

From time to time, we may publish interim, preliminary or topline data from clinical trials. For example, the data as of the October 31, 2024 data cutoff date for the 86 patients from our Phase 2 pivotal clinical trial for anito-cel for the treatment of rrMM is preliminary data. Interim 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. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data previously published. As a result, interim, preliminary and topline data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects.

Moreover, preliminary, interim and topline data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on trial, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we are able to complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates 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 and other nonclinical 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, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval.

**Our product candidates and the method of treatment may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.**

Our product candidates involve genetically modified T cell-based immunotherapies. A number of genetically modified cell therapies, such as CAR-based products, have potentially severe side effects, including cytokine release syndrome, neurologic toxicities, Parkinsonism and Guillain-Barré syndrome, hemophagocytic lymphohistiocytosis, macrophage activation syndrome, and prolonged and/or recurrent cytopenias, that can escalate and require intensive medical intervention and result in injury or death to the patients. Additionally, the administration of CAR-based products for cancer indications involves lymphodepletion and often bridging therapies, which are also associated with adverse events. As we expand clinical study of our T-cell based immunotherapies to other indications outside of cancer, such as autoimmune indications, we may use similar, intensive protocols to manage the risk of adverse events.

There is no guarantee that our product candidates will not have side effects similar to those seen in other genetically modified cell therapies or that we will be able to prevent side effects from escalating to an unsafe level for our patients. Additionally, our initial product candidates have been directed at treating patients with rrMM and AML/MDS. These patients are often elderly and/or have significant co-morbidities, and we expect they will receive our product candidate as a last line of therapy after most other therapies have failed, and these patients may be particularly susceptible to safety and toxicity risks. We received FDA clearance of an IND application for generalized myasthenia gravis in 2024 and have initiated a Phase 1 trial in generalized myasthenia gravis. Similarly, these patients may have co-morbidities and/or their autoimmune disorders may make them particularly susceptible to safety and toxicity risks.

In addition, these side effects that may be associated with treatment may not always be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy may be complicated and difficult to manage, which could result in patient death or other significant issues. Additionally, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects, autoimmune or non-autoimmune patients who may suffer from other medical conditions and be taking other medications.

In June 2023, the FDA issued a partial clinical hold on our IND for anito-cel. Although we aligned with the FDA on modifications to the trial protocol and retrained our clinical trial sites in iMMagine-1 to enhance protocol adherence, there is no assurance that a site or another third party will not deviate from the trial protocol in the future. There is no assurance that the FDA will not issue another clinical hold in the future.

Following FDA investigation of reports of T cell malignancies, including CAR-positive lymphoma, associated with treatment with CAR-T therapies, the FDA sent letters in January 2024 to manufacturers of six approved CAR-T therapies, requiring a boxed warning regarding T cell malignancies that have occurred following treatment with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. This is a class-wide boxed warning required for all approved CAR-T therapies. According to a November 2024 article, in view of reports that indicate the rate of secondary T-cell malignancies may be lower than initially thought, the FDA reported that the agency is reconsidering the need for such labeling. Such safety warning, whether class-wide or specific to certain constructs, will depend on available safety data and the FDA's determination. To the extent the FDA requires any black boxed warning for CAR-T products, class-wide or for certain constructs, or for any of our product candidates, such requirements may reduce their market acceptance and profitability. Additional safety monitoring that manufacturers of such products are required to implement during clinical trials as well as post-approval, including REMS, can increase the time and resources needed to obtain regulatory approval and to market CAR-T therapies, and could decrease our profitability and have a material adverse effect on our business.

We have designed a new binding domain that we believe should have low immunogenicity because we also removed potentially immunogenic sequences from their binding domains, which we refer to as “deimmunization.” However, it has never been tested in humans outside of our current clinical trials and we cannot guarantee that there will not be any unexpected side effects from this binding domain or the SparX proteins that we plan to test as part of our product candidates. Although we have completed multiple preclinical studies designed to screen for toxicity caused by unintended off-target recognition in vivo by our novel binding domains, our product candidates may still cause unintended off-target recognition in patients. Additionally, our genetically modified T-cells, the ddCARs and the ARC-T-cells, may still bind targets other than the target antigens or the TAG on our SparX proteins, respectively. If significant unexpected binding or off-target binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or other unexpected characteristics. Detection of any significant unexpected or off-target binding may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross-reactivity of our product candidates, we cannot be certain that this process will identify all potential off-target tissue that our product candidates may interact with. Any unexpected or off-target binding that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials and ability to proceed to marketing approval and commercialization.

If additional serious adverse events or undesirable side effects arise, we could be required to suspend, delay, or halt the trial(s) in which such events or effects arise or any of our other clinical trials and regulatory authorities could deny approval or require us to limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Undesirable side effects could also result in an expansion in the size of the trial(s) in which such events or effects arise or any of our other clinical trials, increasing the expected costs and timeline of our clinical trials. Side effects that are observed during the trial, whether treatment related or not, could also affect patient recruitment for future trials or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Further, if additional serious adverse events or undesirable side effects are identified during development or after approval and are determined to be attributed to any of our product candidates, we may be required to develop REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry.

Any of these occurrences may harm our business, financial condition and prospects significantly.

**Development of product candidates in combination with other therapies could expose us to additional risks.**

Development of any of our product candidates in combination with one or more other therapies that have either been approved or not yet been approved for marketing by the FDA or comparable foreign regulatory authorities could expose us to additional risks, as combination therapies may increase the rate of serious or unexpected adverse events, which could result in a clinical hold as well as pre-approval and post-approval restrictions by the FDA or other regulatory authorities on the proposed combination therapy, including narrowing of the indication, warnings, additional safety data collection and monitoring procedures, and REMS, even if the cause of such serious or unexpected adverse events is not directly attributed to our product candidate. CAR-T therapies for cancer indications, including anito-cel, are administered following a lymphodepletion regimen and often bridging therapies, these therapies are associated with risks of adverse events. As we expand clinical study of our T-cell based immunotherapies to other indications outside of cancer, such as autoimmune indications, we may use similar, intensive protocols to manage the risk of adverse events. Any of these events or restrictions could have a material adverse effect on our business, delay our regulatory approval, and decrease the market acceptance and profitability of our product candidate if approved for a combination therapy.

We will not be able to market and sell any product candidate in combination with any unapproved therapies that do not ultimately obtain marketing approval. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of other therapies used in combination therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with such therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing approved therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the other therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. Additionally, if the third party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

**Manufacturing genetically engineered products is complex and subject to both human and systemic risks. We or our third party manufacturers may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of key components. If we or any of our third party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.**

The manufacture of biological drug products, such as ddCARs and ARC-SparX, the components thereof, and the viral vectors used to manufacture these product candidates and components, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production and sourcing, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing processes (including the absence of contamination), in light of variations and supply constraints of key components. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including consistency, stability, purity and efficacy of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our 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 cannot assure you that any stability, purity, and efficacy failures, deficiencies, or other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, our product candidates are derived from cells collected from our patients and such cells may vary in type and quality as the patients may vary in age, stage of disease, and history of treatment among many other factors. We have strict specifications for the patient cell material and the product candidates we manufacture, including certain specifications that are reviewed and approved by regulatory authorities. The patient cell material variability may exceed our manufacturing process capability or deviate from the specified ranges, and result in failure in production of the patient therapy, lower quality batches, or even require adjustments to the specifications approved by authorities. The patient cell material may also be variable in factors that we currently may not be detecting with the analytical methods used or may not know how to measure and we may discover failures with the material after production. We may not be able to deliver the quality and consistency of our cell therapy products that we need or may need to re-collect cell material which can increase costs and/or cause delay, adversely impact patient outcomes and otherwise harm our clinical trials, reputation, business and prospects.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the product candidate back to the relevant parties and experience delays or shortages of certain clinical or commercial grade supplies and components. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, including the pandemic, geopolitical tensions related to the Russia and Ukraine conflict, the resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions, business interruptions, global supply chain issues, and weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing processes and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

**Material modifications in the methods of product candidate manufacturing may result in additional costs or delay.**

As product candidates progress from preclinical studies to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, materials and processes, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent purity, identity, potency, quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and could affect planned or other clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. This could delay completion of clinical trials and could require non-clinical or clinical bridging and comparability studies, which could increase costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved.

**If we or our third-party manufacturers or collaborators use hazardous and biological 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, by our third-party manufacturers. We currently outsource all manufacturing to third parties, but we and our manufacturers 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 manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we 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. We do not currently have any insurance for liabilities arising from medical or hazardous materials. 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.

**The process for treating patients using T cell therapy is subject to human and systemic risks.**

The "vein-to-vein" cycle for treating patients using T-cell therapy typically takes approximately four to six weeks and involves a large number of steps and human participants. First, the patient's lymphocytes are isolated by apheresis at the clinical site and shipped to the manufacturing site. Under cGMP conditions at the manufacturing site, the patient's lymphocytes are washed, and then enriched for CD3-positive T-cells using specialized reagents. After overnight culture and T-cell activation, the T-cells are transduced using lentiviral vector transduction technology to introduce the CAR and ARC genetic construct into the enriched T cell population. At the completion of T cell transduction, the T-cells are expanded for several days, harvested, formulated into the final drug product and then cryopreserved for delivery to patients. In the United States, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of a T cell therapy treatment process, and we cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated.

Given the complexities of the manufacturing process and administration of our product candidates, including the need for clinical sites or facilities with the resources and the technology to perform apheresis, the success of our product candidates, if approved, is dependent on factors that impact patient access to facilities that offer apheresis, additional costs to patients and healthcare systems associated with apheresis, and hospital infrastructure and bottlenecks, among others. The availability of apheresis can be a limiting factor for accessing our product candidates, if approved, which can have a material adverse effect on our business.

Further, as discussed above, FDA has announced that it was investigating the risk of secondary cancers for approved BCMA-directed and CD19-directed genetically modified autologous CAR-T cell immunotherapies as a class, and advised that patients and clinical trial participants receiving treatment in this class of products should be monitored life-long for new malignancies. Such safety concerns could have a material adverse effect on our business.

**Prior treatments can alter the cancer and negatively impact chances for achieving clinical activity with our product candidates.**

Patients with hematological cancers typically receive highly toxic chemotherapy as their initial treatments that can impact the viability of the T-cells collected from the patient and may contribute to highly variable responses to CAR-T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended product candidate and thereby these patients may have cancer cells with low or no expression of the target antigen. As a result, our product candidates may not recognize the cancer cell and may fail to achieve clinical activity.

**We may not be able to file additional INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.**

We expect to submit additional INDs for our current and future product candidates. However, our timing for submitting these INDs is dependent on the results of further research. Additionally, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once clinical trials have begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that the FDA will not change its requirements in the future. These risks also apply to other clinical trials we may seek to commence under other INDs or amendments to existing INDs.

**The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.**

We are initially developing anito-cel as a last line therapy for patients with rrMM with plans to pursue label expansion into earlier lines of therapy and other indications outside of oncology, including certain autoimmune disorders. For example, we received FDA clearance of an IND application in 2024 to evaluate anito-cel for the treatment of generalized myasthenia gravis. However, there is no guarantee that it, or any of our product candidates, even if approved, would be approved for earlier lines of therapy and any approved products may end up having a smaller market opportunity than we anticipated. Additionally, our projections of both the number of people who have the diseases we are targeting, as well as the size of the subset patient population who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. As a result, the number of patients may turn out to be fewer than expected.

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

Because we have limited financial and operational resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we intend to utilize with our clinical development strategy. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. As an example, although we believe that targeting BCMA initially before targeting other antigens will help us validate our platforms more easily, the risks associated with MM patients and the competition in cell therapies targeting BCMA, among others, could outweigh the benefits. 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. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

**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 products or drugs that are able to achieve similar or better results or make it difficult for us to develop our product candidates on a timely basis by limiting our access to patients, clinical trial sites, manufacturers and other resources. Our competitors include large and specialty pharmaceutical companies and biotechnology companies, academic research institutions and governmental agencies, and public and private research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates are safety, efficacy, ensuring consistent quality and purity of the product candidates, delivery, price and the availability of reimbursement from government and other third-party payors.

We anticipate substantial direct competition from other organizations developing advanced CAR-T or other types of genetically modified cell therapies due to their promising clinical therapeutic effect in clinical trials, including, among others, 2seventy bio, Abbvie, Allogene, Amgen, AstraZeneca, Autolus, Bristol Myers Squibb, Caribou Biosciences, CARsgen, Cartesian, Cellectis, Cellular Biomedicine Group, Celyad, Crispr, Gilead, Gracell, GSK, Immix, Innovent, Johnson & Johnson, Legend, Nanjing IASO Biotherapeutics Ltd., Novartis, Pfizer, Poseida Therapeutics, Precision BioSciences, Pregene, Regeneron, and Roche. In addition, we expect to also compete with companies developing:

- T-cells with CARs that are reactive to tumor associated antigens;
- T-cells with T-cell receptors (TCRs) that are reactive to tumor associated antigens;
- T-cells with adapter platforms;
- Bispecifics that bring T-cells and diseased cells into close proximity with each other;
- Other immune cells that can be targeted using antibodies;

- Natural killer (NK)-based cell therapies;
- In vivo CAR-T therapeutics; and
- Allogeneic cell therapies.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, greater access to clinical sites and patients, experienced regulatory, marketing and manufacturing teams and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. 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.

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 inhibited 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 Our Business**

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

As widely reported, global credit and financial markets have experienced volatility and disruptions recently including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, and increased inflationary risk. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the Russia and Ukraine conflict, terrorism or other geopolitical events, including the war in the Middle East. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. 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 environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay 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 these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, 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, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

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 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.

In addition, investor concerns regarding the U.S. or international financial systems and governmental stability could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, the impact of inflation and tariffs on the U.S. and/or global economy, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $625.7 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and marketable securities since December 31, 2024, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents and marketable securities or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

**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 an inability to find suitable replacements could result in delays in product development and harm our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards in the form of stock options and restricted stock units that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and 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 or service 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. 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 in an extremely competitive market for employees and other service providers. That, in turn, is dependent on our ability to maintain a diverse and inclusive workplace culture that supports individual expression and attracts and retains top talent.

**We expect to grow the size of our organization, and we may experience difficulties in managing this growth.**

As our development and commercialization plans and strategies develop, and as we continue our transition into operating as a public company, we expect to need additional research, development, clinical, quality assurance, statistical analysis, managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations, including for in-house manufacturing capabilities. Future growth would impose significant added responsibilities on members of management, including:

- Identifying, recruiting, integrating, retaining and motivating additional employees and other service providers;
- 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 any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities, or spend additional resources to add those capabilities or outsource them.

We currently rely and for the foreseeable future will continue to rely on certain independent organizations, advisors and/or consultants to provide certain services, including regulatory advice, clinical trial support and drug product manufacturing. 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 and at a reasonable cost, or that we can find qualified replacements if the need arises. 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 contractors and consultants on economically reasonable terms in a timely manner, or at all.

We do intend to transition some regulatory, clinical trial execution, and manufacturing capabilities in-house, but in order to do so, will need to identify, recruit and build experienced teams and there are no assurances that we will be able to do so.

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

**Our internal computer systems and networks, or those used by our third-party CROs, other contractors, consultants or collaborators, may fail or suffer security breaches or incidents, which could result in a material disruption of the development programs of our product candidates.**

Despite the implementation of security measures, our internal computer systems and networks and those of our current and future CROs and other contractors and consultants are vulnerable to damage, breakdown, or interruption from computer viruses, ransomware, or other malware, phishing, social engineering, fraudulent inducement, electronic fraud, wire fraud, human error or malfeasance, unauthorized access, natural disasters, and telecommunication and electrical failures. For example, our employees have received and likely will continue to receive phishing or "spoofed" emails to induce them to make payments to fraudulent accounts. While we have not to date experienced any such material system failure or material security breach or incident, any such event impacting ourselves or our current or future CROs or other contractors or consultants could result in a material disruption of our development programs and our business operations and could lead to the loss of confidential information, financial assets, trade secrets or other intellectual property, or could lead to unauthorized access to or use, modification, unavailability, disclosure, loss, acquisition, or other processing of, or the public exposure of, personal information (including sensitive personal information) of our employees, customers and others, or confidential information of ourselves or of third parties that we maintain, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. For example, the loss, corruption, or unavailability of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products/services) or the third-party information technology systems that support us and our services.

Any disruption or security breach or incident could compromise our networks and systems, or those of our current or future CROs or other contractors or consultants, could result in a loss or unavailability of, or damage to, our data or applications, or unauthorized access to or use, modification, unavailability, disclosure, loss, acquisition, or other processing of, or the public exposure of, personal information (including sensitive personal information) of our employees, customers and others, or confidential information of ourselves or of third parties that we maintain, and could result in legal claims or proceedings, regulatory investigations or other proceedings, liability under laws that protect the privacy of personal information, mandatory notification and reporting obligations, additional regulatory oversight, significant regulatory penalties and remediation expenses.

In addition, these breaches and incidents and other inappropriate access can be difficult to detect, remediate, and otherwise address, and may remain undetected or not fully addressed for an extended period. Any delay in identifying them and responding to or otherwise remediating them may lead to increased harm of the type described above. Geopolitical tensions and conflicts (including the Russia and Ukraine conflict and the conflict in the Middle East) may increase the security risks we and our current or future CROs or other contractors or consultants may face. We expect to continue to expend significant resources to protect against security breaches and incidents and could be required to expend significant amounts to remediate and otherwise respond to security breaches and incidents, including in connection with making notifications to individuals or other persons or implementing additional security measures. With the increase in personnel working remotely during and after the COVID-19 pandemic, we and our vendors are at increased risk for security breaches and incidents.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to privacy, data protection, or security. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy, data protection, or security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. We are exposed to the risk of employee fraud or other illegal or detrimental activity by our employees, independent contractors, consultants, commercial partners, vendors and agents acting on behalf of us or our affiliates. Misconduct by these parties could include, without limitation, intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA or foreign health authorities; provide true, complete and accurate information to the FDA or foreign health authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us; or that negatively reflects on our reputation or business.

**We will face increasing regulation as we advance our product candidates through clinical trials and pursue commercialization, if approved.**

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. Further, in June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA and other federal agencies to challenge longstanding decisions and policies, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the agencies' authority, lead to uncertainty in the industry, and disrupt the agencies' normal operations. Changes in the leadership of the FDA and other federal agencies under the current presidential administration can result in changes in the funding, operations, and policies of the FDA and other federal agencies, which may impact our clinical development plans and timelines.

These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws, including the civil False Claims Act (FCA), that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines.

- The Civil Monetary Penalty Act of 1981 and implementing regulations, which impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offered or transferred remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization.

- The federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act (ACA), and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

- Additional requirements and regulations applicable to the distribution of pharmaceutical products, including extensive record-keeping, licensing, price reporting, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Our board of directors has adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, 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 ourselves 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, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings 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.

**We may not realize the benefits of any acquisitions, in-licenses or strategic alliances that we enter into.**

In the future, we may seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates, including artificial intelligence, machine learning and other technology-based platforms that may supplement our discovery efforts.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, 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, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

**We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.**

We face an inherent risk of product liability as a result of the 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 ourselves 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 or products that we may develop;
- Impairment of our business 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;
- The inability to commercialize any product candidate; and
- A decline in our share price.

Failure to obtain or retain 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. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life- threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates or course of treatment. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our product candidates, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

**Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.**

Recent changes in tax law may adversely affect our business or financial condition. For example, in 2021, there were numerous changes proposed to U.S. federal income tax law, including an increase to the U.S. corporate tax rate, international business operations reform and the imposition of a global minimum tax. If these or similar changes are enacted, our effective tax rate may be adversely impacted in future years. Additionally, many countries, including the United States, and organizations such as the Organization for Economic Cooperation and Development are actively considering changes to existing tax laws or have proposed or enacted new laws that could increase our tax obligations in countries where we do business or cause us to change the way we operate our business. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock. On January 1, 2022, a provision of the legislation commonly known as the Tax Cuts and Jobs Act of 2017 (the TCJA) went into effect, eliminating the option to deduct domestic research and development costs in the year incurred and instead requiring taxpayers to amortize such costs over five years.

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

Under the TCJA, net operating losses arising in tax years beginning after December 31, 2017, can only offset 80% of annual taxable income for tax years beginning after December 31, 2020, but can be carried forward indefinitely. In addition, we will be unable to use our net operating loss carryforwards and tax credit carryforwards if we do not generate taxable income sufficient to offset our available net operating loss carryforwards and tax credit carryforwards prior to their expiration.

We have incurred substantial losses during our history and do not expect to become profitable in the near future and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, except as described below.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) by 5-percent shareholders in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (including tax credit carryforwards) to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. As a result of our most recent private placements, our initial public offering, and other transactions that have occurred over the past three years, we experienced such an "ownership change." We performed an ownership change study as of December 31, 2023 and we determined that certain net operating losses and research and developments tax credits for both federal and state purposes were severely limited and therefore we removed a significant amount of net operating losses and research and development tax credits from our deferred tax assets. In the future we may experience additional ownership changes from future offerings or other changes in the ownership of our stock that could further limit the amount of net operating losses or other tax attributes presented in our financial statements. In addition, California has recently enacted a temporary suspension on the use of state net operating loss carryforwards for certain businesses, which may adversely affect our company if it earns taxable income in the impacted tax years. Other state tax limitations may apply.

