Annual Report

2025

Dear Fellow Shareholders,

2025 was a year of strong execution and meaningful scientific progress for ALX across both of our programs. I am pleased to report that our clinical development timelines remain firmly on track and that we are entering the next 12-18 months with more confidence in where our science is headed, and what it can do for patients. The recent financing in Q1 ’26 also gives us strength in our balance sheet to execute on our ongoing clinical trials and move towards key milestones across both our programs.

Evorpacept: Strong Confidence Built Over 800+ Patient Experience

Based on our learnings from over 800 patients across more than a dozen clinical trials we are prioritizing evorpacept development in combination with anti-cancer antibodies that directly induce antibody-dependent cellular phagocytosis (ADCP), the primary proposed mechanism of action for evorpacept. The mechanism of combining evorpacept with Fc active antibodies has been validated across 5 different cohorts in multiple tumor settings. This data validates our approach and will continue to anchor our go-forward strategy.

CD47 as Biomarker: Two Datasets, One Consistent Story

In November 2025 at the Society for Immunotherapy of Cancer conference, we shared biomarker data from our HER2 positive gastric study, showing a compelling clinical response across all efficacy measures in HER2+ gastric cancer patients with high CD47 expression. Shortly after, top-line data from the Phase 1 study of evorpacept and zanidatamab breast cancer trial delivered a second independent validation, where responders were largely restricted to CD47 over expressers. Across two datasets, there is one consistent biomarker story.

ASPEN-Breast Ph2 Trial: On Track for Mid 2027 Readout

These findings sharpen our conviction in ASPEN-Breast, our Phase 2 trial in HER2-positive breast cancer evaluating patient responses by CD47 level. Site activations are progressing globally at a strong pace and enrollment is tracking to plan. We continue to expect top line data for 80 patients in mid 2027. With over 50,000 patients in this setting, Evorpacept has the potential to be both a best in class and first-class option – and the only therapy designed to directly address CD47 expression in this population to date.

ALX2004: Progressing Per Plan

Our novel Epidermal Growth Factor Receptor (EGFR) targeted Antibody-Drug Conjugate (ADC), ALX2004 is also advancing well and on track. We have cleared the first two dose cohorts in our phase 1 dose escalation study targeting EGFR over expressing tumors in Lung, Head & Neck, Colorectal and Esophageal cancers. We expect full safety data from the dose escalation cohort in the second half of 2026. Given the differentiated design built to overcome some of the traditional EGFR toxicities that have constrained prior EGFR ADCs, we believe ALX2004 has the potential to address significant gaps in the standard of care in multiple cancers.

What It All Means for Patients

The patients our programs target have often exhausted standard options. We are excited with the potential that both our programs have to offer for these patients.

I look forward to sharing more at our annual Investor Meeting and am deeply grateful for your continued support and partnership.

Jason Lettmann
Chief Executive Officer

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-39386

ALX ONCOLOGY HOLDINGS INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-0642577**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
323 Allerton Avenue	
South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 650-466-7125

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ALXO	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 its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2025, the last business day of its most recently completed second fiscal quarter, was $18.0 million based on the closing sales price of the registrant's common stock on that date.

The number of shares of registrant's Common Stock outstanding as of March 2, 2026 was 131,608,278.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement relating to the Company's 2024 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the implementation of our strategic plans for our business and product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and 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 reliance on third parties to conduct preclinical research activities, and for the manufacture of our product candidates;
- the beneficial characteristics, mechanisms of action, safety profile, efficacy and therapeutic effects of our product candidates;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the ability of our clinical trials, including collaborations and investigator sponsored trials, to demonstrate the safety and efficacy of our product candidates, and other positive results;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our continued reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;
- our ability to retain the continued service of our key personnel, the impacts of any executive officer changes, and to identify, hire, and then retain additional qualified personnel;

- the impact of macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, U.S. federal government shutdowns, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic;
- our plans for and prospects of our acquisitions and other business development activities, and our ability to successfully capitalize on these opportunities;
- changes in our financial and internal controls; and
- our anticipated use of our existing cash and cash equivalents, short-term and long-term investments, and the funds available from our term loan.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

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PART I

Item 1. Business.

BUSINESS

Overview

We are a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives. Our clinical pipeline includes two clinical-stage product candidates, the CD47 blocker evorpacept and an epidermal growth factor receptor (EGFR)-targeted antibody drug candidate (ADC) ALX2004. Our lead product candidate, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built for patients whose cancer over-expresses CD47. Evorpacept is currently being evaluated in combination with trastuzumab and chemotherapy in patients with metastatic HER2-positive breast cancer in the Phase 2 ASPEN-09-Breast clinical trial and is also being studied in clinical trials with other targeted anti-cancer antibodies. Cancer cells leverage CD47, a cell surface protein, as a "don't eat me" signal to evade macrophage phagocytosis. We are developing evorpacept to be a next-generation checkpoint inhibitor designed to have a high affinity for CD47 and to avoid the limitations caused by hematologic toxicities inherent in other CD47 blocking approaches. Our second pipeline candidate, ALX2004, is a novel EGFR-targeted antibody-drug conjugate with a differentiated mechanism of action entered into a Phase 1 clinical trial in August 2025.

Anti-cancer agents, including many chemotherapies, other small molecules and anti-cancer antibodies, can stimulate immune cells such as macrophages to engulf and kill cancer cells, a process known as phagocytosis, by providing so-called "eat me" signals on cancer cells. In response, cancer cells frequently overexpress CD47 to counteract these "eat me" signals. As a result, high expression of CD47 on cancer cells has been associated with reduced patient survival in multiple cancers. The therapeutic blockade of CD47 in combination with an "eat me" signal enables the immune system to detect and phagocytose cancer cells. However, healthy blood cells and nearly all other cells in the body also express CD47 as a way to protect against pathologic phagocytosis by immune cells. There have been a number of approaches to blocking CD47, including monoclonal antibodies and fusion proteins that include an active Fc region. These approaches have encountered limitations, including limited dosing and therapeutic window, limited ability to combine with other anti-cancer agents, limited efficacy in solid tumors and limited indications due to patient selection, that have challenged their ability to maximize the full potential of CD47 blockade. In addition, most of these therapeutic approaches to CD47 blockade have resulted in the destruction of patients' healthy blood cells, causing cytopenias that limit the dosing and therapeutic potential of those molecules.

ALX Oncology was founded to address fundamental challenges in blocking CD47 and to realize the full potential of this therapeutic target. Clinical data on competing CD47 blockers to date have come from molecules that incorporate an active antibody Fc region in addition to a CD47 blocking region. The Fc region provides a positive, pro-phagocytic "eat me" signal to macrophages and other cells of the immune system. Since healthy blood cells also express CD47, these competing therapeutic approaches can cause a reduction in the number of blood cells in the body, resulting in anemia, thrombocytopenia and neutropenia, which can be dangerous to patients and may limit the ability to combine these agents with other anti-cancer medicines.

Evorpacept is a next-generation CD47 blocking therapeutic that we believe has significantly enhanced properties compared to competing CD47 blocking approaches. Evorpacept is a fusion protein that combines a high-affinity CD47 binding domain with a proprietary inactivated Fc domain. The CD47 binding domain of evorpacept is an affinity enhanced extracellular domain of SIRPα, a protein found on myeloid cells such as macrophages, that is the natural receptor to CD47. We have engineered the Fc domain of evorpacept so that it does not provide a pro-phagocytic signal while still maintaining an antibody-like half-life for the molecule. We believe our inactive Fc approach improves tolerability when compared to other CD47 blocking approaches that have an Fc domain that engages activating receptors on macrophages, causing phagocytosis and death of healthy cells in addition to cancer cells.

Evorpacept's design has several additional advantages that we believe will make it broadly applicable to treating a number of oncology indications. Due to the inactive Fc, evorpacept is specifically designed for use in combination with other anti-cancer agents that provide a positive immune-stimulating signal. We believe evorpacept has a favorable tolerability profile that may enable higher dosing levels, increased tumor penetration, and greater combination potential with other leading anti-cancer agents. Additionally, the molecular weight of evorpacept is half that of a typical antibody, therefore allowing for higher dosing (10 mg/kg of evorpacept is equivalent to 20 mg/kg of a regular antibody). The relatively smaller size of our molecule may facilitate increased penetrance into the tumor microenvironment. We believe these properties may enable evorpacept to provide superior therapeutic benefits.

Clinical data to date in evorpacept have not shown the dose-dependent hematologic toxicities characteristic of other CD47 blockers that incorporate an active Fc domain. Approximately 800 subjects have been treated with evorpacept in combination with targeted anti-cancer agents, small molecules, and checkpoint inhibitors to date. Evorpacept has not reached a maximum tolerated dose in any of the combinations evaluated to date.

We are focused on evorpacept development with the standard-of-care agents that provide a stimulatory signal to the innate immune system. We are combining evorpacept with anti-cancer targeted antibodies with an active Fc domain, where evorpacept enables the Fc-mediated antibody dependent phagocytosis that is impaired by the expression of CD47 on cancer cells.

Data from the randomized ASPEN-06 Phase 2 clinical trial supports the clinical validation of this mechanism of action. ASPEN-06 evaluates the contribution of evorpacept to HERCEPTIN® (trastuzumab) plus standard of care (CYRAMZA® (ramucirumab) + paclitaxel) (Evo-TRP), versus trastuzumab, ramucirumab, and paclitaxel (TRP) in second line or later human epidermal growth factor receptor 2 (HER2)-positive gastric/gastroesophageal junction (GEJ) cancer, where all patients had received an anti-HER2 agent in prior lines of therapy. The full data set was previously presented. Results from a pre-planned exploratory analysis were presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting:

- In a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer, CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression. Retained HER2 expression is defined as patients who are HER-2 positive on a tumor biopsy after receiving a HER2-targeted treatment or by HER2 amplification by circulating tumor DNA (ctDNA). The data was highlighted as part of a poster presentation at the SITC Annual Meeting in November 2025.
    - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% objective response rate (ORR) versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
    - The duration of response (DOR) was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had a median DOR (mDOR) of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. Progression free survival (PFS) and overall survival (OS) data were evaluated in these patients. Treatment with Evo-TRP resulted in a median PFS (mPFS) of 18.4 months versus 7.0 months for TRP, hazard ratio (HR) of 0.39. Treatment with Evo-TRP resulted in a median OS (mOS) of 17 months versus 9.9 months for TRP, HR of 0.70.

Evorpacept has been combined in clinical trials with multiple anti-cancer antibodies in addition to trastuzumab, including the CD20-targeted antibody rituximab, the CD38-targeted antibody isatuximab-*irfc*, and the HER2-targeted bispecific antibody zanidatamab. Our earlier ASPEN-01 Phase 1 positive data in combination with rituximab in non-Hodgkin lymphoma (NHL); the Phase 1/2 investigator-sponsored trial (IST) of evorpacept in combination with rituximab and lenalidomide in patients with relapsed refractory B-cell NHL (R/R B-NHL) and subsequently, in patients with newly diagnosed indolent B-cell NHL (iNHL); and the Phase 1b/2 trial of evorpacept with zanidatamab in patients with HER2-positive breast cancer provide additional support for the clinical validation of this mechanism of action and support exploring combinations of evorpacept with other anti-cancer antibodies.