**Our business may be significantly adversely affected if events out of our control disrupt our business or that of our third-party providers.**

Our business could be significantly adversely affected by business disruptions to us or our third-party providers that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CMOs, and other contractors, consultants, and third parties could be subject to global pandemics (such as the COVID-19 pandemic), other geopolitical uncertainty and instability (including the Russia and Ukraine conflict and the conflict in the Middle East), earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

While the extent of the impact of the COVID-19 pandemic on our business and financial results to date has been limited, the lasting effects of the pandemic on the drug development industry remains uncertain. Another prolonged public health crisis could have a material negative impact on our business, financial condition and operating results. We have experienced and may in the future experience disruptions from public health emergencies to our business in a number of ways, including:

- Delays in supply chain and manufacturing, including the closure of apheresis collection centers, suspension of cell transport, limitations on transfer of technology, shutdown of manufacturing facilities and delays in delivery of supplies and reagents;

- Delays in discovery and preclinical efforts;

- Changes to procedures or shut down, or reduction in capacity, of clinical trial sites due to limited availability of clinical trial staff, reduced number of inpatient intensive care unit beds for patients receiving cell therapies, diversion of healthcare resources away from clinical trials and other business considerations;

- Limited patient access, enrollment and participation due to travel restrictions and safety concerns, as well as housing and travel difficulties for out of town patients and relatives; and

- Changes in regulatory and other requirements for conducting preclinical studies and clinical trials during the pandemic.

To the extent there is another pandemic, public health emergency, or other national or global event that causes disruption to our business, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects in our trials, such as the COVID-19 guidance documents issued by FDA during the COVID-19 public health emergency. If another public health emergency or other national or global event were to occur, or if the government promulgates new policies and regulatory requirements, or in light of rapid changes in laws, governance, and political climate resulting from the recent change in administration in the U.S., our clinical development plans and normal operations may be disrupted, which can have a material adverse effect on our people and our business.

**If we fail to establish and maintain proper and effective internal controls over financial reporting, our operating results and our ability to operate our business could be harmed.**

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We document, review, and work to improve our internal controls and procedures for compliance with Section 404 of the Sarbanes- Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting. We continue to evaluate our current needs and may recruit additional finance and accounting personnel to meet such requirements.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal controls over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

**If we are unable to maintain effective disclosure controls and procedures, our business, financial position and results of operations could be adversely affected.**

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

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

**Risks Related to Reliance on Third Parties**

**We rely, and will continue to rely on third parties to conduct our clinical trials. If these third parties do not properly and 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 do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We depend and will depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to negotiate budgets and contracts with CROs, trial sites and CMOs, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements 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 or foreign health 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 foreign health 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 cGMP regulations and may require a significant 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 not and will not be our employees and, except for remedies available to us pursuant to our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to such trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other 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 these third parties terminate, we may not be able to enter into arrangements with alternative providers or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

**We rely and expect to continue to rely on third parties to manufacture our clinical product supplies and clinical candidates, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates or fail to do so at acceptable quality levels or prices.**

We do not currently own any facility that may be used as a clinical-scale manufacturing and processing facility, and we rely on outside vendors and collaborators to manufacture supplies and process our product candidates. For certain of our components or product candidates, we rely on single suppliers or manufacturers to supply or manufacture, but we plan to expand the number of suppliers and manufacturers as we advance our product candidates through clinical development. Our product candidates are not yet manufactured or processed on a commercial scale and we may remain unable to do so for any of our product candidates. Although in the future we may develop our own manufacturing facilities, we may also continue to use third parties as part of our manufacturing processes and may, in any event, never be successful in developing our own manufacturing facilities. Our anticipated reliance on third-party manufacturers 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 must inspect any manufacturers for current cGMP.

- Non-compliance of our third party manufacturers with requirements of our marketing application(s). In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates.

- Third party manufacturers may have little or no experience with our product candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates.

- Third party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Third party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.

- Third party manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates 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, if any.

- 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 processes for our product candidates.

- Our third party manufacturers could breach or terminate their agreements with us, and we may be required to pay fees upon suspension or termination of the agreement even if the manufacturers do not deliver adequate supply of the product candidates or their components.

- Raw materials and components used in the manufacturing processes, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to factors beyond our control.

- Our third party manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over their ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification 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 and the FDA could place significant restrictions on our company until deficiencies are remedied. Furthermore, our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms or to comply with cGMP could adversely affect our business in a number of ways, including:

- An inability to initiate or continue clinical trials of our product candidates under development;

- Delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;

- Loss of the cooperation of future collaborators;

- Subjecting third party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;

- Requirements to cease development or to recall batches of our product candidates; and

- In the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

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

Additionally, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation.

We presently contract with a Chinese biotechnology company to manufacture the vector for our clinical stage ARC-SparX programs. Although, if we are proscribed from working with our current manufacturer, we believe we can secure alternate manufacturers for ARC vector, although in the interim we may experience manufacturing disruptions and delays and/or a diversion of management attention, each of which could negatively impact our operations. More generally, if we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations could be materially and adversely affected.

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

**We have entered into a Collaboration Agreement with Kite, and pursuant to the terms of that agreement, are dependent on Kite for certain development, manufacturing and commercialization activities with respect to certain of our product candidates.**

In January 2023, we announced the closing of the Collaboration and License Agreement (Kite Collaboration Agreement) with Kite Pharma, Inc., a Gilead Company (Kite), pursuant to which we agreed to collaborate with Kite to co-develop and co-commercialize anito-cel and next-generation autologous and non-autologous CAR-T cell therapy products that use the same D-domain BCMA binder used in anito-cel, in each case for the treatment of multiple myeloma. We also granted Kite an option to include autologous CAR T-cell therapy products that utilize our ARC-SparX platform that are directed to BCMA, such as ACLX-001, as well as ARC-SparX products directed to CS1. In December 2023, we amended the Kite Collaboration Agreement, expanding the scope of the collaboration to include lymphomas. Kite also exercised its option to negotiate a license for ACLX-001.

Pursuant to the Kite Collaboration Agreement, we and Kite will jointly develop anito-cel and any next-generation autologous CAR-T cell therapy product for which we may exercise our option to co-promote with Kite (collectively, the Co-Promote Products) in accordance with mutually agreed development plans and development budgets. We will conduct the iMMagine-1 trial for anito-cel and Kite will conduct all other development of the other Co-Promote Products. Kite will be responsible for commercialization of anito-cel and such other MM or lymphoma products, outside the United States, to the extent they are approved by the applicable regulatory authorities. Kite is responsible for manufacturing anito-cel under the collaboration. We cannot control whether Kite will devote sufficient attention or resources to this collaboration or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve any of the Co-Promote Products, Kite may elect not to proceed with the commercialization of the resulting product in one or more countries.

In the United States, we and Kite will equally share profits and losses from the commercialization of the Co-Promote Products. For Co-Promote Products outside of the United States and for any other products we may license to Kite that are not a Co-Promote Product (Non-Co-Promote Products), we will be eligible for tiered royalties in the low to mid teen percentages. The milestones that trigger a payment or royalties under the Kite Collaboration Agreement may never be reached and failure to do so could harm our business and financial condition.

Kite has customary rights to terminate the Kite Collaboration Agreement, and if Kite elects to exercise these termination rights, it will result in a delay in or could prevent us from developing or commercializing certain product candidates. Further, disputes may arise between us and Kite, which may delay or cause the termination of this collaboration, result in significant litigation, cause Kite to act in a manner that is not in our best interest or cause us to seek another collaborator or proceed with development, commercialization and funding on our own. If we seek a new collaborator but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of such development candidates we may have to curtail or abandon that development or commercialization, which could harm our business.

**In addition to our collaboration with Kite, we may seek to establish future collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.**

In addition to our collaboration with Kite, we may seek future collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or are allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- Collaborators may not perform their obligations as expected;
- Collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;

- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- Collaborators could fail to make timely regulatory submissions for a product candidate;

- Collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;

- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- Product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- A collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;

- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

- Collaborators may not properly maintain or defend our 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

- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, if we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K would also apply to the activities of any such future collaborators.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our future collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our platforms.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, 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 the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development 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 development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our platforms and our business may be materially and adversely affected.

## Risks Related to Our Intellectual Property

**If we are unable to obtain and maintain sufficient intellectual property protection for our platforms and our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.**

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platforms, product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued that protect our product candidates or their intended uses or that effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import.

If we, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Composition of matter patents for biological and pharmaceutical products such as proprietary binding domains and CAR-based product candidates often provide a strong form of intellectual property protection for these types of products 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 U.S. 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 or administrative tribunals in the United States or foreign countries.

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

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, derivations, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

**The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied.**

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued for such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance;

- Patent applications may not result in any patents being issued;

- Patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise may not provide any competitive advantage;

- Our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both in the United States and abroad for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- Countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

**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, confidentiality agreements, trade secret protection and intellectual property and confidentiality 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.

We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- If and when patents will issue based on our patent applications;
- The scope of protection of any patent issuing based on our patent applications;
- 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 any of our intellectual property will provide any competitive advantage;
- Whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- Whether we will need to initiate or defend litigation or administrative proceedings to enforce and/or defend our patent rights, which may be costly whether we win or lose; or
- Whether the patent applications that we own or may in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position 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. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts or administrative tribunals in the United States or foreign countries.

The strength of patents in the biotechnology and cell therapy fields involve complex legal and scientific questions and can be uncertain. The patent applications that we own or may 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 validity, enforceability or scope thereof, which may result in such patents being 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 around our claims. If the breadth or strength of protection provided by the 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. 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 we were the first to file any patent application related to our product candidates. Furthermore, for U.S. 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. Various post grant review proceedings, such as inter partes review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. While these post grant review proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and other 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. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties 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.

**Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.**

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- Pending patent applications that we own or may license may not lead to issued patents;
- Patents, should they issue, that we own or may license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- Others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents that we own or may license, should any such patents issue;
- Third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- We (or any licensors) might not have been the first to make the inventions covered by a pending patent application that we own or may license;
- We (or any licensors) might not have been the first to file patent applications covering a particular invention;
- Others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- We may not be able to obtain necessary licenses on reasonable terms or at all;

- Third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;

- We may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights, which will be costly whether we win or lose;

- We may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

- We may not develop or in-license additional proprietary technologies that are patentable; and

- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

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

Our commercial success depends in part on our 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, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. 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.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when one of our product candidates is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to 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. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing processes of our product candidates, constructs or molecules used in or formed during the manufacturing processes, 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 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, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose 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.

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

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. 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 infringement claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of any 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 post-grant 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 any 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.

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

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

**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. Failure by us or any licensor to maintain protection of our patent portfolio could have a material adverse effect on our business, financial condition, results of operations, and prospects.

**Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.**

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. 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 products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, a patent's life can be increased based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

If we or a licensing partner 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 re-examination, inter parties review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

**Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.**

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and any licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our 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 and proprietary rights throughout the world.**

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary 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, could put 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or may license.

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

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

Although we are not currently aware of any claims challenging the inventorship of our patents or ownership of our 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. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may receive 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 alleged trade secrets or other confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Although we try to ensure that our employees and consultants do not use intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

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

In addition to seeking patents for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

**Risks Related to Government Regulation**

**We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.**

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign health authorities in other countries. These regulations differ from country to country. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. To gain approval to market our product candidates, we must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- Our inability to satisfactorily demonstrate that the product candidates have acceptable safety and efficacy profiles for the requested indication;
- The FDA's disagreement with our trial designs or the interpretation of data from preclinical studies or clinical trials;
- The population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- Our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- The FDA's determination that additional preclinical or clinical trials are required;
- The FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- The FDA's failure to accept the manufacturing processes, drug product characteristics or facilities of third-party manufacturers with which we contract; or
- The potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If FDA requires us to narrow our indications to smaller patient subsets, our market opportunities for our product candidates, if approved, and our ability to generate revenues may be materially limited. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

**The FDA regulatory approval process is lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval of our product candidates or be unable to generate product revenue.**

We have not previously submitted a BLA to the FDA or similar marketing applications to foreign health authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and efficacy for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. The novel nature of our product candidates may introduce uncertain, complex, expensive and lengthy challenges that could impact regulatory approval. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or foreign health authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- The availability of financial resources to commence and complete the planned trials;
- 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;
- Obtaining approval at each clinical trial site by an IRB or ethics committee;
- Recruiting suitable patients to participate in a trial;
- Enrolling and retaining sufficient number of patients to complete a trial, including post-treatment follow-ups;
- Clinical trial sites deviating from trial protocol or dropping out of a trial;
- Adding new clinical trial sites; or
- Manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also experience delays in physicians enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments or other clinical trials. Furthermore, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or foreign health 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 or foreign health authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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 will be harmed, and our ability to generate product revenue will 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.

Although the FDA has issued and lifted one partial clinical hold, there is no assurance that the FDA will not issue another clinical hold in the future. To the extent FDA issues another clinical hold, addressing a clinical hold takes considerable time and expense and there can be no assurance that the FDA will remove a clinical hold in a timely manner, or at all, in which case our business and prospects for development and approval of anito-cel would be materially harmed.

Securing regulatory approval also requires the submission of information about the manufacturing processes and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or foreign health authorities may fail to approve our manufacturing processes or facilities, whether run by us or our CMOs. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical and/or clinical studies to bridge our modified product candidates to earlier versions.

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. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- The FDA or foreign health authorities may disagree with the design, implementation or data analyses of our clinical trials;
- The FDA or foreign health authorities may determine that our product candidate(s) do not have adequate risk-benefit ratio or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- The population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- The FDA or foreign health 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 support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- The FDA or foreign health authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- The approval policies or regulations of the FDA or foreign health authorities may significantly change in a manner rendering our clinical data insufficient for approval.

**We have or may pursue Fast Track, orphan drug, and/or RMAT designations from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track, orphan drug, and/or RMAT designations, we may be unable to obtain and maintain the benefits associated with such designations. These designations may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.**

We have or may pursue Fast Track, orphan drug, and Regenerative Medicine Advanced Therapy (RMAT) designations from the FDA for one or more of our product candidates, such as those which have been granted for anito-cel and ACLX-002. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions with an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. However, if we do not continue to meet the criteria of the Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. Fast track designation also does not guarantee our product candidate will be approved in a timely manner, if at all. Although the FDA has previously issued and lifted one partial clinical hold, there is no assurance the FDA will not issue another clinical hold in the future.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union, the prevalence of the condition must not be more than 5 in 10,000. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient 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 for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain orphan designation to a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators 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 the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition.

Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. If we or our collaborators do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates. In view of the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities, lead to uncertainty in the industry, and disrupt the FDA's normal operations. Changes in the leadership of the FDA and other federal agencies under the current presidential administration can result in changes in the funding, operations, and policies of the FDA and other federal agencies, which may impact our clinical development plans and timelines.

A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (1) it is 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 potential 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 post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post- approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. RMAT designation does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In March 2023, FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

**We may pursue Breakthrough Therapy designation for one or more of our product candidates in the future. Even if granted by the FDA, such designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.**

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Although Breakthrough Designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. We may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues relating to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical trials may delay approval by the FDA, even if the product qualifies for breakthrough designation or access to any other expedited program. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

**If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.**

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

**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 surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require REMS as a condition of approving our product candidates, which could include 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 foreign health authorities approve our product candidates, the manufacturing processes, 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. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- Restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- Fines, 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;
- Withdrawal of the drug from the market or voluntary or mandatory product recalls;
- Adverse publicity, fines, warning letters or holds on clinical trials;

- 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 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.

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a drug product may not be promoted by manufacturers for uses that are not approved by the FDA, as reflected in the FDA-approved labeling, although healthcare professionals are permitted to use drug products for off-label uses. The FDA, the DOJ, the Inspector General of the Department of HHS, among other government agencies, actively enforce the laws and regulations prohibiting manufacturers' promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including large civil and criminal fines, penalties, and enforcement actions. The FDA has also imposed consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed for companies that engaged in such prohibited activities. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

**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. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.**

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, 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 trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries, such as countries in Europe or Asia. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any jurisdiction. 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. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that product candidate may be significantly diminished, and 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 obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.**

In order to market any product outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

**The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.**

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

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, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future, including future challenges or significant revisions to the ACA. 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 we believe is fair for our products;
- Our ability to obtain coverage and reimbursement approval for a product;
- Our ability to generate revenue and achieve or maintain profitability;
- The level of taxes that we are required to pay; and
- The availability of capital.

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.

As discussed above, U.S. Supreme Court's overturn of the *Chevron* doctrine may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA. Further, changes in the leadership of the FDA and other federal agencies under the current presidential administration can result in significant changes in the funding, operations, and policies of the federal agencies, which may impact our clinical development plans and timelines.

**Risks Related to Commercialization of Our Product Candidates**

**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.**

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, existing cell therapies are currently offered only in tertiary academic hospitals that have intensive care units that can support the safety and toxicity issues associated with cell therapies. If we are unable to demonstrate sufficient safety to permit a broader use of our product candidates, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- The clinical indications for which our product candidates are approved;
- The willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- Physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe, pure and effective treatment;
- The potential and perceived advantages of our product candidates over alternative treatments;
- Our ability to demonstrate the advantages of our product candidates over other conventional CAR-T therapies;
- The perceived prevalence and severity of any side effects for our product candidates compared to the prevalence and severity of any side effects for conventional CAR-T products and other cell therapies;
- Product labeling, limitations, warnings or product insert requirements of the FDA or foreign health authorities, including FDA's requirement for manufacturers of approved CAR-T therapies to include boxed warning regarding T cell malignancies;
- The timing of market introduction of our product candidates as well as competitive products;
- The cost of treatment in relation to alternative treatments;
- Factors that impact access to apheresis, including but not limited to availability of facilities that offer apheresis, additional costs associated with apheresis and administration of CAR-T therapies, and other hospital infrastructure and bottlenecks;
- The availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- The willingness of patients to pay out-of-pocket in the absence of coverage 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.

**We may face difficulties from changes to current regulations and future legislation. Current and future legislation may increase the difficulty and cost for us to commercialize our drugs, if approved, and affect the prices we may obtain, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.**

Existing regulatory 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 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. In both domestic and foreign markets, successful sales of our product candidates, if approved, will depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent novel approaches to the treatment of cancer and autoimmune diseases, we cannot accurately estimate the potential revenue from our product candidates.

Patients who receive medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, 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;
- Medically necessary and has acceptable risk-benefit ratio;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

Obtaining coverage and reimbursement approval 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, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Due to the high costs associated with cell therapies, patients are unlikely to use our product candidates unless coverage is provided or reimbursement is adequate to cover a significant portion of the cost of 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. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. 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 the European Union, 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. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

The ACA made extensive changes to the delivery of health care in the United States. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a negative effect on our expenses and profitability in the future. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. For example, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by increasing the minimum basic Medicaid rebate on most branded prescription drugs. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program.

Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the current presidential administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover over payments to providers from three to five years. Legislators, regulators and third-party payers may continue to put forth proposals to reduce costs while expanding individual healthcare benefits, including proposals that impose additional limitations on the rates we will be able to charge for our product candidates, if approved, or the amount of reimbursement available for such approved products from governmental agencies or third-party payers. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 drug products.

For example, the American Rescue Plan Act of 2021 provided that Medicaid statutory rebates will no longer be capped at 100% of average manufacturer price. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges, future judicial challenges against the federal government in view of the Supreme Court's overturn of the *Chevron* doctrine, as well as future legislative, executive, and administrative actions and agency rules implemented by the current presidential administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time- intensive and expensive, resulting in a material adverse effect on our business.

At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. These measures could reduce the demand for our products, if approved, or impose additional pricing pressures on how much we can charge for our products if approved.

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other jurisdictions. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

**We currently have no sales organization and have a limited marketing organization and limited experience in marketing cell therapy products. If we are unable to establish adequate marketing and sales capabilities or establish or maintain relationships 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 or distribution capabilities and have limited marketing capabilities and limited experience in marketing cell therapy products. If any of our product candidates ultimately obtains regulatory approval, we, whether alone or with Kite for programs that we commercialize together, may not be able to effectively or successfully market the approved product.

For any approved product for which we share co-commercialization and co-promotion responsibilities, we may experience challenges, costs or other issues in having to work together with our collaborators. Our inability to work together to successfully market and sell any such products could have a material adverse effect on our business and overall financial condition.

For any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and relying on arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. By relying on third parties for such activities, we may have little or no control over the marketing and sales efforts conducted on our behalf and our revenue from product sales may be lower than if we had commercialized our product candidates in-house. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates and may have difficulties maintaining the relationships already established.

There can be no assurance that we will be able to develop adequate in-house sales and distribution capabilities or establish or maintain successful relationships with third-party collaborators to commercialize any product in the United States or abroad.

**Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.**

We may be subject to or affected by data protection laws and regulations, such as laws and regulations that address privacy and security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health information and other personal information could apply to our operations. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, the California Consumer Privacy Act (CCPA) took effect in January 2020 and became enforceable in July 2020. The CCPA created new individual privacy rights for California consumers (as the word is broadly defined in the law) and placed increased privacy and security obligations on many organizations that handle personal information of consumers or households. The CCPA requires covered companies to provide disclosures to consumers about such companies' data collection, use and sharing practices, and to provide such consumers a right to opt-out of certain sales or transfers of personal information, and provides consumers with a new cause of action for certain data breaches. California voters voted to approve the California Privacy Rights Act (CPRA) in November 2020, which modified the CCPA significantly, with most modifications effective as of January 1, 2023. Additionally, numerous other states have proposed or enacted laws addressing privacy and security, including Washington's My Health, My Data Act, and several laws imposing obligations similar to those of the CCPA. For example, Virginia, Colorado, Utah, and Connecticut all have enacted general privacy legislation that became effective in 2023; Florida, Montana, Oregon, and Texas have enacted similar legislation that became effective in 2024; Delaware, Iowa, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, and Tennessee have enacted similar legislation that has or will become effective in 2025; and Indiana, Kentucky, and Rhode Island have enacted similar legislation that becomes effective in 2026. The U.S. federal government also has proposed general privacy legislation. The CCPA, CPRA, and other new and evolving legislation may increase our compliance costs and potential liability.

Compliance with laws and regulations relating to privacy, data protection and security could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with such laws and regulations could result in government investigations and/or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

**A variety of risks associated with seeking regulatory approval for and marketing our product candidates internationally could materially adversely affect our business.**

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- Differing regulatory requirements in foreign countries, including constraints on manufacturing;
- Additional trials in foreign countries;
- Requirement to secure and validate region-specific manufacturing and clinical and commercial supply;
- Unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- Foreign 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;
- Potential liability under the Foreign Corrupt Practices Act of 1977 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;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- Business interruptions resulting from geo-political actions, including war (including ongoing geopolitical tensions related to the Russia and Ukraine conflict, resulting sanctions imposed by the United States and other countries and retaliatory actions taken by Russia in response to such sanctions, and the war in the Middle East), armed conflict, terrorist activities, global pandemics and terrorism.

These and other risks associated with our international operations, including relating to privacy and security, may materially adversely affect our ability to attain or maintain profitable operations.

The European Union system for authorization of medicinal products for human use offers several routes: the centralized procedure, the decentralized procedure, and the mutual recognition procedure, as well as domestic national routes. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States as well as the European Economic Area (EEA) countries of Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain categories of investigational products, including human products containing a new active substance indicated for the treatment of certain diseases, including cancer, AIDS, diabetes and neurodegenerative illness; orphan medicinal products; and medicinal products manufactured using biotechnological processes. Applications for marketing authorization for such medicines must be submitted to the European Medicines Agency (EMA), in which the Committee for Medicinal Products for Human Use (CHMP) is generally responsible for conducting the initial assessment of a product.

The decentralized and mutual recognition procedures are applicable to the majority of conventional medicinal products and are both based on the principle of recognition of a marketing authorization by one or more Member States. Any national marketing authorization granted by a European Union Member State's national authority can be used to support an application for its mutual recognition by other Member States. Marketing authorization applications can also be submitted directly to the Member State's national competent authority under the national route (if the centralized route is not compulsory). Following Brexit, there are now multiple routes to obtain a marketing authorization in the United Kingdom, Great Britain or Northern Ireland, including national routes and international routes. The application procedure will depend on the relevant procedure chosen. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. Further, even after obtaining market authorization, differences in GMP, pharmacovigilance, and other regulatory requirements in different jurisdictions can increase our compliance costs and exposure to potential liability.

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

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 and the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other foreign, federal, state, or local regulatory agencies, such as furloughs or government shutdowns, restrictions due to the COVID-19 pandemic or other public health concerns, travel restrictions, or staffing shortages, may also increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

**Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti- corruption laws, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations, all of which can subject us to criminal liability and other serious consequences for violations.**

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (the FCPA), and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees and third-party business partners, representatives and agents from engaging in corruption and bribery, including offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a government official or commercial party in order to influence official action, direct business to any person, gain any improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with government officials, including potentially officials of non-U.S. governments.

Additionally, in many countries, healthcare providers are employed by the government, and the purchasers of biopharmaceuticals are government entities. As a result, our dealings with these providers and purchasers are subject to regulation and such healthcare providers and employees of such purchasers may be considered "foreign officials" as defined in the FCPA. Recently, the SEC and the DOJ have increased their FCPA enforcement activities with respect to biotechnology companies. In addition to our own employees, we may in the future leverage third parties to conduct our business abroad, such as obtaining government licenses and approvals. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies, state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of our employees, our third-party business partners, representatives and agents, even if we do not explicitly authorize such activities. There is no certainty that our employees or the employees of our third-party business partners, representatives and agents will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, debarment from U.S. government contracts, substantial diversion of management's attention, significant legal fees and fines, severe criminal or civil sanctions against us, our officers, or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, financial condition and stock price.

Furthermore, 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 business. Moreover, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to conduct activities at clinical trial sites within regions covered by such sanctions. For example, as a result of the Russia and Ukraine conflict, the United States and its European allies have imposed sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk in Ukraine, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any economic countermeasures by the governments of Russia or other jurisdictions, could adversely impact our ability to continue activities at clinical trial sites within regions covered by such sanctions or directly or indirectly disrupt our supply chain. 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.

**Risks Related to Ownership of our Common Stock**

**We do not know whether an active, liquid, and orderly trading market will be sustained for our common stock.**

Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the levels of trading activity may decline. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of our common stock as consideration.

**The price of shares of our common stock has been, and may continue to be, volatile and may be adversely impacted by future events, and you could lose all or part of your investment.**

The trading price of our common stock has been, and is likely to continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which are beyond our control. In addition to the factors discussed in this Risk Factors section, and elsewhere in this Annual Report on Form 10-K, these factors include:

- Our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- The commencement, enrollment, or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- Results from ongoing clinical trials and future clinical trials of our competitors;
- Any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

- Our failure to achieve product development goals in the time frames we announce;
- Adverse results or delays in clinical trials;
- Adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- Changes in laws or regulations applicable to our product candidates, including, but not limited to, clinical trial requirements for approvals;
- Adverse developments concerning our manufacturers;
- Our inability to obtain adequate supply for any product candidate, or any component thereof, or approved product or inability to do so at acceptable prices;
- Our inability to establish collaborations if needed;
- Our failure to commercialize our product candidates;
- Unanticipated serious safety concerns related to the use of our product candidates;
- Introduction of new products or other therapies offered by us or our competitors;
- Announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- Additions or departures of key scientific or management personnel;
- Our ability to effectively manage our growth;
- The size and growth of our initial cancer or autoimmune target markets and the markets of any other indications that we choose to target;
- Our ability to successfully treat additional types of cancers or at different stages;
- Our ability to successfully treat the indications outside of cancer, such as autoimmune indications, that we pursue;
- Actual or anticipated variations in quarterly operating results;
- Our cash position;
- Our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- Publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- Changes in the market valuations of similar companies;
- Our operating performance and the performance of other similar companies;
- Overall performance of the equity markets;
- The expiration of contractual lock-up or standstill agreements;
- Sales of our common stock by us or our stockholders in the future;
- Trading volume of our common stock, which may be limited;

- Changes in accounting practices;
- Ineffectiveness of our internal controls;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- Significant lawsuits, including patent or stockholder litigation;
- General political and economic conditions, such as global pandemics or geopolitical uncertainty and instability, including ongoing geopolitical tensions related to the Russia and Ukraine conflict, resulting sanctions imposed by the United States and other countries, and retaliatory actions taken by Russia in response to such sanctions, and also those related to military conflicts in the Middle East; and
- Other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

The trading market for our common stock relies in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.**

We expect that significant additional capital may be needed in the future to continue our planned operations, which include conducting clinical trials, pursuing commercialization efforts, expanding research and development activities, and continuing to operate as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our drug candidates, or grant licenses on terms that are not favorable to us.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Pursuant to the 2022 Equity Incentive Plan (the 2022 Plan), our board of directors or its duly authorized committee is authorized to grant equity awards to our employees, directors, and consultants.

Initially, the aggregate number of shares of our common stock that was able to be issued pursuant to equity awards under the 2022 Plan was 4,296,875 shares, plus the number of shares subject to awards granted under our 2017 Equity Incentive Plan (the 2017 Plan) that expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that could (and can) be added to the 2022 Plan pursuant to awards under the 2017 Plan is 6,269,300). The number of shares of our common stock reserved for issuance under the 2022 Plan is cumulatively increased on the first day of each fiscal year, which began with our 2023 fiscal year and will end on the ten year anniversary of the date our board of directors approved the 2022 Plan equal to the *least* of (i) 4,296,875 shares, (ii) 5.0% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a number of shares determined by the administrator of the 2022 Plan. As a result of the 2022 Plan, our stockholders may experience additional dilution. On January 1, 2025, the number of shares available for issuance under the 2022 Plan was increased by 2,714,041 additional shares.

Pursuant to our 2022 ESPP, our employees may receive the right to purchase shares of our common stock. Initially, the aggregate number of shares of our common stock available for sale under our 2022 ESPP was 312,500 shares. The number of shares of our common stock available for sale under our 2022 ESPP is cumulatively increased on the first day of each fiscal year, beginning with the fiscal year following the fiscal year in which the first enrollment date (if any) occurs under the 2022 ESPP, which occurred in the Company's 2022 fiscal year, and ending on the twenty year anniversary of the date our board of directors approved the 2022 ESPP equal to the *least* of: (i) 312,500 shares, (ii) 1.0% of the total number of shares of our common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a number of shares determined by the administrator of the 2022 ESPP. As a result of the 2022 ESPP, our stockholders may experience additional dilution. On January 1, 2025, the number of shares available for issuance under the 2022 ESPP was increased by 312,500 additional shares.

**Gilead holds 6,720,803 shares, or approximately 13%, of our outstanding shares of common stock which are restricted from immediate resale pursuant to the terms of the Amended Standstill Agreement but may be sold into the market in the near future. Such resale could cause the market price of our common stock to drop significantly, even if our business is doing well.**

Pursuant to the Amended Standstill Agreement, the shares of common stock acquired by Gilead pursuant to the Purchase Agreement and second common stock purchase agreement with Gilead are subject to certain transfer and standstill restrictions and registration rights, and such shares are restricted from immediate resale. Gilead is subject to certain transfer restrictions during the period from January 26, 2023 until the earliest to occur of (x) 18 months after January 26, 2023, (y) a change of control and (z) the termination of the Kite Collaboration Agreement, as amended. Pursuant to the Amended Standstill Agreement, Gilead has certain demand registration rights to require us to register the shares acquired by Gilead pursuant to the Purchase Agreement and second common stock purchase agreement with Gilead for resale. Once we register the shares held by Gilead, however, they can be freely sold in the public market. As these securities are registered for resale, the market price of our stock could decline if Gilead sells them or is perceived by the market as intending to sell them.

The sale by Gilead of a significant number of shares of common stock could have a significant negative impact on the market price of our common stock. In addition, the perception in the public markets that Gilead may sell all or a portion of the shares held by them as a result of the registration of such shares for resale could also in and of itself have a material adverse effect on the market price of our common stock. We cannot predict the effect, if any, that market sales of those shares or the availability of those shares for resale will have on the market price of our common stock. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

**We do not intend to pay dividends on our common stock, so any returns will be limited to the capital appreciation of our stock.**

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

**Certain 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 amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could discourage, 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, which could delay the ability of stockholders to change the membership of a majority of our board of directors;

- The exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death, disqualification or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- A prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;

- A requirement that special meetings of stockholders be called only by the chairperson of our board of directors, our Chief Executive Officer, our President, or our board of directors acting pursuant to a resolution adopted by a majority of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- Advance notice requirements for stockholder proposals and nominations for election to our board of directors, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us;

- 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 not less than a majority of the shares present in person or by proxy at the meeting and entitled to vote, which could delay the ability of stockholders to change the membership of our board of directors;

- A requirement of approval of not less than two-thirds 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, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and

- The authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval (except as required by Nasdaq rules), which preferred stock may include rights superior to the rights of the holders of common stock and could be used to significantly dilute the ownership of a hostile acquirer.

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. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers 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 and limit opportunities for you to realize value in a corporate transaction.

**Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.**

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- Any derivative action or proceeding brought on our behalf;

- Any action asserting a claim of breach of fiduciary duty;

- Any action asserting a claim against us arising under the Delaware General Corporation Law (DGCL), our amended and restated certificate of incorporation or our amended and restated bylaws; and

- Any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. For the avoidance of doubt, this provision shall not apply to any claim brought to enforce a duty or liability created by the Exchange Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

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

**Item 1B. Unresolved Staff Comments.**

None.

**Item 1C. Cybersecurity.**

**Risk Management and Strategy**

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. This program includes:

- Robust Firewalls and Intrusion Detection Systems: The company has invested in state-of-the-art firewalls and intrusion detection systems designed to prevent unauthorized access to its networks.
- Regular Security Assessments: The company conducts regular security assessments to identify vulnerabilities and address them promptly. This includes penetration testing, vulnerability scanning, and third-party audits.
- Employee Training and Awareness: The company provides comprehensive cybersecurity training to all employees to educate them about potential risks, phishing attacks, and best practices for protecting sensitive information.
- Incident Response Plan: The company has developed an incident response plan that outlines the steps to be taken in the event of a cybersecurity breach. This includes isolating affected systems, investigating the breach, and notifying relevant stakeholders.
- Cyber Insurance: The company has obtained cyber insurance coverage to mitigate the financial impact of a cybersecurity breach. This insurance policy covers expenses related to incident response, legal fees, and potential customer compensation.

By implementing these risk management strategies, we aim to minimize the likelihood and impact of a cybersecurity breach, thereby safeguarding our assets and maintaining the trust of our stakeholders.

We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. We devote significant resources and designate high-level personnel, including our Director of Information Technology, who reports to our Chief Financial Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage assessors, consultants, or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. To oversee and identify risks from cybersecurity threats associated with our use of third-party service providers, we require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with its work with us, and to promptly report any suspected breach of its security measures that may affect our company.

For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

**Governance**

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function primarily through the audit committee.

Our Director of Information Technology and members of our cybersecurity committee (a management committee), which includes legal and privacy representatives, are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers. Our Director of Information Technology has expertise in security frameworks and standards (such as the Cybersecurity Framework established by the National Institute of Standards and Technology at the U.S. Department of Commerce), proficiency in security tools such as security information and event management systems, intrusion detection systems and vulnerability scanners, and has experience with threat intelligence, threat modeling, risk assessment, and risk management practices, as well as analyzing logs, investigating security incidents, and performing forensic analysis.

Our Director of Information Technology and members of our cybersecurity committee oversee our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The processes by which our Director of Information Technology and members of our cybersecurity committee are informed about and monitor the prevention, detection, mitigation, and remediation of cybersecurity incidents includes the following: Security Awareness Training, Patch Management Process, Endpoint Detection and Response, Managed Detection and Response, Incident Response Plan, Data Encryption, Access Control, Network Security, and Vulnerability Management.

Our Director of Information Technology, our Controller, and members of our cybersecurity committee provide quarterly briefings to the audit committee regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.

**Item 2. Properties.**

Our corporate headquarters are located in Redwood City, California, where we lease 51,822 square feet of office and laboratory space pursuant to a lease agreement that expires on January 31, 2034. In July 2022, we entered into an operating lease agreement for 57,902 square feet of office and laboratory space in Rockville, Maryland pursuant to a lease agreement that expires on May 31, 2035. In October 2018, we entered into an operating lease agreement for 22,930 square feet of office and laboratory space in Gaithersburg, Maryland pursuant to a lease agreement that expires on January 31, 2030. On January 30, 2024, we entered into an Assignment of Lease with a third party sublessee, pursuant to which we agreed to transfer and assign to a sublessee all of our rights, title, and interest under the Gaithersburg, Maryland lease.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. As of December 31, 2024 we were not a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of 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 under the symbol "ACLX" on the Nasdaq Global Select Market.

***Holders of Our Common Stock***

As of February 21, 2025, there were approximately 16 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

***Dividend Policy***

We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors.

***Recent Sales of Unregistered Equity Securities***

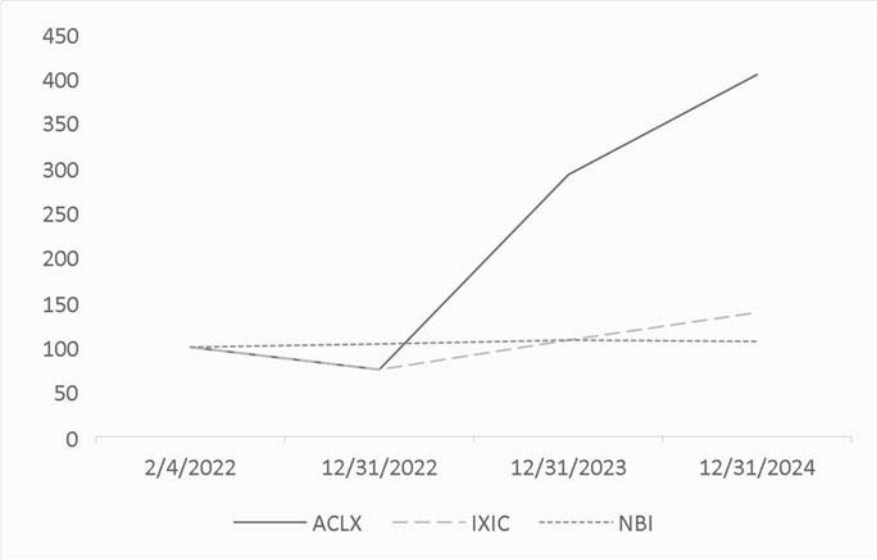
There were no sales of unregistered securities by us during the year ended December 31, 2024 that were not previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the SEC.

***Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

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

***Performance Graph***

The following graph shows the total stockholder's return on an initial investment of $100 in cash at market close on February 4, 2022 (the first day of trading of our common stock), through December 31, 2024 for (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of pre-tax amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



| $100 investment in stock or index | Ticker | 2/4/2022 | 12/31/2022 | 12/31/2023 | 12/31/2024 |
|---|---|---|---|---|---|
| Arcellx | ACLX | $ 100 | $ 75 | $ 292 | $ 404 |
| NASDAQ Composite Index | IXIC | $ 100 | $ 75 | $ 108 | $ 138 |
| NASDAQ Biotech Index | NBI | $ 100 | $ 104 | $ 107 | $ 106 |

**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 the related notes thereto included elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks, uncertainties and assumptions. You should review the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. For convenience of presentation, some of the numbers have been rounded in the text below. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.*

**Overview**

We are a clinical-stage biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases. We believe cell therapies are one of the forward pillars of medicine, and our mission is to advance humanity by engineering cell therapies that are safer, more effective and more broadly accessible. Although cell therapies have shown benefits to date, cell therapies have primarily been constrained to existing biologic structures, which has limited their impact and opportunity. Our novel synthetic binding scaffold, the D-Domain, is designed to overcome the limitations of traditional Chimeric Antigen Receptor T-cells (CAR-Ts). Existing cell therapy solutions, most of which use a biologic-based, single chain variable fragment (scFv) binding domain, tend to be difficult to manufacture, beneficial to a limited segment of patients, often result in high toxicity, and have narrow applicability in treatable indications. We believe we can address these limitations by engineering a new class of D-Domain powered cell therapies, including classical single infusion CAR-Ts called "ddCARs" and dosable and controllable universal CAR-Ts called "ARC-SparX", to address hematologic cancers, solid tumors, and indications outside of oncology, such as autoimmune diseases.

Our lead program is a BCMA-targeting ddCAR product candidate called "anito-cel", which is currently being evaluated in our pivotal Phase 2 iMMagine-1 and the Phase 3 iMMagine-3 trials in patients with relapsed or refractory multiple myeloma (rrMM). We have partnered anito-cel with Kite Pharma Inc., a Gilead company (Kite), through our co-development/co-commercialization collaboration agreement (as described in more detail in the section below titled "Components of Results of Operations - Revenue" included in this Annual Report on Form 10-K). Recently, Kite initiated a global Phase 3 randomized controlled clinical trial (iMMagine-3) of anito-cel in patients with second through fourth line rrMM. Kite will manufacture anito-cel for iMMagine-3. This follows the completion of the technical transfer to Kite, which was announced in May 2024, as well as the transfer to Kite of the Investigational New Drug (IND) application for anito-cel in rrMM, which has been cleared by the U.S. Food and Drug Administration (FDA).

Outside of our collaboration with Kite, we intend to evaluate anito-cel for the treatment of certain non-oncology indications, including some autoimmune disorders. We received FDA clearance of an IND application and have initiated a Phase 1 trial in generalized myasthenia gravis (gMG) in 2024.

We also are developing two clinical-stage ARC-SparX programs in Phase 1 trials, ACLX-001, which targets BCMA in rrMM, and our wholly-owned ACLX-002, which targets CD123 in relapsed or refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). In November 2023, Kite exercised its option under the Kite Collaboration Agreement to negotiate a license for ACLX-001.