Our second product candidate is ALX2004, a novel EGFR-targeted ADC. ALX2004 was created from our proprietary linker-payload library and fully designed and developed in-house by our scientists. ALX2004 comprises a matuzumab-derived affinity-selected EGFR antibody backbone engineered for optimal activity as an ADC, a proprietary topoisomerase I inhibitor payload with enhanced bystander effect, and a linker with enhanced stability. EGFR is clinically validated as a therapeutic target with several U.S. Food and Drug Administration (FDA)-approved targeted antibodies and small molecules. However, there are currently no approved EGFR-targeted ADCs and early-generation attempts to develop EGFR-targeted ADCs were limited by drug design, on-target off-tumor toxicities and toxicity of older generation payloads

We are engaged in the following clinical programs, collaborations, and investigator-sponsored trials:

Evorpacept

Combination with the HER2-targeted antibody trastuzumab

- ASPEN-09-Breast – HER2+ Breast Cancer
    - In March 2025, we announced intent to initiate a randomized Phase 2 clinical trial evaluating evorpacept in combination with trastuzumab and chemotherapy for the treatment of patients with HER2-positive metastatic breast cancer after prior treatment with fam-trastuzumab deruxtecan-nxki.
    - In August 2025, we announced that based on the magnitude of benefit in patients with high CD47 expression in HER2-positive gastric cancer, the ASPEN-09-Breast study in HER2-positive breast cancer evaluating evorpacept in combination with trastuzumab and chemotherapy has been amended to a single-arm design in all previously treated HER2 positive patients and will be evaluated by CD47 expression.
    - In January 2026, we announced that the first patient had been dosed in the trial.

- ASPEN-06 – Gastric/GEJ Cancer
  - In January 2020, the FDA granted Fast Track designation for evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-overexpressing advanced gastric or GEJ adenocarcinoma with disease progression on or after prior trastuzumab and fluoropyrimidine or platinum containing chemotherapy.
  - In January 2022, the FDA's Office of Orphan Products Development granted Orphan Drug Designation (ODD) to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In March 2022, we announced the dosing of the first patient in the multi-center, international ASPEN-06 trial, a randomized Phase 2/3 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of second- and third-line advanced HER2-overexpressing gastric/GEJ cancer, where all patients had received an anti-HER2 agent in prior lines of therapy.
  - In June 2023, the European Commission granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In October 2023, we announced positive prespecified interim Phase 2 clinical data from our ASPEN-06 clinical trial. This prespecified interim analysis reported results from 54 randomized patients with second and third line gastric/GEJ cancer, including patients previously treated with fam-trastuzumab deruxtecan-nxki and checkpoint inhibitors. A confirmed ORR of 52% was demonstrated for the Evo-TRP treatment arm compared to 22% for the TRP control arm. An mDOR was not reached for the Evo-TRP treatment arm compared to 7.4 months for the control group. The safety profile of evorpacept was consistent with previous clinical trials and was well-tolerated.
  - In July 2024, we announced the topline data from our ASPEN-06 Phase 2 clinical trial. This topline data reported results from 127 randomized patients with second and third line gastric/GEJ cancer and was generally well-balanced across arms based on prespecified stratification factors including line of therapy, prior ENHERTU® use, Asia region, tumor location (GC or GEJ), HER2 expression level, and having HER2-positive disease based upon a tissue biopsy after anti-HER2 treatment. A confirmed ORR of 40.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm. The mDOR was 15.7 months for the Evo-TRP treatment arm and 7.6 months for the TRP control arm in the full trial population. In patients with fresh HER2-positive biopsies (n=48), Evo-TRP demonstrated an ORR of 54.8% compared to 23.1% for the TRP control.
  - In January 2025, we presented updated results from the ASPEN-06 Phase 2 clinical trial in an oral presentation at the 2025 American Society of Clinical Oncology Gastrointestinal Cancers Symposium. A confirmed ORR of 41.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm in the intent-to-treat patient population. In patients with confirmed HER2-positive expression as determined by either fresh biopsy or ctDNA HER2-positivity (n=96), the addition of evorpacept to TRP resulted in a 48.9% ORR, an mDOR of 15.7 months and mPFS of 7.5 months, compared to a 24.5% ORR, an mDOR of 9.1 months and mPFS of 6.7 months in the TRP control group, with a PFS HR of 0.64.
  - In April 2025, we received guidance from the FDA that the ASPEN-06 Phase 2 trial data evaluating Evo-TRP was not eligible for submission for accelerated approval given the availability of ENHERTU. A Phase 3 versus ENHERTU trial would be needed to pursue a regulatory approval of evorpacept in the second-line setting for HER2-positive gastric and GEJ. Given our disciplined focus and the allocation of our resources, we will not pursue a U.S. registrational path with a Phase 3 trial in gastric cancer and will consider exploring development partnerships to advance this program in gastric cancer.
  - In August 2025, we announced topline results from pre-planned exploratory analysis of the ASPEN-06 trial in gastric cancer, where CD47 overexpression was identified as a key predictive biomarker for response and durable benefit.
  - In November 2025, we presented a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer in which CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression.
    - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% ORR versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
    - The DOR was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had an mDOR of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. PFS and OS data were evaluated in these patients. Treatment with Evo-TRP resulted in an mPFS of 18.4 months versus 7.0 months for TRP, HR of 0.39. Treatment with Evo-TRP resulted in an mOS of 17 months versus 9.9 months for TRP, HR of 0.70.

Combination with the EGFR-targeted antibody cetuximab

- ASPEN-CRC – Colorectal Cancer (CRC)
  - In March 2025, we announced intent to initiate a Phase 1b study evaluating evorpacept in combination with the EGFR-targeted antibody cetuximab and FOLFIRI for the treatment of patients with second-line metastatic CRC.
  - In August 2025, we streamlined evorpacept development program to focus our resources on the ASPEN-09-Breast trial and paused the ASPEN-CRC study announced earlier in March 2025.

Collaborations and Investigator-Sponsored Trials (ISTs)

Combination with the HER2-targeted bispecific, zanidatamab, and HER2-targeted ADC, fam-trastuzumab deruxtecan-nxki

- Jazz Pharmaceuticals plc – Breast Cancer
  - Our collaborator, Jazz Pharmaceuticals plc (Jazz), sponsored and managed the Phase 1b/2 trial of zanidatamab, a HER2-targeted anti-cancer antibody, for the treatment of advanced HER2-expressing breast cancer and other solid tumors in combination with evorpacept (Zanidatamab Trial). We announced the dosing of the first patient in this trial in October 2021.
  - Our initial collaborator for the Zanidatamab Trial was Zymeworks Inc. (Zymeworks), however in a series of transactions commencing in October 2022, Jazz assumed responsibility from Zymeworks for the development and commercialization of zanidatamab in the United States, Europe, Japan and certain other territories, including responsibility for the Zanidatamab Trial.
  - In December 2024, Phase 1b/2 data were presented in a poster presentation at the 2024 San Antonio Breast Cancer Symposium (SABCS). The SABCS poster presentation data-cut reported on efficacy findings from all three of the part-two trial cohorts: Cohort 1 (n=21) consisted of patients with HER2-positive breast cancer who had received prior ENHERTU and also a median of six prior systemic therapies in the metastatic setting. Patients were enrolled based on local assessment of tumor samples or central assessment. Of the 21 patients enrolled in Cohort 1, nine were found to be HER2-positive based on central assessment. Cohort 2 (n=15) consisted of patients with HER2-low breast cancer who had received a median of five prior systemic therapies. Cohort 3 (n=8) consisted of patients with other HER2-expressing cancers. Patients in Cohort 1 who were HER2-positive by central assessment (n=9) showed the greatest anti-tumor activity with a confirmed ORR of 55.6% and an mPFS of 7.4 months. Overall, patients in Cohort 1 (n=21) had a confirmed ORR and mPFS of 33.3% and 3.6 months, respectively. Patients in Cohort 2 had a confirmed ORR and mPFS of 20.0% and 1.9 months, respectively. As of the August 2024 data cutoff, median follow-up was 9.6 months, with six patients still on treatment. The mDOR was not reached for Cohort 1 patients (range: 3.6-25.9 months) and was 5.5 months for Cohort 2 patients (range: 3.6-11.0 months), with responses ongoing, including the longest observed response, in each cohort. The combination therapy was well tolerated with a manageable safety profile that was consistent with prior experience of each agent.
  - In January 2026, we announced that an exploratory biomarker analysis showed responses in the trial were largely restricted to patients with higher CD47 expression.

Combination with the CD20-targeted antibody rituximab

- MD Anderson Cancer Center – Non-Hodgkin Lymphoma
  - In 2021, an IST of evorpacept was initiated in combination with rituximab and lenalidomide (R^2) for the treatment of patients with indolent and aggressive NHL, sponsored by MD Anderson Cancer Center in Texas. We announced the dosing of the first patient in September 2021.
  - In April 2024, MD Anderson Cancer Center reported clinical data from the ongoing Phase 1/2 IST of evorpacept in combination with R^2 in patients with R/R B-NHL. The new data were presented in an oral presentation at the 2024 American Association for Cancer Research (AACR) Annual Meeting. The Phase 1 part of the clinical trial enrolled a total of 20 patients with indolent (n=18) and aggressive (n=2) R/R B-NHL where all patients had received prior rituximab and 72% had received prior chemoimmunotherapy. Patients received evorpacept 30 mg/kg every two weeks (Q2W) (n=3) or 60 mg/kg every four weeks (Q4W) (n=17) in combination with standard R^2 treatment. The regimen was well tolerated, and there were no dose-limiting toxicities. Patients with indolent R/R B-NHL (n=18) had a best ORR of 94% and a complete response rate of 83%. The mDOR was not reached.
  - In April 2025, final data for the Phase 1 portion of the MD Anderson Cancer Center IST was presented at the 2025 AACR Annual Meeting. In the total population (n=20), after a median follow-up of 28 months (95% CI, 18-28 months) the two-year PFS rate was 69% and two-year OS rate was 84%. The Phase 2 portion of the clinical trial in patients with previously untreated indolent NHL is ongoing and has completed enrollment.

- In December 2025, data for the Phase 2 portion of this trial, which enrolled patients with untreated indolent NHL was presented at the 2025 American Society of Hematology Annual Meeting. The combination of evorpacept with R^2 generated complete responses in 92% of patients comparing favorably to an approximate 50% historical complete response rate for R^2 alone.

Combination with the CD38-targeted antibody isatuximab-irfc

- Sanofi – Multiple Myeloma
  - In April 2023, we announced a collaboration with Sanofi who will sponsor and manage a Phase 1/2 trial of SARCLISA® (isatuximab-irfc), an anti-cancer antibody, and dexamethasone in combination with evorpacept for the treatment of patients with relapsed or refractory multiple myeloma. We announced the dosing of the first patients in September 2024.
  - In August 2025, we announced that the dose escalation portion of this trial was complete and Sanofi had begun the dose optimization portion of the trial.

Based on our clinical results to date in multiple oncology indications that show encouraging anti-tumor activity and tolerability, our strategy is to pursue evorpacept as a potentially critical component of future oncology treatments in combination with anticancer antibodies.

ALX2004

- In March 2025, we filed an investigational new drug (IND) application for our first ADC program, ALX2004 and in April 2025, the FDA cleared the IND to evaluate ALX2004 in a Phase 1 clinical trial for patients with EGFR-expressing solid tumors.
- In August 2025, we announced the dosing of the first patient in the first-in-human, open-label multi-center Phase 1 clinical trial of ALX2004 for the treatment of advanced or metastatic select EGFR-expressing solid tumors.
- In January 2026, we announced that the trial had begun enrolling patients in the third dose cohort at 4 mg/kg after successfully clearing the second dose cohort. No dose-limiting toxicities were observed in the first two dose cohorts.

Our team of industry veterans plans to continue to advance a broad development plan for evorpacept that balances speed to market, scale of unmet need and existing clinical evidence for evorpacept's combination mechanisms. Members of our management team have brought multiple drugs to the FDA approval. Our Chief Executive Officer, Jason Lettmann, brings a broad suite of expertise as an institutional healthcare investor, most recently at Lightstone Ventures, and has been involved with ALX Oncology for nearly a decade since its founding, having co-led the Company's first institutional financing and serving as a member of the Company's Board of Directors. He also previously served as Chief Executive Officer of Promedior, Inc. During his tenure, Promedior was acquired by Roche in 2020 for up to $1.39 billion. Our Chief Medical Officer, Barbara Klencke, M.D., brings more than 30 years of experience in patient care, academic and scientific research and clinical drug development in hematology and oncology. She has served in various executive leadership roles at a range of small, mid-sized, and large biotech companies including Sierra Oncology, Inc., Onyx Pharmaceuticals and Genentech, a member of the Roche Group. Our Chairman and founder, Corey Goodman, Ph.D., an elected member of the National Academy of Sciences, has co-founded seven biopharmaceutical companies, including Exelixis and Labrys (acquired by Teva Pharmaceuticals in 2014), and led Pfizer's Biotherapeutics and Bioinnovation Center. Our Chief Financial Officer, Harish Shantharam, has over 20 years of experience guiding public life science companies. Most recently, he was Chief Financial Officer of Cymabay Therapeutics, and prior to this role he was Vice President and Head of Global Commercial Finance at Gilead Sciences. We have funded our operations to date primarily through the issuance and sale of our convertible preferred stock, the issuance and sale of our common stock through an initial public offering in July 2020 and a registered offering in December 2020, a term loan facility in October 2022, a registered offering in October 2023, a registered offering in February 2026, and sales under our ATM offering program.

Our Strategy

Our goal is to transform treatment options for patients with cancer by developing evorpacept as a foundational checkpoint immunotherapy.

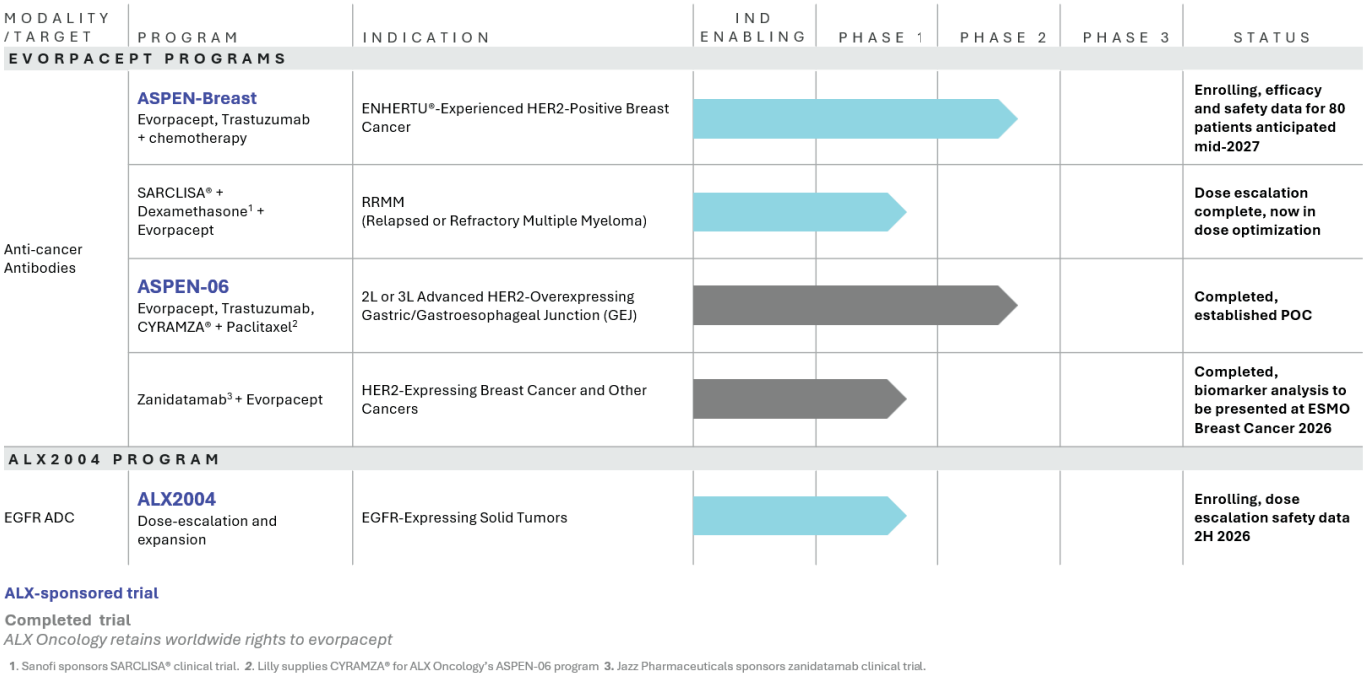
Key elements of our strategy to support this goal include:

- **Expanding the therapeutic potential of CD47 blockade by combining with anti-cancer antibodies.** We believe evorpacept can overcome the limitations of other CD47 blocking approaches.
- **Developing a best- and first-in-class EGFR-targeted ADC.** We believe that our differentiated design of ALX2004 based on an affinity-selected matuzumab-derived antibody can overcome the toxicity challenges that limited the therapeutic window of earlier generation EGFR-targeted ADCs.

- **Continuing to develop strategic partnerships to broaden the potential impact of our current and future product candidates across patient populations.** In order to advance treatment options for the most patients, we have in the past and may in the future partner with other companies with complementary resources that will maximize the value of our current and future product candidates. Such partnerships may allow us to pair evorpacept and any future product candidates with other novel agents owned fully or in part by strategic partners. Partnerships may and will also help realize the full potential of our product candidates in markets where we are unlikely to pursue development or commercialization on our own. We intend to maintain significant economic interests in our product candidates and selectively consider partnership opportunities.

Pipeline

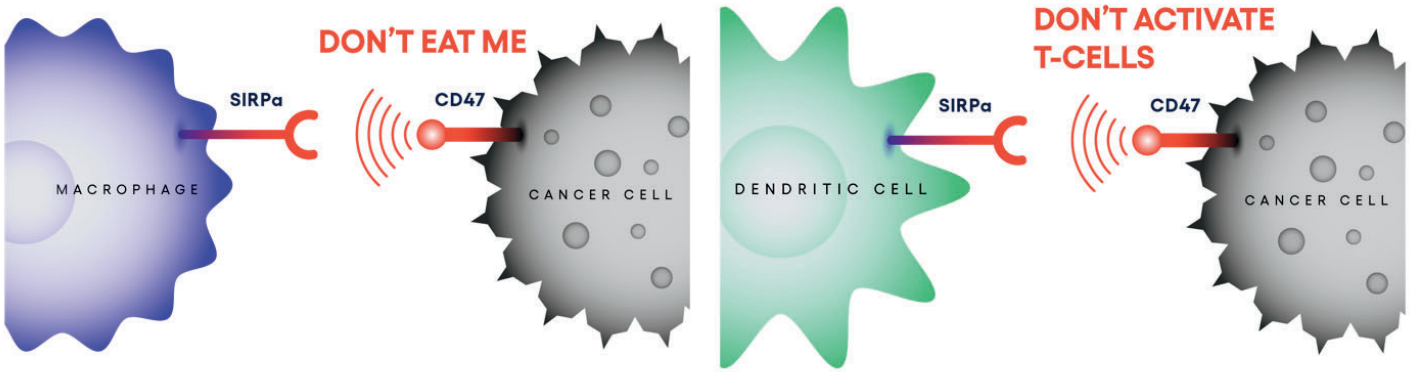
The chart below summarizes the development status of our product candidates pipeline.



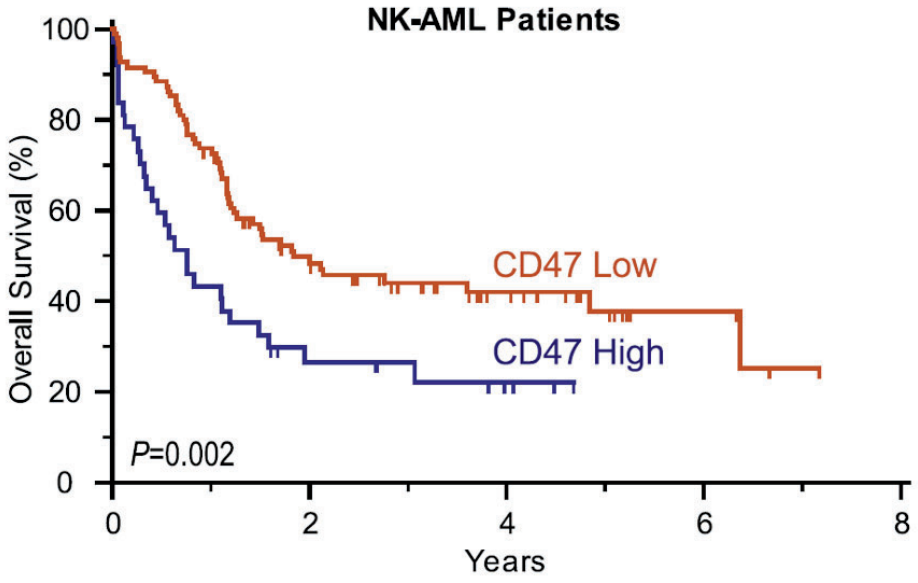
CD47 Scientific Background

Cancer immunotherapies targeting adaptive immune system checkpoints, notably those related to T cells, have transformed the standard of care in oncology across multiple cancer types. Initial clinical successes in this area have focused on stimulating the adaptive immune system. However, emerging evidence demonstrates that the innate immune system plays a crucial role in the first line of defense to eliminate transformed malignant cells and the subsequent activation of the adaptive immune system. Dendritic cells and macrophages are a type of myeloid cell and are important parts of the innate immune system. These cells eliminate cancer cells by phagocytosis and present tumor-derived antigens to T cells, a process known as cross-priming, which activates the adaptive immune system.

Cancer cells evade phagocytosis by up-regulating CD47, a transmembrane protein that mainly functions as an anti-phagocytic "don't eat me" signal for healthy cells. CD47 interacts with its cognate receptor SIRPα, a regulatory membrane glycoprotein, that is expressed on macrophages and other myeloid cells and serves to prevent phagocytosis ("don't eat me") and cross-priming of the adaptive immune system ("don't activate T cells") when bound to CD47. By overexpressing CD47, cancer cells are able to avoid phagocytosis by macrophages and thereby evade subsequent detection by the adaptive immune system.



High CD47 expression in cancer cells has been shown to be a prognostic indicator of decreased survival in multiple oncology indications. A study published by Majeti, et al. in 2009, assessed this association in a validation cohort of 137 subjects with acute myeloid leukemia, or AML. As shown in the figure below, normal karyotype AML, or NK-AML, subjects with high levels of CD47 expression had shorter mOS of 9.1 months compared to subjects with low levels of CD47 expression who had an mOS of 22.1 months.



Evorpacept's 1-2 Punch: Harnessing the Power of CD47 Blocking to Unmask and Directly Unleash Combination Agent on Cancer Cells

Data generated by our and other studies in the field have demonstrated that activating the immune system against cancer requires both blocking phagocytosis checkpoints and inducing pro-phagocytic signals. This can be achieved by combining CD47 blockade with either conventional chemotherapies or targeted therapies, which together promote phagocytosis by macrophages and maximize adaptive immune system response.