Since our formation, we have devoted substantially all our resources to discovering and developing our product candidates. We have incurred significant operating losses to date. Our net losses were $107.3 million, $70.7 million, and $188.7 million for the years ended December 31, 2024, 2023 and 2022. Our accumulated deficit totaled $496.8 million as of December 31, 2024. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. We expect our operating expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

- Advance the clinical program for anito-cel and subsequent clinical trials focused on earlier lines of therapy in collaboration with our partner Kite;

- Grow our supply and contract manufacturing infrastructure to support the continued development of anito-cel and our other product candidates;
- Initiate clinical trials to evaluate anito-cel in other indications outside of oncology, such as generalized myasthenia gravis;
- Initiate or continue to advance clinical trials to evaluate our clinical-stage ARC-SparX product candidates, ACLX-001 and ACLX-002, and other preclinical pipeline programs;
- Expand our pipeline of product candidates, including through our own product discovery and development efforts or through acquisition or in-licensing;
- Continue to develop our proprietary platforms to extend their use;
- Attract, hire, and retain additional clinical, scientific, manufacturing, management and administrative personnel;
- Add operational, financial, and management information systems and personnel, including personnel to support our product development, as well as to support us as a public reporting company;
- Determine and execute our long-term manufacturing strategy for anito-cel in collaboration with our partner Kite;
- Pursue regulatory approval of product candidates that successfully complete clinical trials;
- Establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval; and
- Obtain, maintain, expand and protect our intellectual property portfolio.

As a result, we may require substantial additional funding to develop our product candidates and our platforms and to support our continuing operations. Our ability to generate product revenue will depend on the successful development, regulatory approval, and eventual commercialization of one or more of our product candidates. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances, and licensing arrangements. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, or financial condition, and could force us to delay, reduce or eliminate our product development or future commercialization efforts. We may also be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Based on our expected operating cash requirements and capital expenditures, we believe our current cash and cash equivalents and investments in marketable securities are adequate to fund operations into 2027.

**Recent Developments**

In December 2024, we announced preliminary data from our pivotal iMMagine-1 study in patients with rrMM, which were presented during an oral presentation at the 66th ASH Annual Meeting and Exposition.

In November 2024, we announced with Kite that the first patients have been dosed in the global iMMagine-3 randomized control trial evaluating anito-cel in patients with rrMM exposed to an immunomodulatory (IMiD) drug and an anti-CD38 monoclonal antibody.

## Components of Results of Operations

### Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. Our revenue consists of amounts recognized from our collaboration with Kite for our research and development performed under the Kite Collaboration Agreement and its amendment, recognized on a cost-to-cost percentage of completion basis applied to the total estimated transaction price. In the future, we may generate revenue from payments received under the Kite Collaboration Agreement and its amendment, including payments of upfront fees, license fees, milestone-based payments, and reimbursements for research and development efforts.

### Operating Expenses

#### *Research and Development Expenses*

We expense research and development costs in the periods in which they are incurred. We track external costs on a program-by-program basis beginning with lead candidate selection. External costs that are not allocated to a program are classified as preclinical and discovery costs. We do not track internal costs by program because these costs are deployed across multiple programs, and as such, are not separately classified.

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with our anito-cel program, the development of our ARC-SparX product candidates, and the ongoing discovery and development efforts for additional product candidates.

External expenses include:

- Payments to third parties in connection with the clinical development of our product candidates, including contract research organizations (CROs) and consultants;
- The cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (CMOs) and consultants;
- Payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and for sponsored research arrangements with third parties;
- Laboratory supplies used in the preclinical development of our product candidates; and
- Allocated facilities, depreciation, and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities.

Internal expenses include employee-related costs, including salaries, related benefits, and share-based compensation expense for employees engaged in research and development functions.

Our Manufacturing Services Agreement with Lonza Houston, Inc. (Lonza) expired in December 2024. Previously, we had identified embedded leases within the agreement, which had resulted in right-of-use assets that were expensed as research and development expenses in 2022 and 2023 as the right-of-use assets had no alternative future use.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially in the foreseeable future as we continue to advance anito-cel, in multiple myeloma and other indications outside of oncology, through clinical development, the regulatory approval process and, if approved, commercial launch activities; initiate or continue to advance our ARC-SparX product candidates, including expanding ACLX-001 and ACLX-002; continue to discover and develop additional product candidates to expand our pipeline; maintain, expand, protect, and enforce our intellectual property portfolio; and hire additional personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing, and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- Successful enrollment in, and completion of, clinical trials;
- Sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- Achieving favorable results from clinical trials;
- Receipt of marketing approvals from applicable regulatory authorities;
- Establishing and maintaining sufficient manufacturing capabilities, whether internally or with third parties, including securing raw material supply;
- Existence of, and our ability to identify, an addressable patient population for our product candidates;
- Effectively competing with other therapies;
- Maintaining a continued acceptable safety profile of any product following approval, if any;
- Submission of INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical trials;
- Identification of additional target antigens for desired indications;
- Identification and engineering of D-Domain-based binding regions that bind to the desired target antigens;
- Developing and implementing successful marketing and reimbursement strategies;
- Obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our product candidates; and
- The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

Any changes in the outcome of any of these factors could significantly impact the costs, timing, and viability associated with the development of our product candidates and our ability to generate significant revenues from product sales.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries, related benefits, and share-based compensation expense for personnel in executive, finance, and administrative functions. General and administrative expenses also include allocated facilities, depreciation, and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, investor and public relations, accounting, and audit services.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support the growth of the company.

***Other Income, net***

Other income, net consists primarily of interest earned on our cash and cash equivalents, restricted cash, and marketable securities, net accretion and amortization on marketable securities and interest expense related to our finance lease obligations.

***Income Tax Provision***

We have recorded an income tax expense of $2.1 million, $663 thousand and zero for the years ended December 31, 2024, 2023 and 2022, respectively.

Based on the available objective evidence during the year ended December 31, 2024, we believe it is not more likely than not that the tax benefits of our net deferred income tax assets may be realized. Accordingly, we did not record the tax benefits of net deferred income tax assets previously incurred as of December 31, 2024. The primary difference between the effective tax rate and the statutory tax rate relates to change in state deferred income tax rate.

**Results of Operations**

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

| | Year Ended December 31, | | | Change | | | |
|---|---|---|---|---|---|---|---|
| | 2024 | 2023 | 2022 | 2024 vs 2023 | | 2023 vs 2022 | |
| Collaboration revenue | $ 107,936 | $ 110,319 | $ — | $ (2,383) | -2% | $ 110,319 | 100% |
| Operating expenses: | | | | | | | |
| Research and development | 157,093 | 133,849 | 149,555 | 23,244 | 17% | (15,706) | -11% |
| General and administrative | 88,414 | 66,350 | 41,704 | 22,064 | 33% | 24,646 | 59% |
| Total operating expenses | 245,507 | 200,199 | 191,259 | 45,308 | 23% | 8,940 | 5% |
| Loss from operations | (137,571) | (89,880) | (191,259) | (47,691) | 53% | 101,379 | -53% |
| Interest and other income (expense), net | 33,322 | 23,695 | 4,300 | 9,627 | 41% | 19,395 | 451% |
| Interest expense | (1,030) | (3,842) | (1,720) | 2,812 | -73% | (2,122) | 123% |
| Total other income, net | 32,292 | 19,853 | 2,580 | 12,439 | 63% | 17,273 | 669% |
| Income tax expense | (2,069) | (663) | — | (1,406) | 212% | (663) | 100% |
| Net loss | $(107,348) | $ (70,690) | $(188,679) | $ (36,658) | 52% | $ 117,989 | -63% |

***Collaboration Revenue***

Collaboration revenue was $107.9 million for the year ended December 31, 2024 compared to $110.3 million for the year ended December 31, 2023.

Collaboration revenue was $110.3 million for the year ended December 31, 2023 compared to zero for the year ended December 31, 2022, as we began recognizing collaboration revenue in 2023 under the Kite Collaboration Agreement and its amendment.

***Research and Development Expenses***

The detail of our external and internal research and development costs is as follows (in thousands, except percentages):

| | Year Ended December 31, | | | Change | | | |
|---|---|---|---|---|---|---|---|
| | 2024 | 2023 | 2022 | 2024 vs 2023 | | 2023 vs 2022 | |
| External costs: | | | | | | | |
| anito-cel in rrMM | $ 50,141 | $ 73,530 | $ 96,513 | $(23,389) | -32% | $(22,983) | -24% |
| ACLX-001 | 1,975 | 2,939 | 8,764 | (964) | -33% | (5,825) | -66% |
| ACLX-002 | 14,294 | 5,667 | 6,458 | 8,627 | 152% | (791) | -12% |
| Other research and development costs | 21,364 | 3,701 | 5,467 | 17,663 | 477% | (1,766) | -32% |
| Total external costs | 87,774 | 85,837 | 117,202 | 1,937 | 2% | (31,365) | -27% |
| Internal costs | 69,319 | 48,012 | 32,353 | 21,307 | 44% | 15,659 | 48% |
| Total research and development expenses | $ 157,093 | $ 133,849 | $ 149,555 | $ 23,244 | 17% | $(15,706) | -11% |

Research and development expenses were $157.1 million for the year ended December 31, 2024 compared to $133.8 million for the year ended December 31, 2023, an increase of $23.2 million. The increase in research and development expenses was primarily attributable to an increase in internal costs of $21.3 million due to higher personnel-related costs, of which $10.4 million was due to non-cash share-based compensation; an increase of $5.4 million in anito-cel programs; an increase of $8.6 million in costs relating to ACLX-002 program; and an increase of $17.7 million in costs relating to other pipeline programs (including ACLX-003 in AML, anito-cel in myasthenia gravis, and additional discovery programs). The increase was partially offset by a decrease of $28.8 million relating to expense in our anito-cel clinical program for a related right of use asset associated with an embedded lease for our Lonza manufacturing services agreement for which there is no alternative use.

Research and development expenses were $133.8 million for the year ended December 31, 2023 compared to $149.6 million for the year ended December 31, 2022, a decrease of $15.7 million. The decrease in research and development expenses was primarily attributable to a decrease of $29.0 million relating to expense in our anito-cel clinical program for a related right of use asset associated with an embedded lease for our Lonza manufacturing services agreement for which there is no alternative use. This decrease was partially offset by an increase of $6.2 million in external costs. There was a decrease of $7.2 million in manufacturing costs associated with other clinical programs. Internal costs had an increase of $9.1 million in personnel related costs due to an increase in headcount ($4.0 million of which was due to non-cash stock-based compensation expense), an increase of $4.1 million in facilities costs, and an increase of $1.2 million in depreciation expenses.

***General and Administrative Expenses***

General and administrative expenses were $88.4 million for the year ended December 31, 2024 compared to $66.4 million for the year ended December 31, 2023, an increase of $22.1 million. This increase was driven primarily by an increase of $14.4 million in personnel-related costs, of which $8.9 million was due to non-cash stock-based compensation, and an increase of $3.4 million in depreciation expense, and $2.0 million in commercial readiness.

General and administrative expenses were $66.4 million for the year ended December 31, 2023 compared to $41.7 million for the year ended December 31, 2022, an increase of $24.6 million. This increase was driven primarily by an increase of $19.3 million in personnel related costs due to an increase in headcount ($16.2 million of which was due to non-cash stock-based compensation expense), $3.2 million in facilities costs, and $1.4 million in consulting fees.

***Other income, net***

Other income, net was $32.3 million for the year ended December 31, 2024 compared to $19.9 million for the year ended December 31, 2023, an increase of $12.4 million. This increase was driven primarily by higher marketable securities balances and a corresponding increase in the interest earned.

Other income, net was $19.9 million for the year ended December 31, 2023 compared to $2.6 million for the year ended December 31, 2022, an increase of $17.3 million. This increase was driven primarily by higher overall cash and cash equivalents and marketable securities balances and a corresponding increase in the interest earned.

## Liquidity and Capital Resources

Since inception, we have incurred net losses and negative cash flows from operations and we expect to incur substantial additional losses in future periods. As of December 31, 2024, we had cash and cash equivalents and marketable securities of $625.7 million.

To date, we have not generated any product revenue. We do not expect to generate any meaningful revenue from product sales unless and until we obtain regulatory approval of, and commercialize any of, our product candidates, except that we recognize revenue under the Kite Collaboration Agreement and its amendment on a cost-to-cost percentage of completion basis applied to the total estimated transaction price. We may also enter into other collaborative agreements with third parties, and we do not know when, or if, any 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. Moreover, we expect to incur additional costs associated with operating as a public company, particularly relating to our loss of emerging growth company and smaller reporting company status. Adequate funding may not be available to us on acceptable terms or at all.

Based on our expected operating cash requirements and capital expenditures, we believe our current cash and cash equivalents and investments in marketable securities are adequate to fund operations into 2027.

In May 2023, we entered into a sales agreement (Sales Agreement) with Stifel, Nicolaus & Company (Stifel) with respect to an at-the-market offering program under which we may issue and sell, from time to time and at our sole discretion, shares of our common stock, in an aggregate offering amount of up to $350.0 million. Stifel acts as our sales agent and will use commercially reasonable efforts to sell shares of common stock from time to time, based upon instruction from us. We will pay Stifel up to 3.0% of the gross proceeds from the sales of any common stock sold pursuant to the Sales Agreement and have agreed to provide Stifel with customary indemnification and contribution rights, plus reimbursement for specified expenses it incurred in connection with entering into the agreement. No sales of our common stock have been made under this arrangement as of December 31, 2024.

***Cash Flows***

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Net cash provided by (used in) operating activities | $ (83,467) | $ 207,573 | $ (99,303) |
| Net cash used in investing activities | (183,045) | (154,512) | (117,674) |
| Net cash provided by (used in) financing activities | (24,087) | 279,163 | 252,625 |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | $ (290,599) | $ 332,224 | $ 35,648 |

***Operating Activities***

Net cash used in operating activities during the year ended December 31, 2024 of $83.5 million was attributable to our net loss of $107.3 million, partially offset by adjustments to net loss of $54.7 million. The adjustments to net loss primarily consist of share-based compensation of $61.1 million, depreciation and amortization of $5.2 million, and noncash operating lease expense of $3.3 million, partially offset by amortization of premiums and discounts on marketable securities of $15.5 million. Changes in operating assets and liabilities decreased cash by $30.8 million, primarily due to changes in contract liability to related party of $86.2 million and operating lease liabilities of $3.8 million, partially offset by changes in prepaid assets and other current and non-current assets of $8.6 million, other non-current liabilities of $8.6 million, and accrued liabilities of $41.9 million.

Net cash provided by operating activities during the year ended December 31, 2023 of $207.6 million was attributable to our net loss of $70.7 million, partially offset by adjustments to net loss of $52.8 million, primarily consisting of expensing of a right-of-use asset of $18.9 million, share-based compensation of $41.8 million, and depreciation and amortization of $2.0 million, offset by net amortization and accretion on marketable securities of $11.0 million. Changes in operating assets and liabilities increased cash by $225.4 million, primarily due to an increase in contract liability to related party of $221.2 million and increases in operating lease liabilities of $13.5 million, offset by increase in prepaid assets and other current and non-current assets of $8.4 million and decreases in accounts payable and other current liabilities and accrued liabilities of $0.9 million.

Net cash used in operating activities during the year ended December 31, 2022 of $99.3 million was primarily attributable to our net loss of $188.7 million, partially offset by adjustments to net loss of $84.9 million, primarily consisting of expensing of a right-of-use asset of $63.3 million, together with share-based compensation of $21.5 million, amortization of premiums and discounts on marketable securities of $2.1 million, and depreciation and amortization of property and equipment of $1.3 million. Changes in operating assets and liabilities increased cash by $4.5 million, primarily due to increases of accounts payable and other current liabilities and accrued liabilities of $7.0 million, and increases in operating lease liabilities of $3.1 million, offset by decreases in prepaid assets and other current and non-current assets of $5.7 million.

***Investing Activities***

Net cash used in investing activities of $183.0 million during the year ended December 31, 2024 consists of $597.3 million in purchases of marketable securities and $13.4 million in purchases of property and equipment, offset by $427.7 million in proceeds from maturities of marketable securities.

Net cash used in investing activities of $154.5 million during the year ended December 31, 2023 consists of $442.4 million in purchases of marketable securities and $21.4 million in purchases of property and equipment, offset by $309.3 million in proceeds from maturities of marketable securities.

Net cash used in investing activities of $117.7 million during the year ended December 31, 2022 consists of $273.7 million in purchases of marketable securities, offset by $158.3 million in proceeds from maturities of marketable securities and $2.3 million in purchases of lab equipment used in the development of our cell therapies.

***Financing Activities***

Net cash used in financing activities of $24.1 million during the year ended December 31, 2024 consists of $39.8 million payments under our finance lease from our Lonza manufacturing services agreement which ended in December 2024, offset by $15.8 million in proceeds from the exercise of stock options and stock issued pursuant to the employee stock purchase plan.

Net cash provided by financing activities of $279.2 million during the year ended December 31, 2023 consisted of $299.7 million proceeds from issuance of common stock to related party, $7.8 million proceeds from exercise of stock options, offset by payments under our finance lease totaling $29.4 million.

Net cash provided by financing activities of $252.6 million during the year ended December 31, 2022 consisted of $129.2 million raised in our IPO, $120.7 million raised in a follow-on public offering, and $10.0 million raised in a private placement, all net of transaction costs. In addition $2.5 million was received from the exercise of stock options, offset by payments under our finance lease totaling $9.7 million.

## Contractual Obligations and Contingencies

We enter into contracts in the normal course of business with contract manufacturers for manufacturing services for our clinical trials and contract research organizations for preclinical studies, clinical trials and other services, which are generally cancellable upon written notice. In addition, certain agreements with our CMOs and third-party vendors contain development and commercial milestone payments and low single-digit royalties on worldwide net sales for certain products we sell that incorporate certain goods provided by our manufacturers and suppliers. As of December 31, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales.

Our operating lease obligations primarily consist of lease payments on our research, lab and office facilities in Rockville, Maryland and Redwood City, California. For additional information regarding our lease obligations, see Note 9 to our consolidated financial statements included elsewhere in this report.

## Critical Accounting Policies and Estimates

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

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

***Revenue Recognition***

We recognize revenue in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers ("ASC 606").* We recognize revenue when a customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

We evaluate the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses; (ii) performance of development services and manufacturing activities, (iii) performance of manufacturing transfer, and (iv) participation on joint committees. The payment terms of these agreements may include nonrefundable upfront fees, cost-sharing arrangements, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration.

We exercise judgment in assessing those promised goods and services that are distinct and thus representative of performance obligations. To the extent we identify multiple performance obligations in a contract, we must develop assumptions that require judgment to determine the estimated standalone selling price for each performance obligation in order to allocate the transaction price among the identified performance obligations. The transaction price is allocated on a relative standalone selling price basis.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. 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 and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required.

We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligations when or as the performance obligations are satisfied. For performance obligations satisfied over time, we estimate the efforts needed to complete the performance obligations and recognize revenue by measuring the progress towards complete satisfaction of the performance obligations using an input measure. The estimated period of performance and level of effort, including third-party costs, are reviewed quarterly and adjusted, as needed, to reflect our current expectations. The measurement of progress is then used to calculate revenue, including any revenue adjustments as a result of the change in estimate. For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligations to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon the performance of the licensee. Funds received in advance are recorded as contract liabilities and are recognized as the related performance obligations are satisfied.

***Accrued research and development expenses***

Research and development costs are charged to expense as incurred. Research and development costs consist primarily of salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, and overhead and facility-related costs. We account for advanced payments, including non-refundable amounts, for goods or services that will be used in future research and development activities as expenses when the related goods have been received or when the service has been performed, or such a time when we do not expect the goods to be delivered or services to be performed, rather than when the payment is made.

Expenses related to clinical trials are accrued based on estimates and representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies, and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. Similarly, we accrue expenses related to the work performed by CMOs based on the progress of the work performed. If the amounts that we are obligated to pay under clinical trial agreements and manufacturing agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

***Share-based compensation***

We account for share-based compensation in accordance with ASC 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all share-based payments to employees and directors, including grants of incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units (together, stock awards), to be recognized as expense based on their grant date fair values. Our policy is to account for forfeitures as they occur.

We estimate the fair value of options granted using the Black-Scholes-Merton option pricing (Black-Scholes) model for stock option grants to both employees and non-employees. We will reconsider the use of the Black-Scholes model if additional information becomes available in the future that indicates another model would be more appropriate or if grants issued in future periods have characteristics that prevent their value from being reasonably estimated using this model.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions. Our methodology for developing the assumptions used in the valuation model are as follows:

*Fair Value of Common Stock*—See the subsection titled "Determination of the fair value of our common stock and fair value of total equity" below.

*Expected Dividend Yield*—The expected dividend yield is based on our historical and expected dividend payouts. We have historically paid no dividends and do not anticipate dividends to be paid in the future.

*Expected Equity Volatility*—Due to the lack of a public market for our common stock (prior to our IPO) and the lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us (e.g., public entities of similar size, complexity, stage of development and industry focus). The historical volatility is calculated based on a period of time commensurate with expected term assumption.

*Risk-Free Interest Rate*—The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options.

*Expected Term*—We use the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Our share-based compensation related to stock options subject to service conditions are recognized as expense ratably over the required service period based on their grant date fair values.