Therapeutic antibodies that target tumor-specific antigens, such as the HER2 receptor, also induce cellular phagocytosis. These antibodies direct macrophages to cancer cells by binding to the tumor-specific antigen and activating the macrophage by engaging the Fcγ receptors to induce phagocytosis. However, if CD47 is not blocked, the "don't eat me" signal can limit the activity of this mechanism. CD47 blocking therapies can therefore maximize a combination agent's clinical efficacy by overcoming the "don't eat me" signal that is co-opted by cancer cells.

Limitations of Prior Approaches to Blocking CD47 by Companies Other than ALX Oncology

There have been a number of approaches to blocking CD47 by companies other than ALX Oncology, including monoclonal antibodies and fusion proteins that include an active Fc region. These approaches have encountered limitations that have challenged their ability to maximize the full potential of CD47 blockade.

The majority of clinical data to date from other CD47 blocking agents come from drug candidates that incorporate an active Fc region that provides an "eat" me signal to macrophage. We believe that using an active Fc region in a CD47 inhibitor limits the therapeutic window of these approaches. Given that healthy blood cells express CD47, providing a pro-phagocytic "eat me" signal while simultaneously blocking CD47, it can lead to the destruction of healthy cells. Clinical trials of CD47 blocking agents with active Fc domains have shown frequent occurrences of treatment-related cytopenias that we believe are caused by this drug design choice.

The majority of clinical data to date from other CD47 blocking agents have come from approaches that incorporate an active Fc region that provides an "eat me" signal to macrophages. Given that healthy blood cells express CD47, the presence of an "eat me" signal coupled with CD47 binding in a single-agent leads to destruction of blood cells. This mechanism is illustrated in the figure below. The trials of these other CD47 blocking agents have resulted in frequent occurrence of treatment-related cytopenias that we believe limits the therapeutic window of these agents. In addition to limiting the dosing, cytopenias can be dangerous for patients undergoing treatment for cancer as they may already have a compromised immune system related to intensive treatment regimens and disease progression.

Advantages of ALX's Approach to Blocking CD47

We founded ALX Oncology because we believed the limitations described above would prevent CD47 blockade from reaching its full potential as a therapy for patients with cancer. From our inception, we designed evorpacept to overcome these limitations and to maximize the utility of CD47 blockade as an effective anti-cancer therapeutic for a broad range of tumors. Specifically, we believe evorpacept may provide the following significant advantages:

- **Broader therapeutic window**: We believe evorpacept's broader therapeutic window will allow for greater drug exposure than other CD47 blocking agents potentially translating into improved efficacy across a range of cancers compared to other CD47 blocking agents. Furthermore, flexibility in dosing has allowed for several administration schedules (weekly, bi-weekly, every three weeks, monthly) that are more amenable to combination therapy dosing schedules.
- **Strong potential for combination with other anti-cancer agents**: CD47 blocking agents are combined with other therapeutics in order to maximize their potential in treating patients with cancer. Unlike other CD47 blocking agents, evorpacept was specifically designed to be combined with other anti-cancer agents. We believe evorpacept's favorable toxicity profile will enable it to be combined with a wider range of anti-cancer agents, including anti-cancer antibodies, chemotherapy and cytotoxic containing regimens, compared to other CD47 blocking agents. Furthermore, we believe that evorpacept's inactive Fc domain will neither compete with nor potentially limit the efficacy of anti-cancer antibodies when used in combination treatments.
- **Targeted immune-oncology development**: Biomarker analyses completed in 2025 and 2026 from clinical trials in with evorpacept combination treatments support the use of CD47 expression as a predictive biomarker for evorpacept activity. We believe that a biomarker-driven approach incorporating CD47 expression may optimize patient selection for evorpacept combinations in subsequent development.

- **Broader potential indications**: We believe evorpacept's tolerability profile will allow for broad treatment of patient populations in a wide range of oncology indications. Toxicities such as cytopenias associated with other CD47 blocking agents may potentially constrain their development strategies. We believe evorpacept is well positioned to expand the therapeutic potential of CD47 blockade across a broad spectrum of hematologic and solid tumor indications.

Evorpacept

Our lead product candidate, evorpacept, is a CD47 blocking biologic in development as a combination therapy with other anti-cancer agents for treatment of various oncology indications, including gastric/GEJ, breast cancer, multiple myeloma, and NHL. We engineered evorpacept to maximize CD47 blockade and to avoid hematologic toxicities. We believe evorpacept enhances the efficacy of both anti-cancer targeted antibodies, numerous small molecule drugs and T cell checkpoint inhibitors and exhibits no dose-dependent cytopenias. Evorpacept has demonstrated encouraging clinical responses in combination with multiple anti-cancer regimens for both hematologic and solid malignancies.

Other companies have pursued CD47 blocking approaches that prioritize single-agent activity, albeit with limited success in efficacy and significant toxicity. Rather than designing a molecule for monotherapy activity that has been associated with cytopenias, we designed evorpacept for use in combination with anti-cancer agents. Our product candidate exclusively blocks the "don't eat me" pathway. A combination anti-cancer agent provides a specific pro-phagocytic signal on cancer cells. This approach may both increase the specificity to cancer cells and avoid dose-dependent destruction of healthy blood cells.

Fusion Protein Design

Evorpacept is a fusion protein designed to provide a high CD47 blocking potency while potentially eliminating any associated toxicities. Our fusion protein comprises an engineered CD47-binding domain of SIRPα that has been genetically linked to a modified human immunoglobulin-derived Fc domain that does not bind to Fcγ receptors. We engineered evorpacept in two important ways:

- We mutated the binding domain to optimize CD47 affinity. Evorpacept binding domain demonstrates an affinity that is over 3,000 times stronger than wildtype SIRPα.
- We fused the CD47-binding region of SIRPα to an inactive Fc domain. Incorporating an inactive Fc domain was intended to eliminate single-agent activation of macrophages while still maintaining an antibody-like pharmacokinetic, or PK, profile.

The successful design of evorpacept required in-house generation of approximately 280 different protein constructs to thoroughly evaluate and optimize the impact of differing designs on multiple important evaluation criteria.

In order to optimize evorpacept's properties we conducted the following processes:

Design of the high-affinity CD47 binding domain:

- Optimization of binding affinity for human CD47;
- Optimization of cross-reactivity to rodent and monkey CD47 to enable key translational experiments; and
- Elimination of partially glycosylated sites in SIRPα to remove heterogeneity and enable consistent manufacturing.

Design of the optimal fusion combination for PK extension:

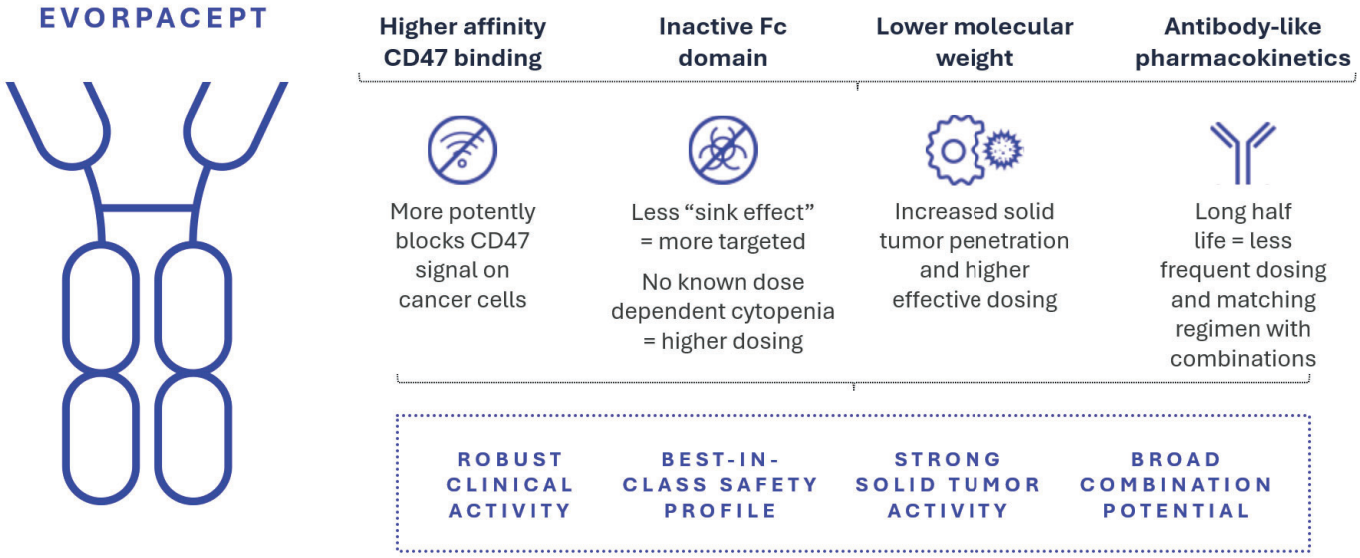
- Selection of an immunoglobulin isotype to prevent hemagglutination; and
- Selection of mutations to immunoglobulin G1, or IgG1, to functionally eliminate Fcγ binding and avoid associated cytopenias while maintaining neonatal Fc receptor binding that enables antibody-like PK.

As illustrated in the figure below, evorpacept comprises:

- A SIRPα binding domain optimized to bind to CD47 with high affinity at a picomolar level; and
- An inactive Fc domain that reduces cytopenias while preserving the desired PK properties of antibodies with an active Fc domain.

The resulting fusion protein has approximately one-half the molecular weight of a typical antibody. Evorpacept's lower molecular weight enables it to deliver the molar equivalent of an antibody at one half the dose. For example, a 10mg/kg of evorpacept is equivalent to 20 mg/kg of a regular antibody. Evorpacept's lower molecular weight may also facilitate increased solid tumor penetration and provide greater potency within the tumor microenvironment. Furthermore, evorpacept can be efficiently and consistently produced at high yield at commercial scale utilizing standard monoclonal antibody manufacturing techniques. We believe evorpacept's differentiated properties potentially overcome the limitations of other CD47 blocking agents and may have utility as a combination agent in oncology.

Our lead candidate, evorpacept, is a fusion protein that potently and selectively binds CD47 to block the SIRPα interaction.



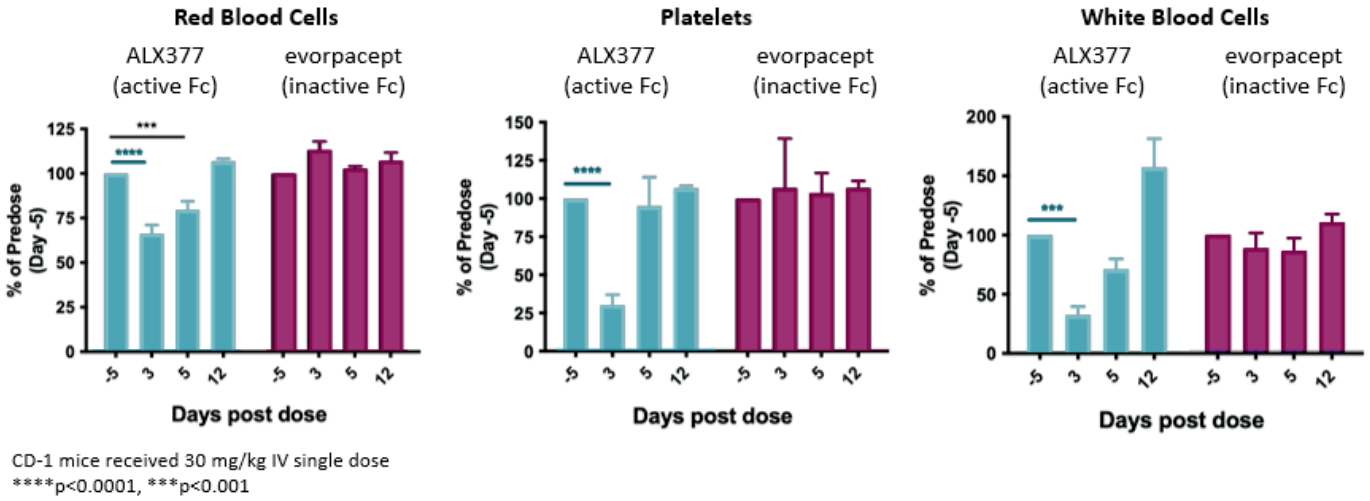
Pre-Clinical Differentiation

Our preclinical studies of evorpacept support a target product profile of favorable tolerability, the ability to be dosed at high levels and increased anti-tumor activity as compared to other CD47 blocking agents. These data include the following:

Lack of hematologic side effects

Our preclinical data demonstrate that CD47 blocking agents with an active Fc domain directly cause adverse hematologic side effects. To support this hypothesis, we engineered a fusion protein with a SIRPα CD47-binding domain identical to evorpacept's binding domain but fused to an active, wild-type IgG1 Fc domain, ALX377. We administered 30 mg/kg evorpacept and 30 mg/kg ALX377 in mouse models and measured red blood cell, or RBC, platelet and white blood cell (lymphocyte, monocytes and granulocytes) counts. As shown in the figure below, mice treated with evorpacept having an inactive Fc domain showed blood count levels that were similar to the pre-dose baseline. In contrast, mice treated with ALX377 having an active Fc domain showed average decreases of 34% in RBC count, 70% in platelet count and 67% in white blood cell count three days post-dosing as compared to baseline counts.

The inactive Fc domain on evorpacept is responsible for improved hematologic tolerability in preclinical models.

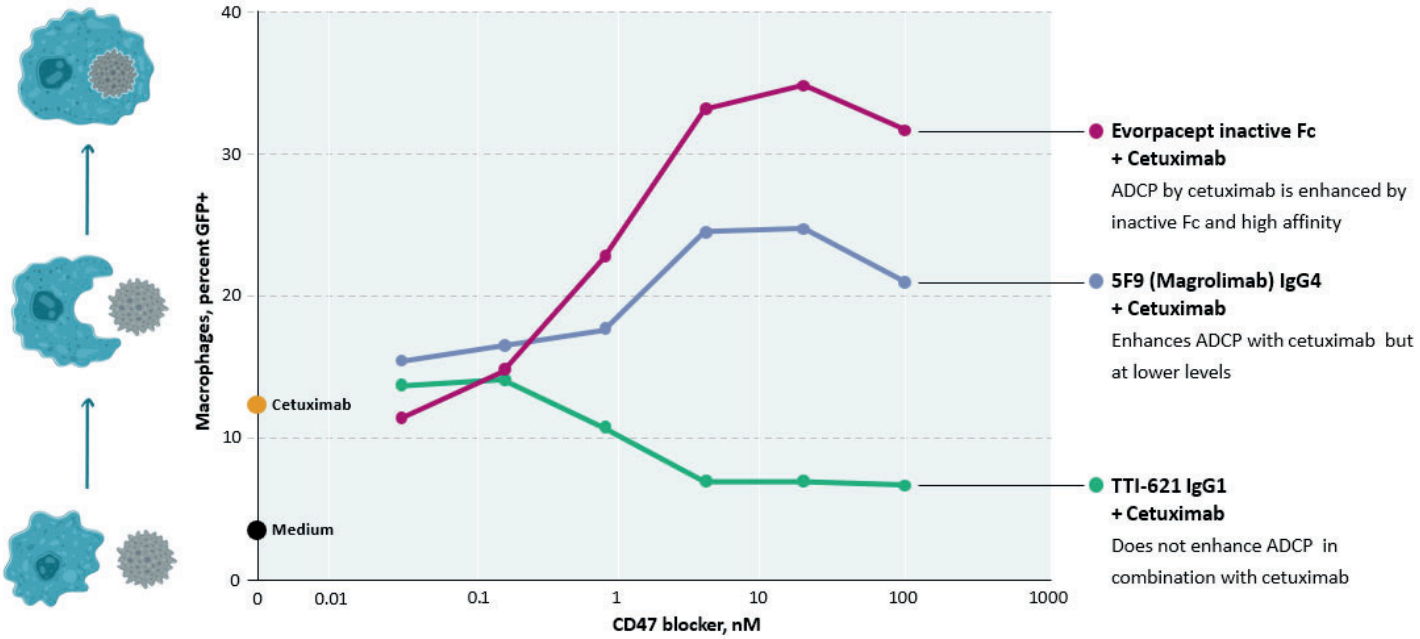


In vitro and in vivo toxicology studies in monkeys show that evorpacept was well-tolerated at intravenous doses of up to 100 mg/kg/week in the 1-month study and up to 30 mg/kg every other week in the 3-month study with no target organ toxicity or toxicity related to the exaggerated pharmacology of evorpacept. Together, these preclinical studies demonstrate that inactivation of the Fc domain of evorpacept avoids adverse effects on normal blood cells seen on other CD47 blocking agents with an active Fc domain. They also support our expectation that evorpacept's lack of overlapping toxicities with other anti-cancer therapies may result in fewer adverse outcomes in the clinic when combined with these therapies than combinations with conventional CD47 blocking agents.

Evorpacept elicits superior phagocytosis in combination with anti-cancer antibodies

The inactive Fc of evorpacept does not compete with the active Fc domain of other therapeutic antibodies for binding with Fcγ receptors on effector cells of the immune system. This fact, coupled with the high-affinity CD47 binding of our agent, results in enhanced phagocytosis from evorpacept in combination with other anti-cancer antibodies to a greater extent than other CD47 blockers. We believe this will allow us to explore evorpacept in combination with a higher number of leading anti-cancer antibodies compared to other CD47 blocking agents in both hematologic malignancies and solid tumors. In order to investigate the potential effects of the Fc domain and CD47 binding affinity on phagocytic activity, we produced two CD47 blocking agents with either an IgG4 or IgG1 active Fc domain, based on published sequences from two other clinical CD47 blockade programs. We combined these agents and evorpacept with cetuximab, an epidermal growth factor receptor, or EGFR, inhibitor that is the FDA approved for several solid tumors, to assess phagocytic activity as compared to single-agent cetuximab. Both cetuximab and the active Fc domain of a CD47 blocking agent bind to the same cell surface Fcγ receptors on a macrophage, potentially creating competition. IgG1 binds to receptors with higher affinity than IgG4 does, and evorpacept's inactive Fc does not bind. This experiment shows that CD47 blocking agents with active Fc domains and lower affinity, combined with cetuximab result in lower phagocytic activity from macrophages as compared to evorpacept with cetuximab. This experiment suggests evorpacept, the only clinical CD47 blocking agent with an inactive Fc domain and high-affinity CD47 binding, may be unique in its anti-tumor activity when combined with anti-tumor antibodies.

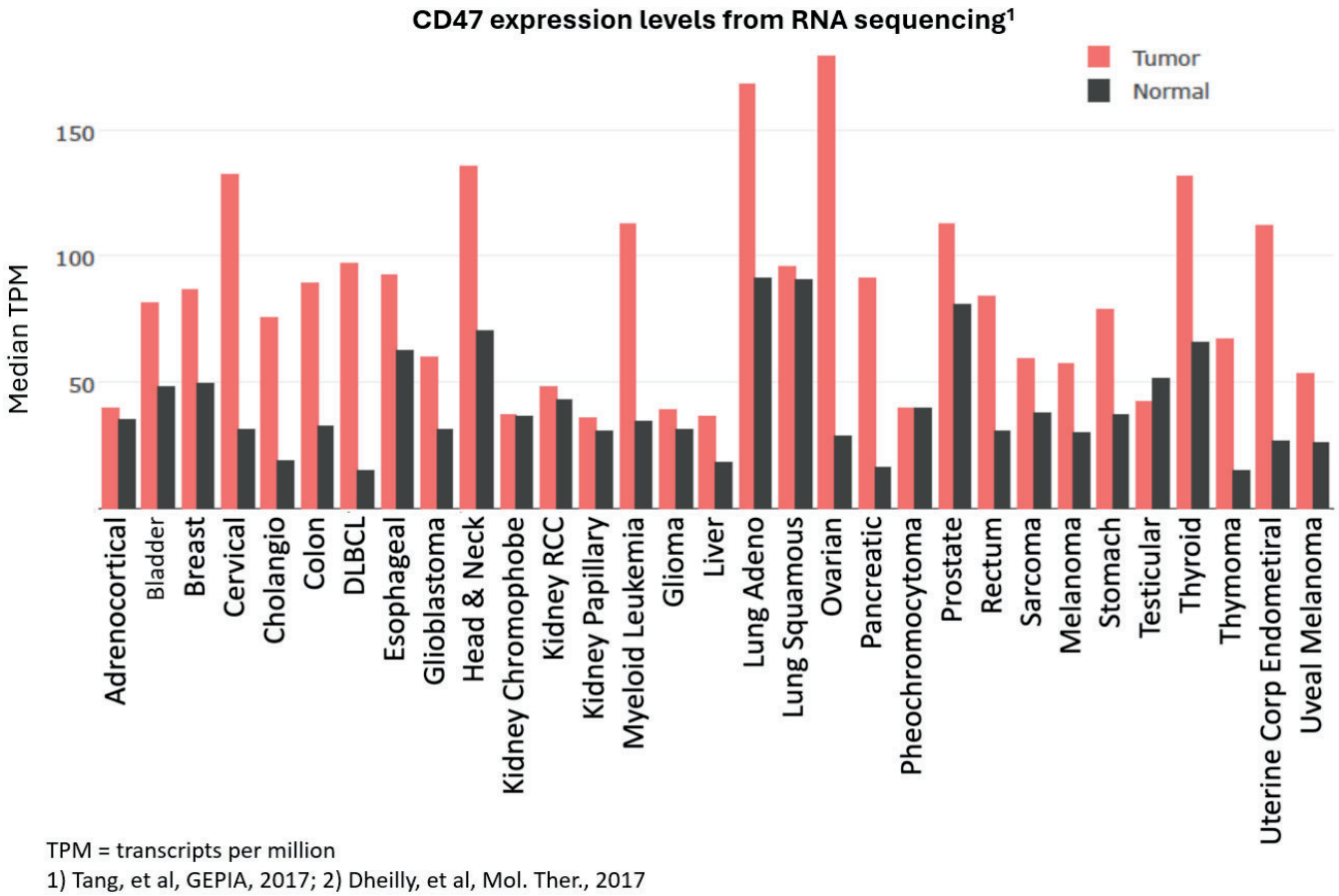
Evorpacept has shown superior antibody-dependent cellular phagocytosis, or ADCP, of solid tumor cells compared to CD47 blockers with an active Fc domain and lower CD47 affinity when combined with an anti-tumor antibody.



ALX2004 scientific background: ADC target selection

EGFR is a transmembrane protein in the ERBB family of receptor tyrosine kinases that consists of EGFR (HER1), HER2, HER3, and HER4 and is over expressed in many cancer types. It is also expressed in normal tissues, but often to a lesser degree. It plays a prominent role in tumor initiation and growth through dysregulation of cell proliferation, differentiation, metabolism, and cell death. Cancers survive and proliferate through aberrant overexpression of and mutational activation of EGFR. Therefore, EGFR has been an attractive target for cancer therapies.