The fair value of restricted stock awards, unrestricted stock awards, and restricted stock units (collectively, awards), unless a market condition exists, is determined based on the fair value of our common stock on the grant date. Vesting of awards is accelerated for certain employees in the event of a change in control or in the event that we remove the employee with or without cause from their position.

We estimate the fair value of awards subject to both a market condition and a performance condition on the grant date using a Monte Carlo simulation model. For awards with vesting subject to the fulfillment of both market and performance conditions, share-based compensation expense is recognized using the accelerated attribution method beginning when the achievement of the performance condition becomes probable over the applicable service period. The amount of share-based compensation expense is dependent on our periodic assessment of the probability of the performance condition being satisfied and our estimate, which may vary over time, of the number of shares that will ultimately be issued. If the performance condition is not met, no compensation expense is recognized, and any previously recognized compensation cost is reversed.

We have granted restricted stock unit awards to our chief executive officer (CEO) which are subject to service, performance, and market conditions. For more information about these awards, see Note 13, Share Based Compensation - Restricted Stock Units - Chief Executive Officer. We used the Monte Carlo simulation model approach to estimate the fair value of such award on the date of grant. In applying the Monte Carlo methodology, the total equity value on various measurement dates were simulated and allocated to the various classes of equity in our capital structure according to the characteristics of that capital structure, such as the number of shares of each class of equity, seniority levels, liquidation preferences and conversion values for redeemable convertible preferred stock, and participation thresholds for common stock and each series of redeemable convertible preferred stock. The fair value of each such award is the average of the discounted proceeds to the common stock across all simulated paths.

Application of the Monte Carlo simulation model required various subjective assumptions that represent management's best estimates of the fair value of common stock, expected equity volatility, risk-free interest rate, discount period, expected dividend yield, and time to achievement of a performance condition:

*Fair Value of Common Stock and Fair Value of Total Equity*—See the subsection titled "Determination of the fair value of our common stock and fair value of total equity" below.

*Expected Equity Volatility*—Due to the lack of a public market for our common stock (prior to our IPO) and the lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us (e.g., public entities of similar size, complexity, stage of development, and industry focus). The historical volatility is calculated based on a period commensurate with the expected date of achievement of a performance condition.

*Risk-Free Interest Rate and Discount Period*—The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected time to achieve of a performance condition. The discount period is the period between the valuation date and the assumed change in control event date, with the assumption that all equity shares in the capital structure are paid out in cash.

*Expected Dividend Yield*—The expected dividend yield is based on our historical and expected dividend payouts. We have historically paid no dividends and does not anticipate dividends to be paid in the future.

*Expected Time to Achievement of a Performance Condition*—The time to the achievement of a performance condition is based on our best estimate of the period of time to achievement of a performance condition that attains the established market capitalization thresholds.

**Recent Accounting Pronouncements**

A description of recently issued and recently adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2024 and 2023, we had cash, cash equivalents and marketable securities of $625.7 million and $729.2 million, respectively, primarily invested in U.S. government agency securities and treasuries, certificate of deposit, corporate bonds, commercial paper and money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are primarily in short-term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. A 10% change in the interest rates in effect on December 31, 2024 would not have a material effect on the fair market value of our cash equivalents and available-for-sale securities.

**Item 8. Financial Statements and Supplementary Data.**

The information required by this Item 8 is included in Part IV, Item 15 of this Annual Report on Form 10-K and is incorporated herein by reference.

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

Not applicable.

**Item 9A. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the fiscal year on December 31, 2024, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act.

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal financial and accounting officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

***Management's Annual Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting 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 issuer; provide reasonable assurance that transactions are recorded as necessary for to permit preparation of our consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer'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.

Management conducted an evaluation of the effectiveness, as of December 31, 2024, of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

The effectiveness of our internal control over financial reporting has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting that occurred during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

**Securities Trading Plans of Directors and Executive Officers**

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

On January 8, 2025, Michelle Gilson, Chief Financial Officer, terminated a trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c), which was adopted as of December 18, 2023.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

We will file a definitive Proxy Statement for our 2025 Annual Meeting of Stockholders, or the Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the Proxy Statement that specifically address the items set forth herein are incorporated by reference.

### Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

***Code of Business Conduct and Ethics***

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the Governance Documents section of our website, which is located at www.arcellx.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

### Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

### Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

a) Financial Statements. The consolidated financial statements filed as part of this Annual Report on Form 10-K are listed in the Index to Financial Statements.

b) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or required, or the information required to be set forth therein is included in the consolidated financial statements or notes thereto included in the Index to Financial Statements of this Annual Report on Form 10-K.

c) Exhibits. The exhibits required to be filed as part of this Annual Report on Form 10-K are listed in the Exhibit List attached hereto and are incorporated herein by reference.

### Exhibit Index

| Exhibit | Description of Document | Filed Herewith | Incorporated by Reference | Form | Exhibit Number | Filing Date |
|---|---|---|---|---|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant, as amended, as currently in effect. | | X | S-1 | 3.2 | 1/14/2022 |
| 3.2 | Amended and Restated Bylaws of the Registrant, as currently in effect. | | X | S-1 | 3.4 | 1/14/2022 |
| 4.1 | Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated March 26, 2021. | | X | S-1 | 4.1 | 1/14/2022 |
| 4.2 | Specimen common stock certificate of the Registrant. | | X | S-1/A | 4.2 | 1/31/2022 |
| 4.3 | Description of Capital Stock. | X | | | | |
| 10.1† | Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers. | | X | S-1 | 10.1 | 1/14/2022 |
| 10.2† | 2017 Equity Incentive Plan, as amended, and forms of agreement thereunder. | | X | S-1 | 10.2 | 1/14/2022 |
| 10.3† | 2022 Equity Incentive Plan and forms of agreements thereunder. | | X | S-1/A | 10.3 | 1/31/2022 |
| 10.4† | 2022 Employee Stock Purchase Plan | | X | S-1/A | 10.4 | 1/31/2022 |
| 10.5† | Amended and Restated 2022 Employee Stock Purchase Plan. | | X | 10-Q | 10.1 | 11/14/2022 |
| 10.6† | Employee Incentive Compensation Plan. | | X | S-1 | 10.6 | 1/14/2022 |
| 10.7† | Outside Director Compensation Policy. | | X | S-1 | 10.12 | 1/14/2022 |
| 10.9† | Confirmatory Employment Letter between the Registrant and Rami Elghandour. | | X | S-1/A | 10.9 | 1/31/2022 |
| 10.10† | Confirmatory Employment Letter between the Registrant and Christopher Heery, M.D. | | X | S-1/A | 10.10 | 1/31/2022 |
| 10.11† | Confirmatory Employment Letter between the Registrant and Michelle Gilson. | | X | 8-K | 10.1 | 5/23/2022 |
| 10.12† | Change in Control and Severance Agreement between the Company and Michelle Gilson | | X | 8-K | 10.2 | 5/23/2022 |
| 10.13† | Amended and Restated Restricted Stock Unit Award Agreement between the Registrant and Rami Elghandour, dated December 7, 2021. | | X | S-1 | 10.13 | 1/14/2022 |
| 10.14† | Restricted Stock Unit Award Agreement between the Registrant and Rami Elghandour, dated January 31, 2023. | | X | 10-K | 10.16 | 3/29/2023 |
| 10.15† | Form of Executive Change in Control and Severance Agreement. | | X | S-1 | 10.5 | 1/14/2022 |
| 10.16^ | Master Services Agreement between the Registrant and Lonza Houston, Inc., dated September 2, 2021. | | X | 10-Q | 10.13 | 5/12/2022 |
| 10.17^ | Statement of Work A-1 between the Registrant and Lonza Houston, Inc. dated February 16, 2022. | | X | 10-Q | 10.14 | 5/12/2022 |
| 10.18^ | Collaboration and License Agreement between the Registrant and Gilead Sciences, Inc. | | X | 10-K | 10.22 | 3/29/2023 |
| 10.19 | Common Stock Purchase Agreement between the Registrant and Gilead Sciences, Inc. | | X | 10-K | 10.19 | 2/28/2024 |
| 10.20 | Amended and Restated Standstill Agreement between the Registrant and Gilead Sciences, Inc. | | X | 10-K | 10.20 | 2/28/2024 |

| Exhibit | Description of Document | Filed Herewith | Incorporated by Reference | Form | Exhibit Number | Filing Date |
|---|---|---|---|---|---|---|
| 10.21 | Amendment 1 to Statement of Work A-1 between Registrant and Lonza Houston, Inc. dated February 16, 2022 | | X | 10-Q | 10.1 | 11/3/2023 |
| 10.22^ | Amendment No. 1 Collaboration and License Agreement between the Registrant and Gilead Sciences, Inc. | | X | 10-K | 10.22 | 2/28/2024 |
| 16.1 | Letter from Ernst & Young LLP, dated March 14, 2024 | | X | 8-K | 16.1 | 3/14/2024 |
| 19.1 | Insider Trading Policy | X | | | | |
| 21.1 | List of Registrant's subsidiaries. | | X | 10-K | 21.1 | 2/28/2024 |
| 23.1 | Consent of Independent Registered Public Accounting Firm. | X | | | | |
| 23.2 | Consent of Independent Registered Public Accounting Firm. | X | | | | |
| 24.1 | Power of Attorney (see signature page to this Annual Report on Form 10-K). | X | | | | |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | | |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X | | | | |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | | |
| 32.2 | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | | |
| 97† | Arcellx, Inc. Clawback Policy | | X | 10-K | 97 | 2/28/2024 |
| 101.INS | Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. | X | | | | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | X | | | | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | X | | | | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | X | | | | |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | X | | | | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | X | | | | |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). | X | | | | |

† Indicates a management contract or any compensatory plan, contract or arrangement.
^ Portions of this exhibit have been omitted in accordance with Item 601 of Regulation S-K.
* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Arcellx, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

**Item 16. Form 10-K Summary**

None

## SIGNATURES

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

ARCELLX, INC.

Date: February 27, 2025

By: /s/ Rami Elghandour

**Rami Elghandour**
**Chief Executive Officer and Chairman**

## POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Rami Elghandour, Michelle Gilson and Maryam Abdul-Kareem, and each of them acting individually, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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

| Name | Title | Date |
|---|---|---|
| /s/ Rami Elghandour<br>**Rami Elghandour** | Chief Executive Officer and Chairman<br>*(Principal Executive Officer)* | February 27, 2025 |
| /s/ Michelle Gilson<br>**Michelle Gilson** | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | February 27, 2025 |
| /s/ Olivia Ware<br>**Olivia Ware** | Director | February 27, 2025 |
| /s/ Ali Behbahani, M.D.<br>**Ali Behbahani, M.D.** | Director | February 27, 2025 |
| /s/ Jill Carroll, M.S.<br>**Jill Carroll, M.S.** | Director | February 27, 2025 |
| /s/ David Lubner, M.S., C.P.A.<br>**David Lubner, M.S., C.P.A.** | Director | February 27, 2025 |
| /s/ Kavita Patel, M.D.<br>**Kavita Patel, M.D.** | Director | February 27, 2025 |
| /s/ Derek Yoon<br>**Derek Yoon** | Director | February 27, 2025 |

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**Audited Consolidated Financial Statements**

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Arcellx, Inc.

***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheet of Arcellx, Inc. and its subsidiary (the "Company") as of December 31, 2024, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for the year then ended, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

***Basis for Opinions***

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the consolidated financial statements 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 audit 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

***Definition and Limitations of Internal Control over Financial Reporting***

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Revenue Recognition – Kite Collaboration Agreement Third Party Contract Costs*

As described in Notes 2 and 8 to the consolidated financial statements, the Company's consolidated revenue was $107.9 million for the year ended December 31, 2024, all of which relates to the Kite Collaboration Agreement. Management uses a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost-based input method of revenue recognition, management measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

The principal considerations for our determination that performing procedures relating to the revenue recognition – Kite collaboration agreement third party contract costs is a critical audit matter is a high degree of auditor effort in performing procedures and evaluating audit evidence related to third-party contract costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the third-party contract costs. These procedures also included, among others, (i) testing the completeness and accuracy of a sample of third party contract costs incurred by tracing information to the underlying vendor contracts, purchase orders, and invoices, (ii) confirming information directly with a sample of external vendors such as key terms and actual costs, (iii) evaluating the reasonableness of the third party contract costs incurred for the services that have not been invoiced by examining vendor contracts to assess the completeness and accuracy of these costs, and (iv) recalculating revenue recognized based on third party contract costs.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 27, 2025

We have served as the Company's auditor since 2024.

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcellx, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Arcellx, Inc. (the Company) as of December 31, 2023, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

***Accounting for the Kite Collaboration Agreement***

*Description of the Matter*

As discussed in Note 8 to the consolidated financial statements, in January 2023 the Company closed on a Collaboration and License Agreement (the "Collaboration Agreement") with Kite Pharma Inc ("Kite") under which it identified one single combined performance obligation for development, manufacture, and commercialization licenses, research and development activities, manufacturing activities, and the transfer of manufacturing know-how. For the year ended December 31, 2023, revenue recognized from the Collaboration Agreement was $110.3 million.

Auditing the Company's accounting for the Collaboration Agreement was challenging because of the significant judgement in the determination of the distinct performance obligation.

| | |
|---|---|
| *How We Addressed the Matter in Our Audit* | To audit the Company's determination of the performance obligation in the Collaboration Agreement, we performed audit procedures that included, among others, inspecting the executed Collaboration Agreement and comparing the promised activities to those identified by the Company. In addition, we obtained representations from management and performed inquires of Company individuals from outside of the accounting department to corroborate the nature of the activities being performed by the Company under the Collaboration Agreement. We also inspected other Company prepared presentations and communications regarding the Collaboration Agreement to identify any potential contrary information. |

/s/ Ernst & Young LLP

We served as the Company's auditor from 2019 to 2024.

Tysons, Virginia
February 28, 2024, except for Note 17, as to which the date is
February 27, 2025

**ARCELLX, INC.**
**CONSOLIDATED BALANCE SHEETS**
***(in thousands, except share and per share amounts)***

| | 2024 | 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 105,679 | $ 394,583 |
| Marketable securities | 481,696 | 307,434 |
| Restricted cash, current | 208 | 1,903 |
| Prepaid expenses and other current assets | 11,727 | 12,443 |
| Total current assets | 599,310 | 716,363 |
| Restricted cash, non-current | 2,418 | 2,418 |
| Marketable securities, non-current | 38,277 | 27,168 |
| Property and equipment, net | 46,456 | 42,728 |
| Operating lease right-of-use assets | 23,789 | 27,099 |
| Prepaid research and development expenses and other long-term assets | 1,077 | 9,356 |
| **Total assets** | $ 711,327 | $ 825,132 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,095 | $ 2,619 |
| Accrued liabilities | 56,716 | 18,302 |
| Operating lease liabilities, current portion | 7,308 | 7,501 |
| Finance lease liabilities, current portion | 230 | 39,283 |
| Contract liability to related party | 59,056 | 50,533 |
| Total current liabilities | 125,405 | 118,238 |
| Operating lease liabilities, net of current portion | 46,542 | 50,841 |
| Contract liabilities, net of current portion to related party | 75,995 | 170,673 |
| Other non-current liabilities | 8,593 | — |
| **Total liabilities** | 256,535 | 339,752 |
| **Commitments and contingencies (Note 11)** | | |
| Stockholders' equity: | | |
| Common stock, par value of $0.001 per share; 1,000,000,000 shares authorized and 54,293,597 shares issued and outstanding as of December 31, 2024; 1,000,000,000 shares authorized and 52,280,077 shares issued and outstanding as of December 31, 2023 | 53 | 52 |
| Additional paid-in capital | 950,719 | 874,261 |
| Accumulated other comprehensive income | 848 | 547 |
| Accumulated deficit | (496,828) | (389,480) |
| Total stockholders' equity | 454,792 | 485,380 |
| **Total liabilities and stockholders' equity** | $ 711,327 | $ 825,132 |

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

**ARCELLX, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
***(in thousands, except share and per share amounts)***

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2024** | **2023** | **2022** |
| **Collaboration revenue from related party** | $ 107,936 | $ 110,319 | $ — |
| **Operating expenses:** | | | |
| Research and development | 157,093 | 133,849 | 149,555 |
| General and administrative | 88,414 | 66,350 | 41,704 |
| Total operating expenses | 245,507 | 200,199 | 191,259 |
| Loss from operations | (137,571) | (89,880) | (191,259) |
| Other income (expense): | | | |
| Interest and other income (expense) | 33,322 | 23,695 | 4,300 |
| Interest expense | (1,030) | (3,842) | (1,720) |
| Total other income, net | 32,292 | 19,853 | 2,580 |
| Loss before income taxes | (105,279) | (70,027) | (188,679) |
| Income tax expense | (2,069) | (663) | — |
| Net loss | (107,348) | (70,690) | (188,679) |
| **Other comprehensive loss:** | | | |
| Unrealized gain (loss) on marketable securities | 301 | 768 | (201) |
| Comprehensive loss | $ (107,047) | $ (69,922) | $ (188,880) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (2.00) | $ (1.47) | $ (5.19) |
| Weighted-average common shares outstanding—basic and diluted | 53,566,153 | 48,061,450 | 36,355,758 |

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

**ARCELLX, INC.**
**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
***(in thousands)***

| | Redeemable Convertible Preferred Stock | | | | | | Stockholders' Equity (Deficit) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series B | | Series C | | Common Stock | | | | | |
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Stockholders' Equity (Deficit) |
| Balance as of December 31, 2021 | 5,413,272 | $ 28,894 | 8,975,585 | $ 85,367 | 10,396,707 | $ 119,118 | 544,210 | $ 1 | $ 8,615 | $ (130,111) | $ (20) | $ (121,515) |
| Issuance of common stock (initial public offering), net of transaction costs of $15,029 | — | — | — | — | — | — | 9,487,500 | 9 | 127,274 | — | — | 127,283 |
| Issuance of common stock (private placement), net of transaction costs of $42 | — | — | — | — | — | — | 590,318 | 1 | 9,957 | — | — | 9,958 |
| Issuance of common stock (follow-on offering), net of transaction costs of $8,081 | — | — | — | — | — | — | 8,050,000 | 8 | 120,711 | — | — | 120,719 |
| Issuance of common stock from early exercise of restricted stock | — | — | — | — | — | — | 42,709 | — | 122 | — | — | 122 |
| Conversion of preferred stock to common stock | (5,413,272) | (28,894) | (8,975,585) | (85,367) | (10,396,707) | (119,118) | 24,785,564 | 25 | 233,354 | — | — | 233,379 |
| Exercise of stock options | — | — | — | — | — | — | 605,680 | — | 2,344 | — | — | 2,344 |
| Share-based compensation | — | — | — | — | — | — | — | — | 21,544 | — | — | 21,544 |
| Unrealized loss on marketable securities | — | — | — | — | — | — | — | — | — | — | (201) | (201) |
| Net loss | — | — | — | — | — | — | — | — | — | (188,679) | — | (188,679) |
| Balance as of December 31, 2022 | — | — | — | — | — | — | 44,105,981 | 44 | 523,921 | (318,790) | (221) | 204,954 |
| Issuance of common stock to related party | — | — | — | — | — | — | 6,720,803 | 7 | 299,699 | — | — | 299,706 |
| Issuance of common stock from vesting of restricted stock | — | — | — | — | — | — | 295,496 | — | — | — | — | — |
| Exercise of stock options | — | — | — | — | — | — | 1,114,015 | 1 | 7,762 | — | — | 7,763 |
| Issuance of common stock pursuant to employee stock purchase plan | — | — | — | — | — | — | 43,782 | — | 1,090 | — | — | 1,090 |
| Share-based compensation | — | — | — | — | — | — | — | — | 41,789 | — | — | 41,789 |
| Unrealized gain on marketable securities | — | — | — | — | — | — | — | — | — | — | 768 | 768 |
| Net loss | — | — | — | — | — | — | — | — | — | (70,690) | — | (70,690) |
| Balance as of December 31, 2023 | — | — | — | — | — | — | 52,280,077 | 52 | 874,261 | (389,480) | 547 | 485,380 |
| Issuance of common stock from vesting of restricted stock | — | — | — | — | — | — | 528,711 | — | — | — | — | — |
| Exercise of stock options | — | — | — | — | — | — | 1,457,826 | 1 | 14,208 | — | — | 14,209 |
| Issuance of common stock pursuant to employee stock purchase plan | — | — | — | — | — | — | 26,983 | — | 1,164 | — | — | 1,164 |
| Share-based compensation | — | — | — | — | — | — | — | — | 61,086 | — | — | 61,086 |
| Unrealized gain on marketable securities | — | — | — | — | — | — | — | — | — | — | 301 | 301 |
| Net loss | — | — | — | — | — | — | — | — | — | (107,348) | — | (107,348) |
| Balance as of December 31, 2024 | — | $ — | — | $ — | — | $ — | 54,293,597 | $ 53 | $ 950,719 | $ (496,828) | $ 848 | $ 454,792 |

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

**ARCELLX, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
***(in thousands)***

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2024** | **2023** | **2022** |
| **Cash flows from operating activities** | | | |
| Net loss | $ (107,348) | $ (70,690) | $ (188,679) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 5,188 | 2,040 | 1,321 |
| Loss on disposal of property and equipment | (260) | 174 | 3 |
| Noncash operating lease expense | 3,310 | 1,010 | 903 |
| Right-of-use asset expensed | 794 | 18,871 | 63,278 |
| Amortization of premiums and discounts on marketable securities | (15,459) | (11,048) | (2,125) |
| Share-based compensation | 61,086 | 41,789 | 21,544 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current and non-current assets | 8,611 | (8,359) | (5,695) |
| Accounts payable and other current liabilities | (70) | (6,474) | 7,419 |
| Accrued liabilities | 42,009 | 5,593 | (395) |
| Operating lease liabilities | (3,767) | 13,461 | 3,123 |
| Contract liability to related party | (86,154) | 221,206 | — |
| Other non-current liabilities | 8,593 | — | — |
| Net cash provided by (used in) operating activities | (83,467) | 207,573 | (99,303) |
| **Cash flows from investing activities** | | | |
| Purchases of property and equipment | (13,434) | (21,428) | (2,277) |
| Purchases of marketable securities | (597,311) | (442,429) | (273,737) |
| Proceeds from maturities of marketable securities | 427,700 | 309,345 | 158,340 |
| Net cash used in investing activities | (183,045) | (154,512) | (117,674) |
| **Cash flows from financing activities** | | | |
| Proceeds from issuance of common stock (initial public offering), net of transactions costs | — | — | 129,156 |
| Proceeds from issuance of common stock in private placement, net of transactions costs ($-, $299,706 and $- from a related party) | — | 299,706 | 9,958 |
| Proceeds from issuance of common stock (follow-on offering), net of transactions costs | — | — | 120,719 |
| Proceeds from exercise of stock options and early exercise of restricted stock | 14,595 | 7,758 | 2,467 |
| Proceeds from issuance of common stock under the employee stock purchase plan | 1,164 | 1,091 | — |
| Payments under finance leases | (39,846) | (29,392) | (9,675) |
| Net cash provided by (used in) financing activities | (24,087) | 279,163 | 252,625 |
| Net increase (decrease) in cash and cash equivalents and restricted cash | (290,599) | 332,224 | 35,648 |
| Cash and cash equivalents and restricted cash, beginning of the year | 398,904 | 66,680 | 31,032 |
| Cash and cash equivalents and restricted cash, end of the period | $ 108,305 | $ 398,904 | $ 66,680 |
| **Supplemental disclosures of cash flow information:** | | | |
| Cash paid for income taxes | $ 1,635 | $ 212 | $ — |
| **Supplemental disclosures of noncash investing and financing activities:** | | | |
| Purchase of property and equipment included in accounts payable and accrued liabilities | $ 325 | $ 1,841 | $ 770 |

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

**ARCELLX, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Nature of the Business

### *Organization*

Arcellx, Inc. (Arcellx or the Company) was incorporated in Delaware in December 2014 and is headquartered in Redwood City, California. The Company is a clinical-stage biopharmaceutical company reimagining cell therapy through the development of innovative therapies for patients with cancer and other incurable diseases.