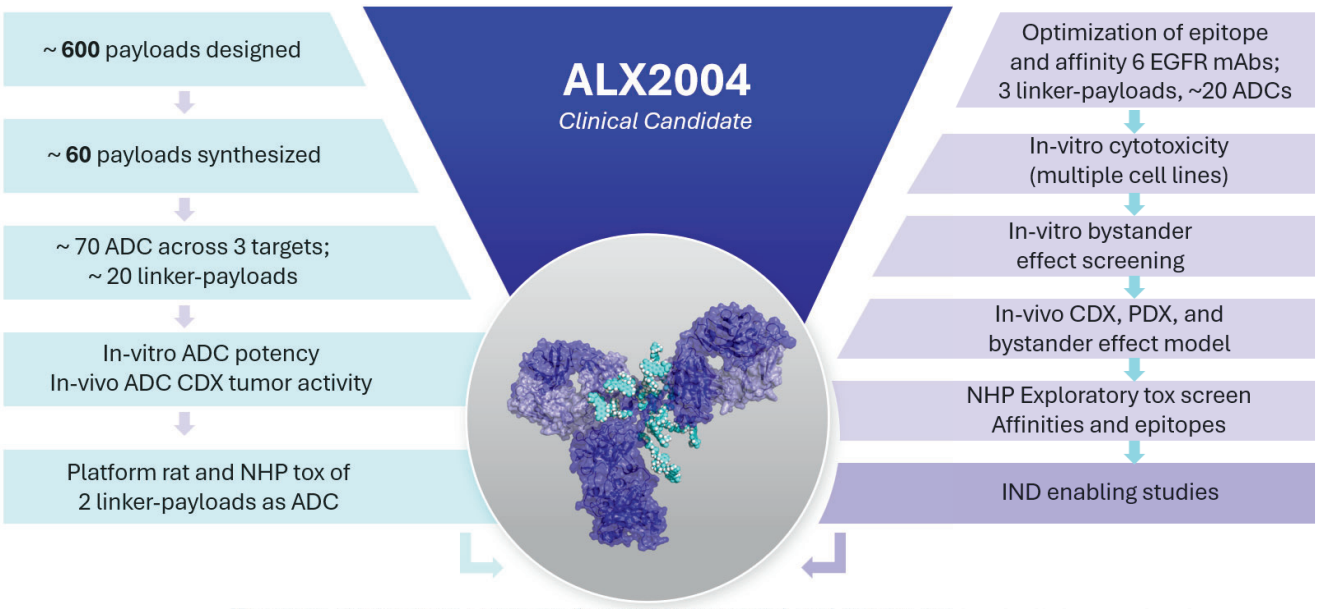
EGFR is a commercially validated antibody target with multiple FDA approved EGFR-targeted antibodies include cetuximab (ERBITUX®) and panitumumab (VECTIBIX®) in addition to several small molecules. However, there are no FDA approved EGFR-targeted ADCs. Earlier generation attempts at anti-EGFR ADCs failed to find a therapeutic window.



EGFR gene expression levels from RNA sequencing. ALX2004 Phase 1 trial includes patients with colorectal cancer, esophageal carcinoma, head and neck squamous cell carcinoma, and lung cancer. Source: GEPIA http://gepia.cancer-pku.cn/

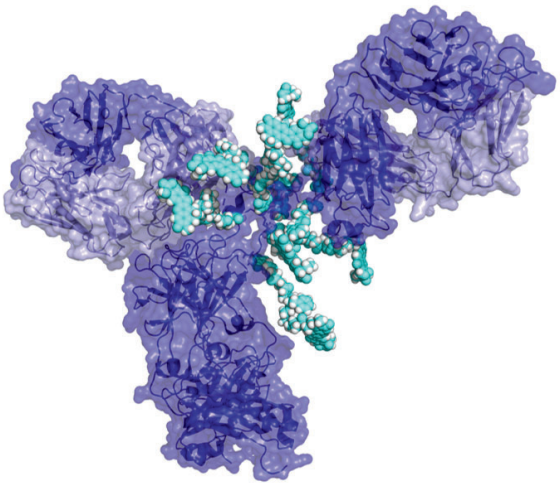
ALX2004 design process and drug candidate selection

ALX2004 was developed in-house by ALX Oncology protein engineers and designed to maximize potential success based on a rigorous optimization and drug candidate selection process. The ALX2004 linker-payload was selected from a starting point of 600 payloads designed *in silico* with 60 topoisomerase I inhibitor payloads subsequently synthesized and tested in lab, which are now part of the ALX ADC library. From this payload library, we generated and tested 70 ADCs across 3 solid tumor antigen targets and 2 ultimately tested in rat and non-human primate (NHP) toxicity studies leading to the final linker and Top1i payload selection for ALX2004.



IP covers proprietary compounds comprising novel and unique payloads, linker-payloads, ADCs and their composition of use

The anti-EGFR antibody for ALX2004 was also selected after a rigorous development process. Six different anti-EGFR antibodies with varying EGFR binding epitopes and binding affinities were tested. The goal of this process was to select an antibody that minimized off-tumor EGFR-related toxicity while maintaining an active therapeutic window. ALX2004 was the culmination of this development process. As part of this process, we also generated a proprietary library of potential ADC payloads for future drug candidates.



ALX2004

EGFR-targeted ADC
DAR 8 topoisomerase I
inhibitor payload (Top1i)

EGFR antibody:
Matuzumab-derived EGFR antibody selected to minimize off-tumor skin toxicity and to maximize therapeutic window

Epitope distinct from that of FDA-approved EGFR antibodies

Proprietary linker-payload:
Lysosomal cleavage like deruxtecan ADCs with improved linker-antibody stability to minimize off-tumor payload release

Proprietary Top1i payload, DAR 8:
Top1i with similar direct cytotoxic potency and enhanced bystander activity compared to deruxtecan

ALX2004 is designed using lessons learned from past attempts at EGFR-targeted ADCs

Several EGFR-targeted ADCs have previously entered clinical trials including depatuxizumab mafadotin, serclutamab talirine, and AMG595. Depatuxizumab mafadotin used a monomethyl auristatin F (MMAF) payload. Serclutamab talirine used a pyrrolobenzodiazapene (PBD) payload. AMG595 used a maytansinoid (DM1) payload. We believe the primary reason these drugs did not reach FDA approval was due to the toxicity profiles of these payload classes and not because they were EGFR-targeted. Consequently, we designed ALX2004 with a topoisomerase 1 inhibitor payload.

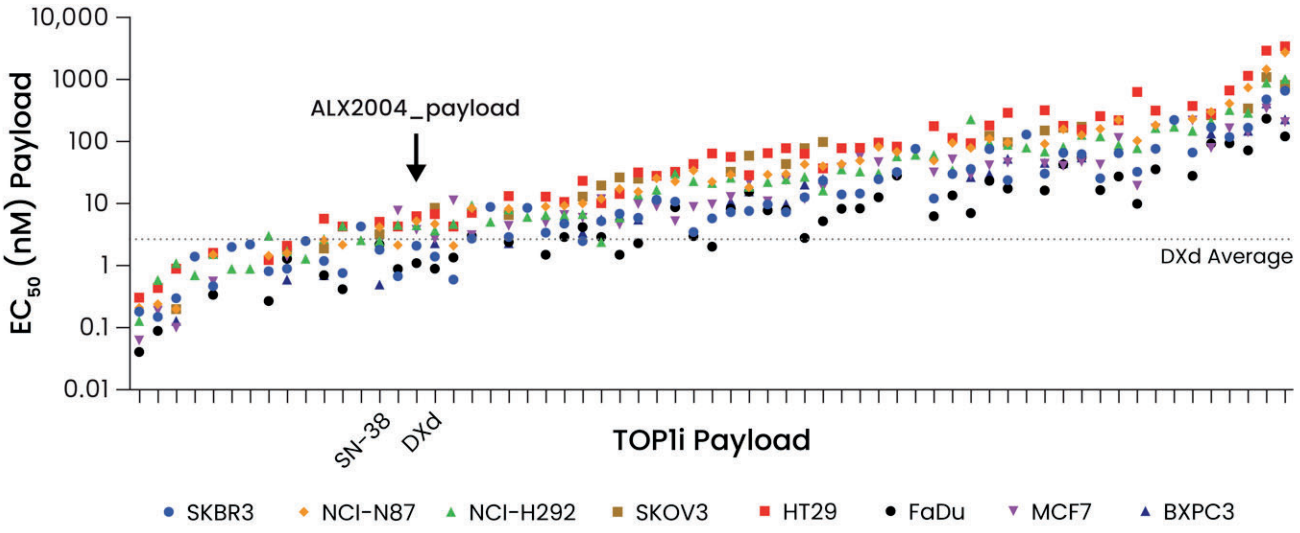
We further aimed to maximize the likelihood of technical success by using a matuzumab-derived anti-EGFR antibody with an affinity selected to minimize on-target, off-tumor skin toxicity. We believe that using a matuzumab-derived antibody increases the likelihood of finding a clinically meaningful therapeutic window. Additionally, matuzumab binds an EGFR epitope that is distinct from other FDA-approved antibodies. Consequently, patients who developed resistance to cetuximab or panitumumab due to mutations in the EGFR extracellular domain, may still be sensitive to ALX2004. This is important for establishing activity during early stage trials in EGFR-expressing tumors where patients may have been previously treated with EGFR-targeted antibodies.

ALX2004 linker payload selection: 600 payloads designed with 60 payloads synthesized and screened

We first designed 600 Top1i payload candidates in silico from which we synthesized and conducted in vitro screening for over 60 novel ALX Top1i payloads across 8 tumor cell lines each and benchmarked potentcy against two Top1i payloads from approved ADCs – SN38 (payload for TRODELVY®) and deruxtecan (payload for ENHERTU®).

Next, 14 payload candidates were selected for testing as full ADCs based on their cytotoxicity and membrane permeability. Each payload was conjugated to ALX's proprietary linker, tested for in vitro activity against 6 tumor cell lines, and benchmarked against the deruxtecan payload. The ALX2004 linker-payload was selected for its consistent potency across these models, relatively high membrane permeability, and comparable activity to the deruxtecan benchmark.

Additionally, this process generated a library of ALX proprietary Top1i payload candidates with a range of potencies and varying properties such as ability to permeate cell membranes as a free payload. Relatively high membrane permeability may improve bystander effect cell killing; whereas low permeability may greatly decrease or eliminate the bystander effect.



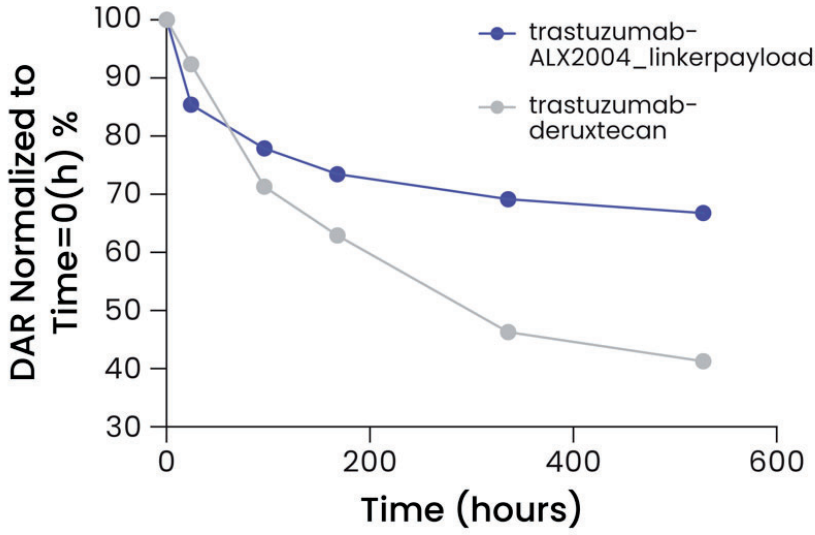
Cytotoxicity EC_{50}(nM) of synthesized TOP1i payloads robustly tested in eight cancer cell lines and compared to SN-38 (govitecan payload) and DXd (deruxtecan payload). Each x-axis tick corresponds to a payload. The arrow marks ALX2004_payload. The dashed lines show the average EC_{50} (nM) of DXd across cell lines.

ALX2004 shows improved stability compared to deruxtecan benchmark

The ALX2004 linker was designed to improve stability of the ADC in circulation in order to minimize off-tumor linker-payload release. Enhanced stability should both decrease off tumor toxicity and increase the amount of payload that is being delivered to the tumor. Deconjugation of the linker payloads from their antibody in circulation remains a challenge and may lead to increased toxicity.

In order to benchmark our lead linker-payload candidate's stability, we conducted a head to head comparison against deruxtecan in non-human primates. We conjugated the ALX2004 linker-payload to trastuzumab (a HER2-targeted antibody) in order to make a direct comparison to trastuzumab deruxtecan. We then compared drug antibody ratios, or DAR, of the drugs in circulation over time. An ADC's DAR is a measurement of how many payloads are conjugated to the antibody. Decreasing DAR over time in circulation indicates that payload has deconjugated from the antibody in a non-targeted way thereby potentially increasing toxicity.

The ALX linker-payload demonstrated superior stability and maintained a higher conjugation level, as indicated by DAR, in circulation over time. These data suggest that ALX2004 may deliver more payload to tumors while limiting exposure to healthy tissues due to decrease in linker-payload deconjugation.



Improved DAR stability of ALX2004_linkerpayload compared to deruxtecan. Graph shows DAR of two ADCs: trastuzumab conjugated to ALX2004_linkerpayload (DAR ~8) and trastuzumab conjugated to deruxtecan (DAR ~8), as a function of time in non-human primate (NHP) dosed at 30 mg/kg (n=2 per group). DAR was analyzed using reduced middle-down RP-LCMS.

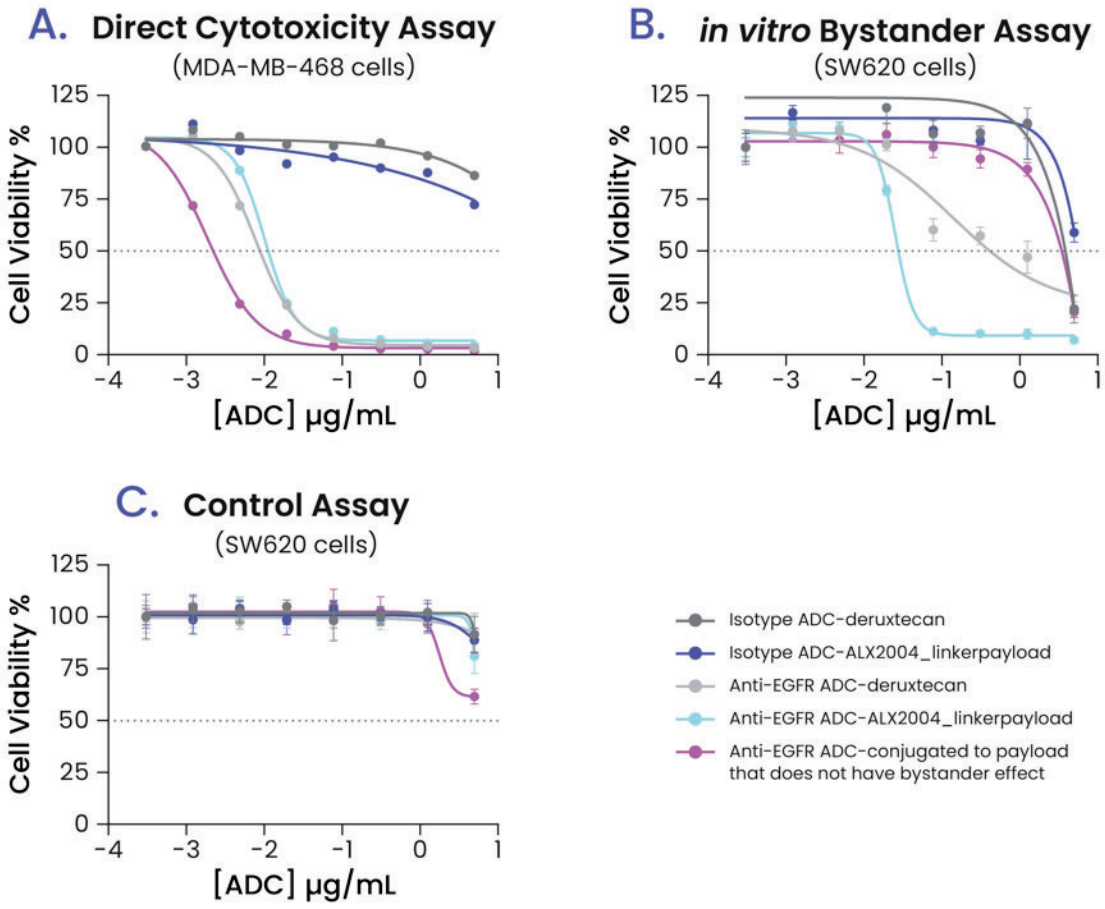
ALX2004 shows comparable direct cell killing and improved bystander effect relative to deruxtecan comparator

ALX2004 was tested in several EGFR-expressing mouse models against a deruxtecan-based ADC comparator generated in-house. These tests showed that ALX2004 matched or exceeded the activity of the deruxtecan comparator ADC both in terms of direct cell killing and bystander effect.

The bystander effect is thought to be an important mechanism of cell killing in solid tumors for ADCs. The bystander effect begins when an ADC binds to its target on the cell surface and is internalized into the cell. Payload is then released within the target-expressing cell which results in the direct killing of the target-expressing cell. For some ADCs, the released payloads are then able to permeate into neighboring cells regardless of whether or not target is expressed killing those neighboring cells as well. In heterogenous solid tumors, it is potentially an important mechanism for tumor control as it results in the killing of both target expressing tumor cells and non-target expressing tumor cells in the tumor microenvironment.

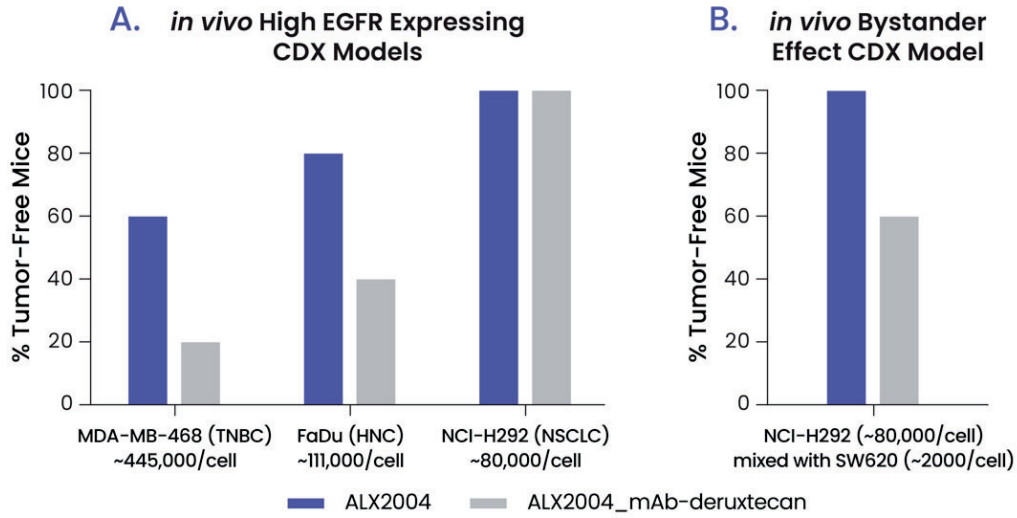
We selected the ALX2004 payload from the over 60 we synthesized in part because we believed it could have enhanced bystander effect relative to deruxtecan due to the membrane permeability testing we conducted. In order to compare ALX2004's direct cell killing and bystander effect to deruxtecan, we synthesized an ADC using the ALX2004 anti-EGFR antibody conjugated to the deruxtecan linker payload.

First, we tested the ALX2004 and deruxtecan comparator ADC in a cell-based bystander assay. As shown below, ALX2004 had comparable direct cytotoxicity (A) and improved bystander killing (B).



We then compared the potency of ALX2004 in several EGFR-expressing mouse models (A below) and a bystander effect model (B below) to the deruxtecan based comparator ADC.

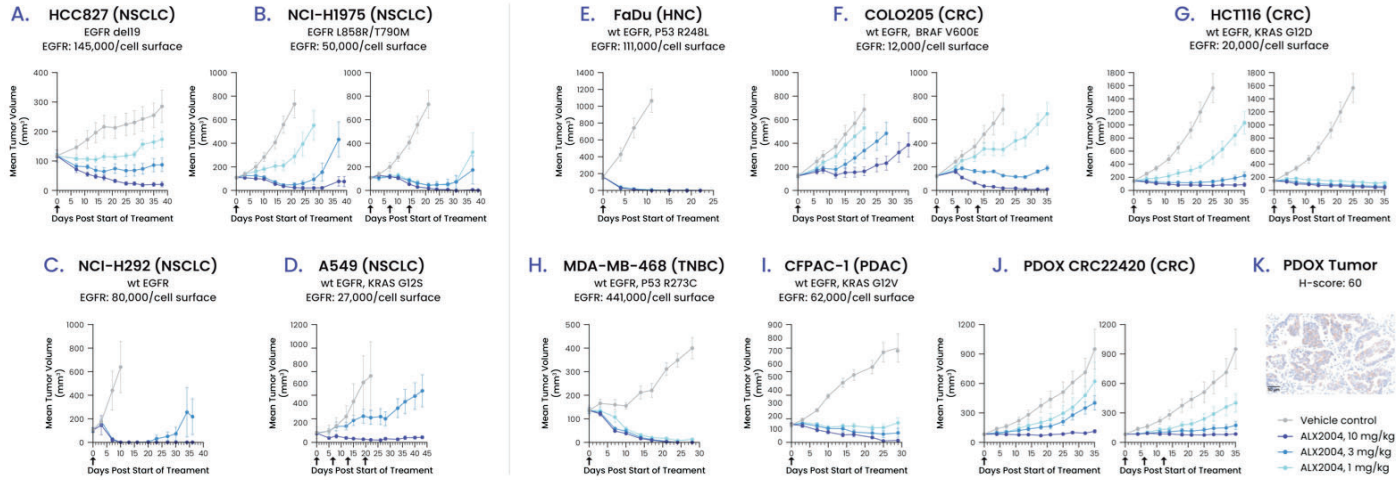
Across multiple mouse models with varying levels of EGFR expression level, ALX2004 demonstrated equivalent or superior tumor eradication as shown by the percent of mice in which tumors were completely eradicated. ALX2004 outperformed the deruxtecan comparator in a bystander effect model that contained both EGFR high expressing and EGFR ultra-low expressing cancer cells.