### *Public Offerings*

On February 8, 2022, the Company closed its initial public offering of 9,487,500 shares of its common stock, including the exercise in full by the underwriters of their option to purchase 1,237,500 additional shares of its common stock, at a public offering price of $15.00 per share. The Company received net proceeds of $127.3 million, after deducting underwriting discounts and commissions of and other offering expenses paid by the Company of approximately $15.0 million.

On June 21, 2022, the Company closed a follow-on public offering of 8,050,000 shares of its common stock, including the exercise in full by the underwriters of their option to purchase 1,050,000 additional shares of its common stock, at a public offering price of $16.00 per share. The Company received net proceeds of $120.7 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company of approximately $8.1 million.

### *Liquidity*

The Company has not commercialized any of its drug candidates and planned commercial operations have not commenced. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future as it continues development of drug candidates, including preclinical and clinical testing and regulatory approval prior to commercialization. The Company has not generated any revenue to date from product sales and does not expect to generate any revenues from product sales in the foreseeable future. The Company plans to seek additional funding through public or private equity offerings or debt financings. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects.

The Company has incurred significant operating losses since inception and has an accumulated deficit of $496.8 million as of December 31, 2024. The Company has relied on its ability to fund its operations through private and public equity financings, and its recent collaboration and license agreement with Kite Pharma, Inc. (Kite), a Gilead Sciences, Inc. (Gilead) company. In January 2023, the Company received in the aggregate $325.0 million in cash which consisted of $100.0 million related to a private placement from the sale of the Company's common stock to Gilead and a $225.0 million non-refundable, upfront payment related to the closing of its Collaboration and License Agreement (Kite Collaboration Agreement) with Kite. In December 2023, the Company received in the aggregate $285.0 million in cash which consisted of $200.0 million related to a private placement from the sale of the Company's common stock to Gilead and a $85.0 million non-refundable, upfront payment related to the closing of its amendment to the Kite Collaboration Agreement with Kite. See Note 8, Collaboration Agreement.

As of December 31, 2024, the Company had $625.7 million of cash, cash equivalents and marketable securities, which management believes will be sufficient to meet the Company's anticipated operating and capital expenditure requirements for at least twelve months following the date of issuance of these financial statements.

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation and Consolidation*

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). The accompanying consolidated financial statements include the accounts of Arcellx, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

***Use of Accounting Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates used in preparing the accompanying consolidated financial statements include, but are not limited to, estimates related to the fair value of assets, collaboration revenue, research and development accruals, and share-based compensation. Although actual results could differ from those estimates, management does not believe that such differences would be material.

***Cash and Cash Equivalents and Restricted Cash***

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in checking and sweep accounts with commercial banks and financial institutions in amounts exceeding FDIC insurance limits. Cash equivalents consist of money market funds.

The Company is required to maintain cash collateral on deposit in segregated money market bank accounts and certificate of deposit accounts as a condition of its lease agreements on its properties, equal to the required security deposit amounts. These amounts are presented as restricted cash, current and non-current on the accompanying consolidated balance sheets.

The following table reconciles cash and cash equivalents and restricted cash per the balance sheets to the statements of cash flows (in thousands):

| | December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Cash and cash equivalents | $ 105,679 | $ 394,583 |
| Restricted cash, current | 208 | 1,903 |
| Restricted cash, non-current | 2,418 | 2,418 |
| Total | $ 108,305 | $ 398,904 |

***Marketable Securities***

The Company carries marketable securities classified as available-for-sale at fair value as determined by prices for identical or similar securities at the balance sheet date. The inputs used to determine the fair value of marketable securities are considered Level 2 within the fair-value hierarchy. The Company records unrealized gains and losses as a component of other comprehensive loss within the statements of operations and comprehensive loss and as accumulated other comprehensive loss in stockholders' equity. Realized gains or losses on available-for-sale securities are determined using the specific identification method and the Company includes net realized gains and losses in other income, net. Marketable securities are classified as either current or non-current assets based on their contractual maturity dates.

For securities available for sale, ASU 2016-13 eliminates the concept of other-than-temporary impairment and instead requires entities to determine if impairment is related to credit loss or non-credit loss. In making the assessment of whether a loss is from credit or other factors, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency and adverse conditions related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows is less than the amortized cost basis, a credit loss exists and an allowance is created, limited by the amount that the fair value is less than the amortized cost basis. Subsequent activity related to the credit loss component in the form of write-offs or recoveries is recognized as part of the allowance for credit losses on securities available for sale. The Company has made the accounting policy election to exclude accrued interest receivable on securities from the estimate of credit losses.

***Fair Value of Financial Instruments***

The Company's financial instruments consist of cash and cash equivalents, restricted cash, marketable securities, accounts payable, and accrued expenses. The carrying amounts of accounts payable and accrued expenses generally approximate their respective fair value due to their short-term nature.

The Company accounts for recurring and non-recurring fair value measurements in accordance with ASC 820, *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1—Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2—Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

Level 3—Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity—e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

***Concentration of Credit Risk***

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents, restricted cash, and marketable securities. The Company maintains its cash and cash equivalents and restricted cash at an accredited financial institution in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company invests in highly rated debt securities consisting entirely of corporate and government bonds, which the Company has the ability to liquidate within one-day should the need for additional cash arise. Accordingly, the Company believes the exposure to credit risk on its marketable securities portfolio is low.

***Property and Equipment, Net***

Property and equipment are recorded at cost and depreciated over its estimated useful life using the straight-line method. Upon retirement or disposal, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is recognized within operating expenses. Routine expenditures for maintenance and repairs are expensed as incurred.

Estimated useful lives for property and equipment are as follows:

| | **Estimated Useful Life** |
|---|---|
| Computer equipment | 3 years |
| Furniture and fixtures | 7 years |
| Lab equipment | 7 years |
| Leasehold improvements | Lesser of estimated useful life or remaining lease term |
| Equipment under finance lease | Lesser of estimated useful life or remaining lease term |

***Impairment of Long-Lived Assets***

The Company reviews the recoverability of its long-lived asset group when events or changes in circumstances occur that indicate that the carrying value of the asset group may not be recoverable. Recoverability of the long-lived asset group is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset group. If these cash flows are less than the carrying value of such asset group, the Company then determines the fair value of the underlying asset group. Any impairment loss to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the estimated fair value of the asset group.

***Collaborative Arrangements and Contracts with Customers***

The Company assesses whether its collaboration agreements are subject to Accounting Standards Codification (ASC) Topic 808, Collaborative Arrangements (ASC 808) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards that depend on the commercial success of the joint operating activities. To the extent that the arrangement falls within the scope of ASC 808, the Company applies the unit of account guidance under ASC Topic 606, Revenue from Contracts with Customers (ASC 606), to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If the Company determines whether a promised good or service within the arrangement is with a customer, it applies the guidance in ASC 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of ASC 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

The Company recognizes revenue when its customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on their estimated standalone selling prices. 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 performance obligations satisfied over time, the Company determines the appropriate measure of progress. The effect of any change made to the measure of progress and, therefore a change to revenue, would be recorded as a change in estimate.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimate of variable consideration included in the transaction price and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

The Company uses a cost based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations. The Company uses the expected value method and most-likely-amount method to estimate variable consideration and will re-evaluate the transaction price in each reporting period, as uncertain events are resolved or other changes in circumstances occur.

The Company's collaborative arrangements can have one or more of the following forms of consideration: (i) license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) fees attributable to options to intellectual property; (v) cost-sharing or research and development (R&D) funding arrangements and (vi) profit and loss sharing. When a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied. The Company classifies contract liabilities as current when it expects to satisfy its performance obligations within one year, and noncurrent when the Company expects to satisfy those performance obligations in greater than one year. Fees attributable to options are deferred until the option expires or is exercised. Changes to collaboration agreements are assessed for whether they represent a modification or should be accounted for as a new contract.

*Upfront Payments and License Fees*

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront 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 judgment 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. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Cost-sharing*

Under certain collaborative arrangements, the Company can be reimbursed for a portion of its research and development expenses or reimburse its collaboration partner for its research and development expenses. The Company estimates reimbursements to be received by a collaboration partner and reimbursements to be paid or payable to a collaboration partner as part of variable consideration. When these research and development services are paid to a collaboration partner, the Company reduces its contract liability.

*Customer Options*

Customer options, such as options granted to allow a licensee to extend a license or research term, to select additional research targets or to choose to research, develop and commercialize licensed compounds are evaluated at contract inception to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price. As a practical alternative to estimating the standalone selling price of a material right when the underlying goods or services are both (i) similar to the original goods or services in the contract and (ii) provided in accordance with the terms of the original contract, the Company allocates the total amount of consideration expected to be received from the customer to the total goods or services expected to be provided to the customer. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

*Milestone Payments*

At the inception of the arrangement, the Company evaluates whether the development or sales-based milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated value is included in the transaction price. Milestone payments that are not within the control of the Company or the Company's collaboration partner, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development or sales-based milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues in the period of adjustment.

For milestone revenues related to sales-based achievements, the Company recognizes the milestone revenues in the corresponding period of the product sale, in accordance with the guidance of ASC 606-10-55-65 for contracts that include a license to intellectual property and the license is the predominant item to which the product sale relates.

*Royalties*

For arrangements that include sales-based royalties, 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 collaborative arrangement.

***Leases***

The Company leases office and laboratory space and equipment. In addition, the Company enters into manufacturing supply agreements with CMOs and CDMOs to manufacture clinical product candidate materials. Such agreements may include an embedded lease due to the exclusive use of identified manufacturing facilities and equipment that are controlled by the Company and for which the Company obtains substantially all the output. The evaluation of leases that are embedded in the Company's CMO and CDMO agreements is complex and requires judgment. If a lease arrangement is determined to exist with a lease term of more than 12 months at the lease commencement date, an ROU asset and corresponding lease liability are recorded on the consolidated balance sheet at the lease commencement date based on the present value of fixed lease payments over the lease term. The lease commencement date, defined as the date on which the lessor makes the underlying asset available for use by the lessee and the date from which the Company is required to recognize lease expenses, may be different from the inception date of the contract.

An ROU asset represents the right to control the use of an identified asset over the lease term and a lease liability represents the obligation to make lease payments arising from the lease. The Company uses the discount rate implicit in the lease, if available, or its incremental borrowing rate on the lease commencement date to determine the present value of lease payments. The lease terms used to calculate the ROU assets and related lease liabilities include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company expenses ROU assets acquired for research and development activities under ASC Topic 730, Research and Development, if they do not have alternative future use, in research and development projects or otherwise.

Leases are classified as either operating or finance leases based on the economic substance of the agreement. For operating leases, the Company recognizes lease expense related to fixed payments on a straight-line basis over the lease term. For finance leases, the Company recognizes the amortization of the ROU asset over the shorter of the lease term or useful life of the underlying asset. Interest accretion on the finance lease liabilities is recorded as interest expense. For both operating and finance leases, lease expense related to variable payments is recognized as incurred based on performance or usage in accordance with the contractual agreements. For short-term lease arrangements with a term of one year or less, the Company has elected to recognize the related lease payments on a straight-line basis over the lease term without recording related ROU assets and lease liabilities.

The Company evaluates changes to the terms and conditions of a lease contract to determine if they result in a new lease or a modification of an existing lease. For lease modifications, the Company remeasures and reallocates the remaining consideration in the contract and reassesses the lease classification at the effective date of the modification.

The Company uses significant assumptions and judgment in evaluating its lease contracts and other agreements, including the determination of whether an agreement is or contains a lease, whether a change in the terms and conditions of a lease contract represent a new or modified lease, whether a lease represents an operating or finance lease, the discount rate used to determine the present value of lease obligations, and the term of a lease embedded in its manufacturing supply agreements.

***Research and Development Expenses***

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical manufacturing, technical development, and overhead and facility-related costs.

The Company makes payments in connection with clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price, or on a time and materials basis. A portion of the obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient trials, and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. Similarly, the Company accrues expenses related to the work performed by contract manufacturing organizations based on the progress of the work performed. If the amounts the Company is obligated to pay under clinical trial agreements and manufacturing agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

The Company may be obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and included in prepaid expenses and other current assets or other non-current assets in the consolidated balance sheets. Such amounts are recognized as expense as the related goods are delivered or the related services are performed, or at such time when the Company does not expect the goods to be delivered or services to be performed.

***Share-Based Compensation***

The Company accounts for its share-based compensation in accordance with ASC 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all share-based payments to employees and directors, including grants of incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards, or restricted stock units, to be recognized as expense based on their grant date fair values. The determination of grant date fair value may require the Company to make assumptions as further discussed below. Changes in the assumptions can materially affect the fair value and ultimately how much share-based compensation expense is recognized. These assumptions are subjective and generally require significant analysis and judgment to develop.

*Stock Options*

The Company's determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model, and is impacted by the Company's common stock price as well as other variables including, but not limited to, the expected term that options will remain outstanding, expected common stock price volatility over the expected term of the option awards, risk-free interest rates and expected dividends.

The fair value of a stock-based award is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense is recognized based on the fair value determined on the date of grant and is reduced for forfeitures as they occur.

Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables as follows:

Expected Term — The Company uses the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years). The Company uses the simplified method as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term that options will remain outstanding.

Expected Volatility — Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. treasury yield in effect at the time of grant for instruments with maturities similar to the expected term of the Company's stock options.

Expected Dividend — The Company has not issued any dividends in its history and does not expect to issue dividends over the life of the options and therefore has estimated the dividend yield to be zero.

*Restricted Stock Awards, Unrestricted Stock Awards, and Restricted Stock Units*

The fair value of restricted stock awards, unrestricted stock awards, and restricted stock units (collectively, awards), unless a market condition exists, is determined based on the fair value of our common stock on the grant date. Vesting of awards is accelerated for certain employees in the event of a change in control or in the event that we remove the employee with or without cause from their position.

The Company estimates the fair value of awards subject to both a market condition and a performance condition on the grant date using a *Monte Carlo* simulation model. For awards with vesting subject to the fulfillment of both market and performance conditions, share-based compensation expense is recognized using the accelerated attribution method beginning when the achievement of the performance condition becomes probable over the applicable service period. The amount of share-based compensation expense is dependent on our periodic assessment of the probability of the performance condition being satisfied and our estimate, which may vary over time, of the number of shares that will ultimately be issued. If the performance condition is not met, no compensation expense is recognized, and any previously recognized compensation cost is reversed.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is not more-likely-than-not that the deferred tax assets will be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. Because of the uncertainty of the realization of deferred tax assets, the Company has recorded a valuation allowance against its net deferred tax assets.

Liabilities are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes. As of December 31, 2024 and 2023, the Company had no interest or penalties related to uncertain income tax positions.

***Segment and Geographic Information***

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

***Recently Adopted Accounting Pronouncements***

In November 2023, the FASB issued ASU No.2023-07 ″Improvements to Reportable Segment Disclosures" which requires an enhanced disclosure of significant segment expenses on an annual and interim basis. This guidance will be effective for the annual periods beginning the year ended December 31, 2024, and for interim periods beginning January 1, 2025. Upon adoption, the guidance should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted ASU No.2023-07 effective December 31, 2024. Refer to Note 17, Segment Reporting for the inclusion of the new required disclosures.

***Recently Issued Accounting Pronouncements***

In December 2023, the FASB issued ASU No.2023-09 ″Improvements to Income Tax Disclosures" which requires incremental annual disclosures around income tax rate reconciliation, income taxes paid and other related disclosures. This guidance requires prospective application and permits retrospective application to prior periods presented. The Company plans to adopt it beginning with its 2025 annual report to be filed in early 2026. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03 "Disaggregation of Income Statement Expenses (DISE)" which requires disaggregated information about certain income statement expense line items on an annual and interim basis. This guidance will be effective for annual periods beginning the year ended December 31, 2027 and for interim periods thereafter. The new standard permits early adoption and can be applied prospective or retrospectively. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements.

## 3. Fair Value of Financial Instruments

The fair value of the Company's financial assets by level within the fair value hierarchy were as follows (in thousands):

| | December 31, 2024 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| Money market fund (cash equivalent) | $ 104,579 | $ — | $ — |
| Money market fund (short-term restricted cash) | 208 | — | — |
| Certificate of deposit (long-term restricted cash) | — | 2,418 | — |
| Marketable securities: | | | |
| Government agency | — | 519,973 | — |
| Total assets measured at fair value | $ 104,787 | $ 522,391 | $ — |

| | December 31, 2023 | | |
|---|---|---|---|
| | Level 1 | Level 2 | Level 3 |
| Money market fund (cash equivalent) | $ 393,096 | $ — | $ — |
| Money market fund (short-term restricted cash) | 1,903 | — | — |
| Certificate of deposit (long-term restricted cash) | — | 2,418 | — |
| Marketable securities: | | | |
| Commercial paper | — | 26,737 | — |
| Corporate debt | — | 5,982 | — |
| Government agency | — | 301,884 | — |
| Total assets measured at fair value | $ 394,999 | $ 337,020 | $ — |

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the years ended December 31, 2024 or 2023.

## 4. Marketable Securities

Available-for-sale marketable securities were as follows (in thousands):

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Government agency | 519,125 | 1,007 | (159) | 519,973 |
| Total | $ 519,125 | $ 1,007 | $ (159) | $ 519,973 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Commercial paper | $ 26,752 | $ — | $ (15) | $ 26,737 |
| Corporate debt | 5,988 | — | (7) | 5,982 |
| Government agency | 301,315 | 584 | (16) | 301,884 |
| Total | $ 334,056 | $ 584 | $ (38) | $ 334,602 |

The fair value of available-for-sale marketable securities by contractual maturity as of December 31, 2024 and 2023 were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Due in 1 year or less | $ 481,696 | $ 307,434 |
| Due in 1 - 2 years | 38,277 | 27,168 |
| Total | $ 519,973 | $ 334,602 |

The Company had 9 securities in an unrealized loss position with an aggregate related fair value of $108.4 million as of December 31, 2024. The Company had 8 securities in an unrealized loss position with an aggregate related fair value of $61.5 million as of December 31, 2023. All securities in an unrealized loss position as of December 31, 2024 and 2023 had been in a loss position for less than twelve months. Unrealized losses on available-for-sale marketable securities as of December 31, 2024 and 2023 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no allowance for credit losses related to the Company's available-for-sale marketable securities was recorded for the years ended December 31, 2024 and 2023. The Company does not intend to sell these securities and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

As of December 31, 2024 and 2023, the Company recognized $2.5 million and $1.4 million, respectively, of accrued interest receivable from available-for-sale securities within prepaid expenses and other current assets on the consolidated balance sheets.

**5. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Prepaid research and development costs | $ 5,882 | $ 6,764 |
| Other prepaid expense and current assets | 5,845 | 5,679 |
| Total prepaid expenses and other current assets | $ 11,727 | $ 12,443 |

**6. Property and Equipment, Net**

Property and equipment consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Lab equipment | $ 16,033 | $ 11,502 |
| Leasehold improvements | 38,373 | 27,153 |
| Lab equipment under finance leases | 230 | 714 |
| Computer equipment | 906 | 661 |
| Furniture and fixtures | 158 | 159 |
| Construction in progress | 200 | 7,792 |
| Property and equipment, gross | 55,900 | 47,981 |
| Less: accumulated depreciation and amortization | (9,444) | (5,253) |
| Property and equipment, net | $ 46,456 | $ 42,728 |

Depreciation and amortization expense was $5.2 million, $2.0 million and $1.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

**7. Related Parties**

*Relationship and transactions with Gilead Sciences, Inc. (Gilead)*

As of December 31, 2024, Gilead Sciences, Inc. (Gilead) held approximately 13% of the Company's outstanding common stock. These holdings resulted from Gilead's investment in the Company of: (i) $100.0 million, by purchasing 3,478,261 shares of common stock at a per share price of $28.75 pursuant to a Common Stock Purchase Agreement with Gilead (Gilead SPA); and (ii) $200.0 million, by purchasing 3,242,542 shares of common stock at a per share price of $61.68 pursuant to a second Common Stock Purchase Agreement with Gilead (Second Gilead SPA). See Note 8 for further discussion of the agreements with Gilead.

The Company partnered anito-cel with Kite Pharma, Inc., a Gilead company (Kite), through its co-development/co-commercialization collaboration agreement, as described in more detail in Note 8 Collaboration Agreement.

As of December 31, 2024, the Company had $135.1 million in contract liability pursuant to the Collaboration and License Agreement with Kite (Kite Collaboration Agreement) and its amendment, of which $76.0 million represented the long-term portion of contract liability. For the year ended December 31, 2024, the Company recognized $107.9 million in revenue under the Kite Collaboration Agreement and its amendment. See Note 8, Collaboration Agreement, for further discussion of the Kite Collaboration Agreement.

**8. Collaboration Agreement**

In December 2022, the Company entered into the Kite Collaboration Agreement, the Gilead SPA and a standstill and stock restriction agreement with Gilead (the Standstill Agreement). Upon closing in January 2023, Kite made an upfront payment of $225.0 million and obtained a license to co-develop and co-commercialize anito-cel, and next-generation autologous and non-autologous CAR-T cell therapy products that use the same D-domain BCMA binder used in anito-cel, in each case for the treatment of multiple myeloma. The Company also granted Kite the ability to negotiate a development and commercialization license for the inclusion of a limited number of pre-specified additional autologous CAR-T-cell therapy products for the treatment of multiple myeloma, which can be exercised by Kite after the Company provides to Kite a phase 1 clinical study report. Gilead made an equity investment of $100.0 million by purchasing 3,478,261 shares of Arcellx common stock at a fixed per share price of $28.75 pursuant to the Gilead SPA, which represented a $15.3 million discount on the sale of the Company's common stock based on the share price on the date of closing.

In November 2023, the Company entered into an amendment to its Kite Collaboration Agreement, the Second Gilead SPA and an amended and restated standstill and stock restriction agreement with Gilead (the Amended Standstill Agreement). Upon closing in December 2023, Kite commenced negotiation of a license for the Company's ARC-SparX program, ACLX-001, in multiple myeloma. The Company and Kite have also expanded the scope of the collaboration for the Company's anito-cel to include lymphomas, which is subject to further negotiation by both parties in order to be developed and is therefore not a performance obligation either at contract inception or at December 31, 2024. In connection with the amendment to the Kite Collaboration Agreement, the Company received a $85.0 million upfront cash payment and are eligible for additional potential milestone payments. Gilead made an equity investment of $200.0 million by purchasing 3,242,542 shares of Arcellx common stock at a fixed per share price of $61.68 pursuant to the Second Gilead SPA, which represented a $15.6 million premium on the sale of the Company's common stock based on the share price on the date of closing.

Under the Kite Collaboration Agreement and its amendment, the Company will be eligible to receive additional clinical, regulatory, and commercial milestone payments of up to $530.0 million, $935.0 million and $507.5 million, for anito-cel, each next-generation autologous CAR-T cell therapy product, and each non-autologous CAR-T cell therapy product, respectively. During the year ended December 31, 2024, the Company achieved a clinical milestone for anito-cel relating to enrollment in the iMMagine-1 trial and received $68.3 million from Kite.

In the United States, the Company and Kite will equally share profits and losses from the commercialization of anito-cel and any next-generation autologous CAR-T cell therapy product for which the Company has exercised its option to co-promote with Kite (collectively, the Co-Promote Products). The Company has the option to designate next-generation autologous CAR-T therapy product as a Co-Promote Product after Kite provides the first phase 1 clinical study report for such product with the proposed core development plan and budget. For Co-Promote Products outside of the United States and for any other products worldwide that are not a Co-Promote Product (Non-Co-Promote Products), including any next-generation autologous CAR-T cell therapy product for which the company has opted out of designating as a Co-Promote Product, the Company will be eligible for tiered royalties in the low to mid teen percentages. The Company and Kite will jointly develop the Co-Promote Products in accordance with mutually agreed development plans and development budgets. On a Co-Promote Product-by-Co-Promote Product basis, the Company may, upon advance written notice to Kite, opt out of sharing development costs and profits and losses from the commercialization of such Co-Promote Product (for example, anito-cel), in which case, it will become a Non-Co-Promote Product and eligible for tiered royalties in the low to mid teen percentages.

Other than certain items expressly set forth in the Kite Collaboration Agreement and its amendment, the out-of-pocket development costs for activities conducted in the United States for Co-Promote Products will be shared equally by the Company and Kite. The out-of-pocket development costs for activities conducted outside the United States as part of a global clinical trial for Co-Promote Products will be borne 60% by Kite and 40% by the Company, however Kite will be solely responsible for its costs for country-specific clinical trials and chemistry, manufacturing and control (CMC) commercial readiness. Kite will be solely responsible for the conduct of development and commercialization of the Non-Co-Promote Products at its sole cost. In the United States, the Company and Kite will be jointly responsible for commercialization of the Co-Promote Products. Kite will manufacture the licensed products and bear the CMC commercial readiness costs and capital expenses, except that the Company is responsible for manufacturing anito-cel prior to transferring the manufacturing process to Kite and the parties share associated out-of-pocket costs. Reimbursement costs expected to be received from Kite or paid to Kite represent variable consideration and are included in the estimated transaction price.

The Company's promises under the Kite Collaboration Agreement include development, manufacture, and commercialization licenses, research and development activities, manufacturing activities, and the transfer of manufacturing know-how to Kite (collectively, the research and development services). These promises represent a single combined performance obligation as the promises are not distinct from each other. The Company determined that the license and research and development services are combined based on the specialized nature of the Company's know-how and manufacturing process.

The Company evaluated the amendment to the Kite Collaboration Agreement and determined that the contract modifications should be accounted for as changes to the original contract, as the services to be provided after the contract modification are not distinct from those services already provided.

The Company uses a cost based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations. The Company uses the expected value method and most-likely-amount method to estimate variable consideration and will re-evaluate the transaction price in each reporting period, as uncertain events are resolved or other changes in circumstances occur.

During the year ended December 31, 2024, no revenue was recognized from performance obligations satisfied in previous periods. As of December 31, 2024, the amount of the transaction price that has not been recognized as revenue was $50.2 million, which may be recognized as revenue over the period of time the Company is performing the research and development activities.

As of December 31, 2024, the balances in contract liability were as follows (in thousands):

| **Contract liability** | **December 31, 2024** |
|---|---|
| Beginning balance at January 1, 2024 | $ 221,206 |
| Cash received, net | 65,640 |
| Less: Revenue recognized | (107,936) |
| Reclass to other liabilities | (43,859) |
| Ending balance at December 31, 2024 | 135,051 |
| Less: current portion | 59,056 |
| Noncurrent portion | $ 75,995 |

**9. Leases**

***Operating Leases***

In July 2022, the Company entered into an operating lease agreement for 57,902 square feet of office and laboratory space in Rockville, Maryland for a term of approximately 12.9 years. The lease contains annual rent escalation and rent abatement clauses as well as an allowance of approximately $12.1 million for tenant improvements. During the year ended December 31, 2023, the landlord and the Company agreed to convert $2.8 million of rent abatement to tenant improvement allowance and agreed to an additional tenant improvement allowance of $2.9 million. The changes were accounted for as lease modifications. The Rockville lease provides for optional two five-year extensions. The optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

In May 2022, the Company entered into an operating lease agreement for 51,822 square feet of office and laboratory space in Redwood City, California for a term of approximately 11.7 years. The lease contains annual rent escalation and rent abatement clauses as well as an allowance of approximately $9.8 million for tenant improvements. The Redwood City lease provides for an optional five-year extension. The optional period is not included in the lease term used to determine the ROU asset or lease liability associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

The Company also leases office and laboratory space in Gaithersburg, Maryland that has a term that expires in 2030 unless renewed. This operating lease agreement contains rent escalation, rent abatement clauses, tenant improvement allowances, and optional renewal clauses. On January 30, 2024, the Company entered into an Assignment of Lease with a third party sublessee, pursuant to which the Company agreed to transfer and assign to a sublessee all of our rights, title, and interest under the Gaithersburg, Maryland Lease.

All three operating leases include variable lease payments, which are primarily related to common area maintenance, taxes and utility charges. The Company also has short-term operating leases with a term of one year or less.

***Finance Leases***

Pursuant to a manufacturing services agreement with Lonza Houston, Inc. (Lonza) in connection with the development and manufacture of autologous drug product anito-cel (Lonza Agreement), the Company entered into a statement of work with Lonza (Lonza SOW) in February 2022, for the technology transfer and cGMP manufacturing of anito-cel and potentially other pipeline products. The Lonza SOW contains an embedded lease as the Company has exclusive use of, and control over, a portion of manufacturing facilities during the contractual term. The Lonza SOW also contains an agreement to purchase inventory that is accounted for separately. Lease commencement occurred during the three months ended September 30, 2022 when the applicable manufacturing facility and equipment became available for cGMP manufacturing under the Company's exclusive use and control. The arrangement provides the Company the ability to early terminate for any reason upon 12 months prior notification to Lonza. The Company did not consider it reasonably certain it would terminate the arrangement when determining the lease term. The arrangement expired in December 2024. Variable costs under this arrangement include materials, external testing, and other services.

The Company elected the practical expedient to combine the lease component and the non-lease components associated with the lease component as a single lease component, except as related to the non-lease component associated with purchase of inventory. The related ROU assets represent assets acquired for research and development activities with no alternative future use and therefore were immediately expensed in the accompanying consolidated statements of operations and comprehensive loss during the year ended December 31, 2022 in the amount of $63.3 million.

In September 2023, the Company signed Amendment 1 to the Lonza SOW entered into in February 2022. The Amendment 1 increased quantity of manufacturing slots from September 2023 through the end of the lease in December 2024, providing the Company additional exclusive use of and control over an additional portion of the manufacturing facilities during the term that was previously shared. The Company now has exclusive use of, and control over, the additional facility space and equipment through the remainder of the lease term.

This change under Amendment 1 was accounted for as a lease modification, and the Company remeasured the lease liabilities for the modified lease as of the Amendment effective date. The remeasurement of the lease liabilities included fixed consideration with an undiscounted value of approximately $51.7 million, or $48.5 million discounted using the expected payment timeline and the incremental borrowing rate of 10.8%, resulting in an increase of $15.9 million in lease liabilities. As the Company acquired ROU assets that represented assets acquired for research and development activities that did not have an alternative future use, the Company recorded the ROU assets as research and development expense immediately in the accompanying consolidated statements of operations and comprehensive loss during the year ended December 31, 2023 in the amount of $18.9 million.

The Company's total lease costs were as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Finance lease costs: | | | |
| Right-of-use assets with no alternative future use | $ 794 | $ 18,871 | $ 63,321 |
| Amortization of right-of-use assets | — | 102 | 102 |
| Interest on lease liabilities | 1,030 | 3,846 | 1,720 |
| Operating lease costs | 5,437 | 6,159 | 3,832 |
| Short-term lease costs | 19 | 32 | 758 |
| Variable lease costs | 7,491 | 8,043 | 1,769 |
| Total lease costs | $ 14,771 | $ 37,053 | $ 71,502 |

Future minimum lease payments were as follows (in thousands) as of December 31, 2024:

| | Operating Leases |
|---|---|
| 2025 | $ 7,606 |
| 2026 | 7,835 |
| 2027 | 8,071 |
| 2028 | 8,315 |
| 2029 | 8,567 |
| Thereafter | 42,472 |
| Total lease payments | 82,866 |
| Less: | |
| Imputed interest | (29,016) |
| Present value of total lease liabilities | $ 53,850 |

Supplemental cash flow information related to leases is as follows (in thousands) for the year ended December 31, 2024 and 2023:

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Cash paid for amounts included in the measurement of lease liabilities: | | | |
| Operating cash flows from finance leases | $ 6,591 | $ 8,770 | $ 1,708 |
| Operating cash flows from operating leases | 7,291 | 4,603 | 1,947 |
| Financing cash flows from finance leases | 39,846 | 29,392 | 9,675 |
| Right-of-use assets obtained in exchange for new finance lease liabilities | 794 | 18,871 | 63,321 |
| Right-of-use assets obtained in exchange for new operating lease liabilities | — | (550) | 29,562 |

Weighted-average remaining lease terms and discount rates were as follows as of December 31, 2024:

| | |
|---|---|
| Weighted-average remaining lease term — operating leases | 9.6 years |
| Weighted-average discount rate — operating leases | 9.8% |

## 10. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Research and development accrued expenses | $ 16,507 | $ 4,559 |
| Accrued bonus | 10,438 | 5,529 |
| Other liabilities | 8,531 | 8,214 |
| Liabilities to related party vendor | 21,240 | — |
| Total accrued liabilities | $ 56,716 | $ 18,302 |

## 11. Commitments and Contingencies

***Commercial and Development Milestones***

In addition to the arrangement with Lonza, we have entered into other contracts in the normal course of business with CROs, CMOs, and other third parties for preclinical research studies and testing, clinical trials, and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice. For such contracts, payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation. We have also entered into agreements with certain vendors for the provision of goods and services, which include manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. In addition, certain agreements with our CMOs and third-party vendors contain (a) development and commercial milestone payments and low single-digit royalties on worldwide net sales for certain products we sell that incorporate certain goods provided by our manufacturers and suppliers, (b) development milestones of up to $25.3 million in the aggregate and (c) commercial milestones of up to $52.0 million in the aggregate, along with royalty buyout provisions.

***Purchase Commitments***

The Company conducts product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. The Company has contractual arrangements with these organizations; however, these contracts are generally cancelable on 30 days' notice and the obligations under these contracts are largely based on services performed.

***Contingencies***

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of December 31, 2024 and 2023, the Company was not involved in any material legal proceedings.

***Indemnification Agreements***

As permitted under Delaware law, the Company indemnifies its executive officers and directors for certain events or occurrences while the executive officer or director is, or was, serving at our request in such capacity. The term of this indemnification is for the officer's or director's lifetime. Additionally, the Company has entered into and expects to continue to enter into indemnification agreements with certain executive officers and directors. Further, in the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date however, the Company has not incurred any material costs as a result of such indemnifications nor experienced any losses related to them. As of December 31, 2024 and 2023, the Company was not aware of any claims under indemnification arrangements and does not expect significant claims related to these indemnification obligations. Therefore, no related reserves were established.

## 12. Redeemable Convertible Preferred Stock and Stockholders' Equity

***"At-the-Market" Offering Program***

In May 2023, the Company entered into a sales agreement (Sales Agreement) with Stifel, Nicolaus & Company (Stifel) with respect to an at-the-market (ATM) offering program under which the Company may issue and sell, from time to time and at the Company's sole discretion, shares of the Company's common stock, in an aggregate offering amount of up to $350.0 million. No sales of the Company stock have been made under this arrangement as of December 31, 2024.

***Gilead SPA and Second Gilead SPA***

On January 26, 2023, the Company issued and sold an aggregate of 3,478,261 shares of common stock in a private placement to Gilead at a price of $28.75 per share for an aggregate purchase price of $100.0 million. The shares were sold pursuant to the Gilead SPA in connection with the Kite Collaboration Agreement and the transaction is considered part of the arrangement. The shares were sold at a discount of $4.39 per share as compared to the closing price of the stock on the date of the expiration of anti-trust provisions and accordingly, the $15.3 million discount is reflected as an increase to additional paid-in capital and decrease to the total fixed transaction price in the arrangement. See Note 8 - Collaboration Agreement.

On December 28, 2023, the Company issued and sold an aggregate of 3,242,542 shares of common stock in a private placement to Gilead at a price of $61.68 per share for an aggregate purchase price of $200.0 million. The shares were sold pursuant to the Second Gilead SPA in connection with the amendment to the Kite Collaboration Agreement and the transaction is considered part of the arrangement. The shares were sold at a premium of $4.80 per share as compared to the closing price of the stock on the date of the expiration of anti-trust provisions and accordingly, the $15.6 million premium is reflected as an increase to additional paid-in capital and decrease to the total fixed transaction price in the arrangement. See Note 8 - Collaboration Agreement.

***Common Stock***

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any. As of the date of the filing of this Annual Report on Form 10-K, no dividends have been declared or paid by the Company.

In the event of any liquidation or dissolution of the Company, the holders of common stock are entitled to the assets of the Company legally available for distribution.

***Redeemable Convertible Preferred Stock***

In connection with the Company's IPO on February 4, 2022, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into shares of common stock at the applicable conversion ratio then in effect. The Company's outstanding shares of preferred stock were converted into 24,785,564 shares of common stock. The Company has authorized 200,000,000 shares of preferred stock, par value $0.0001. There was no preferred stock outstanding as of December 31, 2024 and 2023.

**13. Share-Based Compensation**

The Company's 2017 Equity Incentive Plan (the 2017 Plan) provided for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, and restricted stock awards to the Company's employees, directors, and consultants. The 2017 Plan terminated one business day prior to effectiveness of the 2022 Equity Incentive Plan (the 2022 Plan) with respect to the grant of future awards. The 2022 Plan became effective on February 3, 2022 and provides for the grant of incentive stock options to the Company's employees and for the grant of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units (RSUs), and performance awards to the Company's employees, directors, and consultants.

As of December 31, 2024, the aggregate number of shares of common stock that may be issued pursuant to equity awards under the 2022 Plan was 11,667,993 shares. The number of shares of common stock reserved for issuance under the 2022 Plan is cumulatively increased on the first day of each fiscal year, beginning with the Company's 2023 fiscal year and ending on the ten year anniversary of the date the Company's board of directors approved the 2022 Plan, by an amount equal to the least of (1) 6,502,174 shares, (ii) 5% of the total number of shares of common stock outstanding as of the last day of the immediately preceding fiscal year, or (iii) a lesser number of shares determined by the administrator of the 2022 Plan.

Share-based compensation cost is measured at fair value and is recognized as expense on a straight-line basis over the requisite service period. Share-based compensation expense by type of award was as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Stock options | $ 28,057 | $ 20,661 | $ 14,859 |
| Restricted stock units | 27,257 | 12,254 | 4,056 |
| Restricted stock units - chief executive officer | 5,266 | 8,336 | 2,548 |
| ESPP | 506 | 538 | 81 |
| Total share-based compensation expense | $ 61,086 | $ 41,789 | $ 21,544 |

Share-based compensation expense as reflected in the consolidated statement of operations and comprehensive loss was as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Research and development | $ 21,359 | $ 11,003 | $ 7,007 |
| General and administrative | 39,727 | 30,786 | 14,537 |
| Total share-based compensation expense | $ 61,086 | $ 41,789 | $ 21,544 |

***Stock Options***

Stock options granted under the 2017 Plan and the 2022 Plan vest over one to four years and expire after 10 years. The Company uses the Black Scholes option pricing model to determine the grant date fair value of stock options. A summary of stock option activity for awards under the 2017 Plan and the 2022 Plan is presented below:

| | Options Outstanding and Exercisable | | | |
|---|---|---|---|---|
| | Shares Subject to Outstanding Options | Weighted Average Exercise Price per Option | Weighted Average Remaining Contractual Life Term (in Years) | Aggregate Intrinsic Value (1) (in thousands) |
| Outstanding as of January 1, 2024 | 7,811,231 | $ 12.46 | 7.8 | $ 336,174 |
| Options Granted | 1,031,954 | 56.22 | | |
| Options Forfeited | (145,261) | 11.10 | | |
| Options Exercised | (1,457,826) | 9.75 | | |
| Outstanding as of December 31, 2024 | 7,240,098 | $ 19.28 | 6.9 | $ 415,634 |
| Exercisable as of December 31, 2024 | 4,712,405 | $ 13.30 | 6.6 | $ 298,737 |

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for those options for which the exercise price was below the market price as of December 31, 2024.

The weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2024, 2023 and 2022 was $42.38, $21.86 and $9.95, respectively.

The aggregate grant-date fair value of stock options vested during the years ended December 31, 2024 2023 and 2022 was approximately $27.7 million, $21.4 million and $14.5 million, respectively.

As of December 31, 2024, there was $51.8 million of unrecognized compensation cost related to unvested stock option based compensation arrangements granted under the 2017 Plan and 2022 Plan. This remaining compensation expense is expected to be recognized over a weighted average period of 1.82 years as of December 31, 2024. The aggregate intrinsic value of the options exercised for the years ended December 31, 2024, 2023 and 2022 was $103.5 million, $47.1 million and $10.9 million, respectively.

The assumptions used in the Black-Scholes option pricing model for stock options granted for the years ending December 31, 2024, 2023 and 2022 were as follows:

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Expected term | 5.5 - 6.27 years | 5.5 - 6.25 years | 6.0 - 6.3 years |
| Expected volatility | 86% - 87% | 75% - 80% | 68% - 75% |
| Risk free interest rate | 3.82% - 4.56% | 3.92% - 4.06% | 1.56% - 3.88% |
| Expected dividend yield | — % | — % | — % |

***Restricted Stock Units (RSUs)***

RSUs granted under the 2022 Plan generally vest annually over three or four years. A summary of RSU activity for awards under the 2022 Plan, excluding the 2023 RSU Award and 2021 RSU Award (each defined below) granted to the chief executive officer, is presented below:

| | Shares Subject to Outstanding Awards | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding as of January 1, 2024 | 1,416,446 | $ 25.47 |
| RSUs Granted | 981,531 | 61.66 |
| RSUs Vested | (528,711) | 23.76 |
| RSUs Forfeited | (57,421) | 32.55 |
| Outstanding as of December 31, 2024 | 1,811,845 | $ 45.35 |

For the years ended December 31, 2024, 2023 and 2022, total grant-date fair value of RSUs that vested was $13.4 million, $5.4 million and zero, respectively. As of December 31, 2024, total unamortized share-based compensation relating to RSUs was $56.5 million, which is expected to be recognized over the average period of 1.84 years. The aggregate intrinsic value of RSUs is calculated as the closing price per share of the Company's common stock on the last trading day of the fiscal period, multiplied by the number of RSUs expected to vest as of December 31, 2024. As of December 31, 2024, the aggregate intrinsic value of RSUs was $139.0 million.

***Restricted Stock Units - Chief Executive Officer***

***2023 RSU Award***

In January 2023, the Company granted 495,000 RSUs (the 2023 RSU Award) to its chief executive officer. The 2023 RSU Award has two different scenarios to vesting. The first vesting scenario is subject to service and market conditions. The second vesting scenario adds a performance condition. Each RSU granted in the 2023 RSU Award entitles the chief executive officer to one share of common stock upon vesting subject to the service, performance, and market conditions. All 495,000 RSUs were outstanding and no RSUs were vested as of December 31, 2024. In February 2025, 347,255 shares vested based on performance and market conditions achieved on the measurement date of December 31, 2024.

*Service Condition*

The service condition to vesting of the 2023 RSU Award requires the chief executive officer’s continued employment with the Company through the achievement of any of the performance and market conditions.

*Performance Condition*

The performance condition to vesting of the 2023 RSU Award requires the consummation of a change in control event.

*Market Condition*

The market condition to vesting of the 2023 RSU Award involves evaluating Company market value thresholds depending upon which of the two vesting scenarios is applicable at the time of measurement.

The Company market value is measured each June 30 and December 31 subsequent to the grant of the 2023 RSU Award and represents the Company's Enterprise Value. The Company's Enterprise Value is determined using the total market capitalization of the Company based on the average closing trading price of one share of the Company's common stock over the 60-day period ending on the day prior to the applicable semi-annual measurement date, less cash. On the semi-annual measurement date, (i) one-sixth of the award will vest if a minimum Enterprise Value of $2.5 billion is achieved, (ii) all of the award will vest if a $5.0 billion Enterprise Value is achieved, and (iii) a portion of the award will vest based on a straight-line interpolation if an Enterprise Value of between $2.5 billion and $5.0 billion is achieved.

The Company's Enterprise Value on a change in control event is measured on the date of the change in control and represents the aggregate amount of deal consideration paid at the closing of the change in control by an acquirer for the Company's shares of common stock in connection with such change in control. Upon a change in control, (i) one-sixth of the award will vest if a minimum deal consideration of $2.5 billion is achieved, (ii) all of the award will vest if a $5.0 billion deal consideration is achieved, and (iii) a portion of the award will vest based on a straight-line interpolation if a deal consideration of between $2.5 billion and $5.0 billion is achieved.

The Company utilized Monte Carlo simulation models to estimate the fair value of the 2023 RSU Award on the date of grant in each of the two vesting scenarios. The application of the Monte Carlo simulation model to each of the two vesting scenarios requires various subjective assumptions, including the following:

*Expected Time to Award End Date* – The expected time to the award end date is based on the Company's best estimate of the period of employment for the chief executive officer or the achievement of the performance condition, i.e., the change in control event.

*Expected Equity Volatility* – Due to the limited company-specific historical and implied volatility data, the Company based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company (e.g., public entities of similar size, complexity, stage of development, and industry focus) in addition to the historical volatility of the Company. The historical volatility for the representative group of public companies was calculated based on a period commensurate with the expected time to the award end date.

*Risk-Free Interest Rate* – The risk-free interest rate is based on a U.S. Treasury instrument which term is consistent with the expected time to the measurement dates.

The Company determined the fair value of the 2023 RSU Award using third-party valuation reports. The Company considered several objective and subjective factors, including weighted probability of various scenarios, operating and financial performance, and general and industry-specific economic outlook, among other factors. The assumptions used in the Monte Carlos simulation models to determine the grant date fair value of the 2023 RSU Award for the two vesting scenarios were as follows:

| | Semi-Annual Measurement | Change in Control |
|---|---|---|
| Time to award end date | 10 years | 5 years |
| Equity volatility | 75% | 75% |
| Risk-free interest rate | 3.8% | 3.9% |
| Fair value of the 2023 RSU award (in thousands) | $ 13,811 | $ 10,999 |

The Company began recognizing share-based compensation expense using a fair value of $13.8 million on an accelerated attribution basis over a 10-year anticipated service period according to the semi-annual measurement scenario. The performance condition under the change in control scenario was not deemed probable as of December 31, 2024.

***2021 RSU Award***

In June 2021, the Company granted 952,804 RSUs (the 2021 RSU Award) to its chief executive officer. The 2021 RSU Award is subject to service, performance, and market conditions. In December 2021, the Company added alternative performance conditions for vesting of the same RSUs. These additional performance conditions provided alternative paths to vesting from the 2021 RSU Award; its vesting conditions remained the same, i.e., the original award was not modified.

Each RSU granted in the 2021 RSU Award entitles the chief executive officer to one share of common stock upon vesting subject to the service, performance, and market conditions. All 952,804 RSUs were outstanding and no RSUs were vested as of December 31, 2024. In February 2025, 668,416 shares were vested based on performance and market conditions achieved on the measurement date of December 31, 2024.

*Service Condition*

The service condition to vesting of the 2021 RSU Award requires the chief executive officer's continued employment with the Company through the achievement of any of the performance and the market conditions.

*Performance Condition*

The performance conditions to vesting of the 2021 RSU Award include (i) the consummation of a change in control event, (ii) the consummation of the first firm commitment underwritten public offering covering the offer and sale of Company shares, the consummation of the direct listing or direct placement of Company shares on a publicly traded exchange, or the completion of a merger or consolidation with a special purpose acquisition company in which the shares of the surviving or parent entity are listed on a national securities exchange (IPO), or (iii) a change in control following an IPO. The Company satisfied the IPO performance condition in February 2022 upon completion of the IPO.

*Market Condition*

The market condition to vesting of the 2021 RSU Award involves Company value thresholds depending upon which of the vesting scenarios is applicable at the time of measurement.

The Company value is measured each June 30 and December 31 following the IPO (subject to applicable lock-up period) and represents the Company's Enterprise Value. The methodology to determine the Company's Enterprise Value and the vesting thresholds on the semi-annual measurement dates are the same as those under the 2023 RSU Award.

The Company value on a change in control is measured on the date of the change in control. The methodology to determine the Company value and the vesting thresholds on the change in control date are the same as those under the 2023 Award.

Upon completion of the IPO in February 2022, the IPO performance condition of the 2021 RSU Award was satisfied and the Company began recognizing share-based compensation expense on an accelerated attribution basis over the 10-year anticipated service period based on a $10.3 million aggregate fair value according to the IPO scenario. No other performance condition was deemed probable as of December 31, 2024.

The Company utilized Monte Carlo simulation models to estimate the fair value of the 2021 RSU Award on the date of grant in each of the three performance condition scenarios. The application of the Monte Carlo simulation model to each of the three performance condition scenarios requires various subjective assumptions, including the following:

*Fair Value of Common Stock and Fair Value of Total Equity* – Given the lack of an active public market for the common stock (prior to the Company's IPO), the fair value of the Company's common stock and total equity was determined by the board of directors with input from management and consideration of third-party valuation reports. In the absence of a public trading market, and as a clinical-stage company with no significant revenues, the Company believes that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date and resulting total equity value. In determining the fair value of its common stock and total equity value, the Company used methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' (AICPA) Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation. In addition, the Company considered various objective and subjective factors, along with input from the independent third-party valuation firm. The factors included (1) the achievement of clinical and operational milestones by the Company; (2) the significant risks associated with the Company's stage of development; (3) capital market conditions for life science companies, particularly similarly situated, privately held, early-stage life science companies; (4) the Company's available cash, financial condition, and results of operations; (5) the most recent sales of the Company's redeemable convertible preferred stock; and (6) the preferential rights of the outstanding redeemable convertible preferred stock.

*Expected Equity Volatility* – Due to the lack of a public market for the Company's common stock (prior to the Company's IPO) and the lack of company-specific historical and implied volatility data, the Company based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company (e.g., public entities of similar size, complexity, stage of development, and industry focus). The historical volatility was calculated based on a period commensurate with the expected date of achievement of a performance condition.

*Risk-Free Interest Rate and Discount Period* – The risk-free interest rate is based on a treasury instrument which term is consistent with the expected time to achieve of a performance condition. The discount period is the period between the valuation date and the assumed change in control event date, with the assumption that all equity shares in the capital structure are paid out in cash.

*Expected Dividend Yield* – The expected dividend yield is based on the Company's historical and expected dividend payouts. The Company has historically paid no dividends and does not anticipate dividends to be paid in the future.

*Expected Time to Achievement of a Performance Condition* – The time to the achievement of a performance condition is based on the Company's best estimate of the period of time to achievement of a performance condition that attains the established market capitalization thresholds.

The Company determined the fair value of the 2021 RSU Award considering third-party valuation reports. The Company considered several objective and subjective factors, including weighted probability of various liquidation event scenarios, operating and financial performance, discount for lack of marketability of the Company's equity, and general and industry-specific economic outlook, among other factors. The discount for lack of marketability was applied to reflect the increased risk arising from the inability to readily sell the RSUs. The assumptions used in the Monte Carlos simulation models to determine the grant date fair value of the 2021 RSU Award for each of the three performance condition scenarios were as follows:

| | Change in Control | IPO | Change in Control Following an IPO |
|---|---|---|---|
| Date of grant | June 9, 2021 | December 7, 2021 | December 7, 2021 |
| Time to liquidity event (years) | 1.56 - 3.06 | 10.00 | 1.33 |
| Equity volatility | 100% - 110% | 70% | 65% |
| Risk-free interest rate | 0.1% - 0.3% | 1.5% | 0.4% |
| Discount for lack of marketability | 26% - 32% | 5% | 5% |
| Fair value of the 2021 RSU award (in thousands) | $ 1,580 | $ 10,300 | $ 150 |

As of December 31, 2024, there was $8.0 million of unrecognized share-based compensation cost related to the chief executive officer's 2023 RSU Award and 2021 RSU Award.

**14. Employee Stock Purchase Plan (ESPP)**

In February 2022, the Company adopted the 2022 ESPP, as amended in September 2022. The 2022 ESPP plan was initiated in November 2022 and provides eligible employees with the opportunity to acquire an ownership interest in the Company through periodic payroll deductions, based on a six-month look-back period, at a price equal to the lesser of 85% of the fair market value of the common stock at either the first business day or last business day of the relevant offering period, provided that no more than $25,000 in common stock may be purchased by any one employee during each year. The 2022 ESPP is intended to constitute an “employee stock purchase plan” under Section 423(b) of the Internal Revenue Code of 1986, as amended. The 2022 ESPP may be terminated by the Company’s board of directors at any time. A total of 312,500 shares of common stock were initially reserved for issuance under the 2022 ESPP, subject to an annual increase on January 1 of each year, beginning on January 1, 2023, equal to the least of 312,500 shares of the Company's common stock, 1% or the outstanding shares of the Company's common stock as of the last day of the immediately preceding fiscal year, or such other amount as the administrator under the 2022 ESPP may determine.

The assumptions used in the Black-Scholes option pricing model for the ESPP plan for the year ending December 31, 2024, 2023 and 2022 were as follows:

| | 2024 | 2023 | 2022 |
|---|---|---|---|
| Expected term | 0.5 years | 0.5 years | 0.5 years |
| Expected volatility | 45% - 65% | 65% - 68% | 132% |
| Risk free interest rate | 4.44% - 5.46% | 5.26% - 5.46% | 4.40% |
| Expected dividend yield | — % | — % | — % |

## 15. Net Loss Per Share Attributable to Common Stockholders

The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Options to purchase common stock | 7,240,098 | 7,811,231 | 8,053,704 |
| Restricted stock units | 1,811,845 | 1,416,446 | 927,954 |
| Restricted stock units - executive officer | 1,447,804 | 1,447,804 | 952,804 |
| Employee Stock Purchase Plan (ESPP) | 3,959 | 2,995 | 5,651 |
| Total | 10,503,706 | 10,678,476 | 9,940,113 |

## 16. Income Taxes

The Company's provision for income taxes consists of the following (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Current income tax provision (expense) benefit: | | | |
| U.S. federal | $ (1,910) | $ (427) | $ — |
| State | (153) | (273) | — |
| Total | $ (2,063) | $ (700) | $ — |

A reconciliation of the statutory U.S. federal rate and effective rate is as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| U.S. federal tax | 21.0% | 21.0% | 21.0% |
| State tax, net of federal benefit | 0.3 | 0.6 | 6.6 |
| Change in valuation allowance | (42.9) | (2.8) | (26.9) |
| Nondeductible compensation | (17.0) | (15.2) | (0.2) |
| Research and development tax credits | 26.3 | 16.3 | 0.0 |
| Stock based compensation | 16.5 | 10.2 | 0.4 |
| Change in state deferred income tax rate | (0.5) | (27.2) | 0.0 |
| Changes in unrecognized tax benefits | (5.7) | (4.8) | 0.0 |
| Change in tax rates and other | 0.1 | 0.9 | (0.9) |
| Effective income tax rate | (1.9)% | (1.0)% | 0.0% |

The significant components of the Company's deferred income tax assets (liabilities) were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Deferred income tax assets: | | |
| U.S. federal net operating loss carryforward | $ 10,692 | $ 29,929 |
| State net operating loss carryforward | 287 | 1,110 |
| Research and development expenditures | 65,346 | 44,047 |
| Research and development credits | 26,838 | 9,829 |
| Lease liabilities - operating | 11,641 | 12,710 |
| Stock based compensation | 8,117 | 4,600 |
| Accruals and others | 2,371 | 1,323 |
| Deferred Revenue | 24,423 | — |
| Gross deferred income tax assets | 149,715 | 103,548 |
| Less: Valuation allowance | (137,302) | (91,841) |
| Total deferred income tax assets | 12,413 | 11,707 |
| Deferred income tax liabilities: | | |
| Depreciation | (6,692) | (4,930) |
| Right-of-use asset - operating | (5,143) | (5,903) |
| Section 481(a) adjustment | (578) | (874) |
| Total deferred income tax liabilities | (12,413) | (11,707) |
| Net deferred income tax assets (liabilities) | $ — | $ — |

For tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to Internal Revenue Code Section 174.

The Company records valuation allowances to reduce deferred tax assets to the amount that is not more likely than not to be realized. In assessing the likelihood of realization, management considers (i) future reversals of existing taxable temporary differences; (ii) future taxable income exclusive of reversing temporary difference and carryforwards; (iii) taxable income in prior carryback years if carryback is permitted under applicable tax law; and (iv) tax planning strategies. The Company's net deferred income tax assets are not more likely than not to be utilized due to the lack of sufficient sources of future taxable income and cumulative book losses which have resulted over the years. The net increase in the valuation allowance for the year ended December 31, 2024 of approximately $45.5 million was primarily due to capitalized research and development expenditures, research and development credits and increase in deferred revenue, partially offset by utilization of net operating loss carryforwards. The change in the valuation allowance for the year ended December 31, 2023 of approximately $2.0 million was primarily due to increase in capitalized research and development expenditures and research and development credits, partially offset by utilization of net operating loss carryforwards.

The Company had federal and State net operating loss (NOL) carryforwards of approximately $51.2 million and $74.8 million, respectively, as of December 31, 2024. The Company also had federal and State research and development tax credit carryforwards of approximately $8.9 million and $3.2 million, respectively, and federal orphan drug credit carryforwards of $24.8 million, available to potentially offset future income taxes, as of December 31, 2024. The federal NOL will be carried forward indefinitely, if not utilized, but is limited to eighty percent of taxable income. The State NOL will begin expiring in 2038, if not utilized, while a portion is carried forward indefinitely. The federal research and development tax credit carryforwards and orphan drug credit carryforwards, if not utilized, will begin to expire in 2042. The California research and development tax credit carryforwards do not expire while other State research and development tax credit carryforward will begin to expire in 2031.

Under Section 382/383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally occurs if the percentage of the corporation's stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company performed a Section 382/383 analysis through December 31, 2024. The Company has experienced ownership changes. Some of the Company's federal research and development tax credit carryforwards will be permanently limited as a result of the ownership change, which have been excluded from the Company's deferred income tax assets. Subsequent ownership changes may affect the limitation in future years.

Related to unrecognized tax benefits noted below, interest and penalties related to unrecognized tax benefits are recognized in the provision of income taxes. No penalties or interest were recorded during the years ended December 31, 2024, 2023 and 2022. The Company does not expect its unrecognized tax benefit balance to change materially over the next 12 months. The Company had $9.6 million and $3.5 million, and no unrecognized tax benefits as of December 31, 2024, 2023 and 2022, respectively. Of the unrecognized tax benefits as of December 31, 2024, 2023 and 2022, none would affect the Company's effective tax rate if recognized due to the Company's full valuation allowance position.

| | |
|---|---|
| December 31, 2022 | $ — |
| Additions based on tax positions related to 2023 | 809 |
| Additions for tax positions of prior years | 2,641 |
| December 31, 2023 | 3,450 |
| Additions based on tax positions related to 2024 | 3,177 |
| Additions for tax positions of prior years | 2,951 |
| December 31, 2024 | $ 9,578 |

The Company's federal and State tax returns for all years, 2015 through 2023, remain subject to examination by taxing authorities due to the tax attribute carryforwards. The Company is not currently under examination by income tax authorities in federal or State jurisdictions.

**17. Segment Reporting**

The Company operates in a single operating segment and has one reportable segment, which includes all activities related to the discovery, development, and manufacturing of its product candidates. The determination of a single segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its chief executive officer. The CODM uses consolidated net loss for purpose of assessing performance, making operating decisions and allocating resources. The measurement of segment assets is reported on the balance sheet as total consolidated assets.

The table below provides information about the Company's segment (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Collaboration revenue | $ 107,936 | $ 110,319 | $ — |
| Operating expenses: | | | |
| Research and development | | | |
| anito-cel in rrMM | 50,141 | 73,530 | 96,513 |
| ACLX-001 | 1,975 | 2,939 | 8,764 |
| ACLX-002 | 14,294 | 5,667 | 6,458 |
| Other research and development costs | 21,364 | 3,701 | 5,467 |
| Internal costs [1] | 69,319 | 48,012 | 32,353 |
| General and administrative | 88,414 | 66,350 | 41,704 |
| Total operating expenses | 245,507 | 200,199 | 191,259 |
| Loss from operations | (137,571) | (89,880) | (191,259) |
| Interest and other income (expense), net | 33,322 | 23,695 | 4,300 |
| Interest expense | (1,030) | (3,842) | (1,720) |
| Total other income, net | 32,292 | 19,853 | 2,580 |
| Income tax expense | (2,069) | (663) | — |
| Net loss | $ (107,348) | $ (70,690) | $ (188,679) |

[1]Internal costs primarily consist of employee-related costs, including salaries, related benefits, and share-based compensation expense, as well as facility allocation and depreciation expense.