*Percent of tumor-free mice in CDX models dosed with ALX2004 or ALX2004_mAb-deruxtecan (ADC composed of ALX2004's antibody conjugated to deruxtecan) (both ADCs, DAR ~8). (A) MDA-MB-468 (3 mg/kg, 1 dose), FaDu (1 mg/kg, 3 doses, Q1W), NCI-H292 (3 mg/kg, 3 doses, Q1W), (**B**) Bystander effect CDX model composed of 1:1 NCI-H292 cells (~80,000 EGFR/cell surface) and SW620 cells (~2000 EGFR/cell surface) dosed 3 mg/kg, 3 doses, Q1W. NOD SCID mice, n=5 per group.*

ALX2004 showed tumor suppression across a range of cancer types and target expression levels

We tested ALX2004 in vivo anti-tumor activity in mouse models representing a range of commercially relevant EGFR-expressing tumor types, EGFR-expression levels, and common mutations. ALX2004 inhibited tumor growth in non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), CRC, triple negative breast cancer (TNBC), and pancreatic ductal adenocarcinoma (PDAC) mouse models. These models also show ALX2004's activity in models harboring KRAS, BRAF, and P53 mutations. Importantly, tumor growth inhibition was seen at all levels of EGFR-target expression ranging from 12,000 units/cell surface to over 400,000 units/cell surface.



*ALX2004 has inhibited tumor growth in vivo. Tumor volume (mm^3) after IV administration of a single dose or three doses of ALX2004 at indicated dose levels (mg/kg) and dosing frequencies in CDX mouse models of NSCLC (**A-D**) and other EGFR-expressing tumors (**E-J**): (**A**) HCC827, (**B**) NCI-H1975, (**C**) NCI-H292, (**D**) A549, (**E**) FaDu, (**F**) COLO205, (**G**) HCT116, (**H**) MDA-MB-468, (**I**) CFPAC-1, (**J**) PDOX model CRC22420. Dosing frequency indicated by black arrows. Data represented as mean ± SEM, (**A-B**, **E-J**) n=12 per group, NU/NU mice, (**C-D**) n=5 per group, NOD SCID mice. (**K**) Representative IHC staining of EGFR in PDOX tissue. wt refers to EGFR wild-type tyrosine kinase domain.*

GLP toxicity study in non-human primates supports ALX2004 design for improved therapeutic window

The toxicity and toxicokinetic profile of ALX2004 was evaluated in a 6-week repeat-dose (Q3W dosing) GLP toxicity study in monkeys, at doses of 5, 10, and 20 mg/kg. No dose-limiting major target organ toxicity, including on-target toxicity (i.e., skin or other EGFR-expressing cells), was observed. Furthermore, there was no evidence of ILD which is a concern for some Top1i-based ADCs. The no observable adverse event level (NOAEL) was 10 mg/kg and the highest non-severely toxic dose (HNSTD) was 20 mg/kg. All findings were minimal to moderate and fully recoverable.

These findings in addition to the rest of the preclinical data package for ALX2004 allowed us to start at a 1 mg/kg dose level in ALX2004's first-in-human clinical trial.

ALX2004 first-in-human study is in patients with EGFR-expressing solid tumors

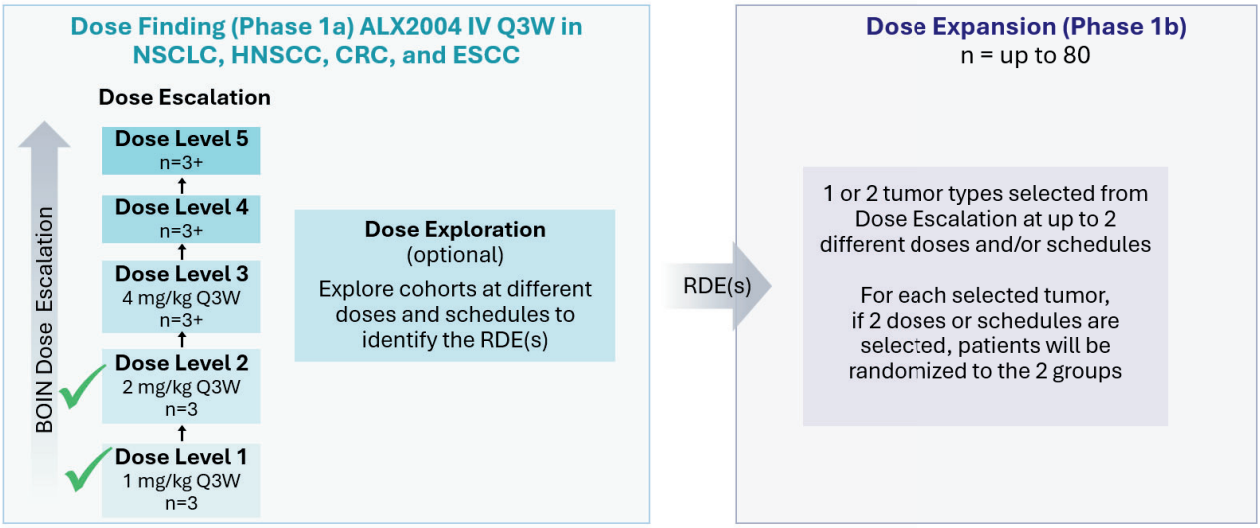
We designed ALX2004's Phase 1 study to maximize both efficiency and the probability of technical success by selecting tumor types with the following characteristics:

- EGFR expression
- Sensitivity to topoisomerase I inhibitors
- Sensitivity to EGFR-targeted antibodies

By evaluating tumor types on these criteria, we selected NSCLC, HNSCC, CRC, and esophageal squamous cell carcinoma (ESCC) as eligible tumor types for the dose finding portion of the Phase 1 trial. Importantly, this group of tumor types represents a significant unmet need with over 450,000 patients living with these tumors in the metastatic stage in the US alone.

The study consists of a Phase 1a dose escalation portion followed by optional dose exploration, and a Phase 1b dose expansion. The dose escalation portion of the trial is enrolling patients with previously treated NSCLC, HNSCC, CRC, and ESCC.

The first patient was dosed in this trial in August 2025. As of January 2026, the first two dose levels had been cleared with no dose-limiting toxicities. Initial safety data is anticipated in the first half of 2026.



Licensing and Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, novel discoveries, product development technologies and knowhow and to operate without infringing on the proprietary rights of others. We seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and related components, their methods of use and processes for their manufacture and any other inventions that are commercially important to our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position.

As of January 4, 2026, we own 11 issued U.S. patents, 86 foreign issued patents, 9 pending U.S. nonprovisional patent applications and a portfolio of national patent application filings in a variety of non-U.S. jurisdictions, including Europe, Hong Kong, Brazil, Mexico, New Zealand, Japan, Australia, Canada, China, India, Israel, Republic of Korea, Singapore, Taiwan and Russia. Of these patents and patent applications, the following relate to evorpacept: seven issued U.S. patents, six pending U.S. nonprovisional patent applications, and a portfolio of granted and pending patent filings in a variety of non-U.S. jurisdictions, including Europe, Hong Kong, Brazil, Mexico, New Zealand, Japan, Australia, Canada, China, India, Israel, Republic of Korea, Singapore and Russia. The following relate to antibody shielding technology and exatecan derivatives: one issued U.S. patent, three pending U.S. nonprovisional patent applications, and 49 pending foreign patent applications.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. Our 11 U.S. issued patents and, if issued as U.S. patents, our 8 U.S. nonprovisional patent applications are expected to expire between August 2036 and November 2043 excluding any additional term for patent term adjustments or patent term extensions, with an expiration of between August 2036 and May 2043 with respect to our patent and patent applications related to evorpacept, excluding any additional term for patent term extensions.

We obtained a worldwide, royalty-bearing, sublicensable license from the Board of Trustees of the Leland Stanford Junior University, or Stanford, under certain patents relating to high-affinity SIRPα variant polypeptides, to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. For more information regarding our license agreement with Stanford, please see "—Exclusive (Equity) Agreement with Stanford University."

The patent portfolio we have exclusively licensed from Stanford contains patent families relating to high-affinity SIRPα variant polypeptides, which includes three issued patents in the U.S. and one each in Australia, Canada, China, Europe, Hong Kong and four in Japan. The European patent has been validated as national patents in 37 different European countries. The patent family includes one pending patent application in each of U.S., Europe, and China and two pending patent applications in Hong Kong. These patents and patent applications are subject to retained rights by Stanford to allow academic and nonprofit research institutions to practice the licensed technology and patents for noncommercial purposes. In addition, these patents are subject to certain pre-existing rights that Stanford has granted to two third parties. These patents are expected to expire in 2033 excluding any extension of patent term that may be available.

We are aware of a European patent (EP 2 429 574) owned by UHN and The Hospital for Sick Children that relates to the treatment of hematologic cancers with polypeptides comprising soluble human SIRPα, or a CD47-binding fragment thereof. This patent was subject to European Patent Office opposition proceedings, which resulted in the patent being upheld in amended form.

Additionally, we are aware of a second European Patent (EP 2 995 315), a divisional of European patent (EP 2 429 574), granted to UHN and The Hospital for Sick Children. This patent relates to the eradication of hematological CD47+ cancer cells and tumors with polypeptides comprising soluble human SIRPα, or a CD47-binding fragment thereof. This patent was upheld as granted by the European Patent Office Opposition Division on November 28, 2025. This decision is currently under appeal.

The patent claims of both EP 2 429 574 and EP 2 995 315 could potentially limit our ability to pursue evorpacept in certain indications in certain territories in the EU in the future unless we obtain a license under these patents, these patents are determined to be invalid or unenforceable by the European Patent Office or a national court in one or more relevant territories, these patents are revoked or otherwise limited by the European Patent Office or a national court, or until these patents expire. A license may however not be available on commercially reasonable terms or at all. The U.S. counterpart to EP 2 429 574 was granted in 2021 as US patent 10,907,209. However, we believe that we do not infringe claims listed in this U.S. patent. Further, with respect to the development of our ALX2004 program, many companies have filed, and continue to file, patent applications related to antibody drug conjugates and components thereof that are similar to our approach. As the biotechnology industry expands and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products, if any, or impair our competitive position.

For more information regarding the risks related to our intellectual property, including the above referenced intellectual property proceedings, see "Risk Factors—Risks Related to Our Intellectual Property."

Exclusive (Equity) Agreement with Stanford University

In March 2015, we entered into a license agreement, or the Stanford Agreement, with The Board of Trustees of the Leland Stanford Junior University under which we obtained a worldwide, royalty-bearing, sublicensable license under certain patents relating to our current product candidates, to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. The license granted to us in the Stanford Agreement includes an exclusive grant, subject to certain pre-existing non-exclusive or exclusive rights that Stanford retained for grant to third parties with respect to certain categories of the licensed patents in certain fields of use and retained rights by Stanford and all other nonprofit institutions to use and practice the licensed patents and technology for internal research and other nonprofit purposes. The license granted to us in the Stanford Agreement also includes non-exclusive grants to certain Stanford patents.

In consideration for the rights granted to us under the Stanford Agreement, we paid Stanford a nonrefundable license royalty and reimbursed Stanford for past patent expenses, together totaling less than $0.1 million, and granted Stanford a specified number of our common stock. In addition, we are obligated to pay Stanford ongoing patent expenses and an annual license maintenance fee, which are nominal and will be creditable against any royalties payable to Stanford in the applicable year. We are required to make milestone payments up to an aggregate of $5.0 million in respect of a specified number of licensed products that successfully satisfy certain clinical and regulatory milestones. We recorded the first milestone payment of $0.2 million during the year ended December 31, 2021. There have been no milestones met during the year ended December 31, 2025. We also agreed to pay Stanford tiered royalties on a specified percentage of net sales made by us, our affiliates and our sublicensees of licensed products at rates ranging within low single-digit percentages, subject to certain reductions and offsets. Our license, on a licensed product-by-licensed product and country-by-country basis, shall become royalty-free and fully paid-up upon the later of the date on which the last valid claim included in the exclusively or non-exclusively licensed patents expires and ten years after the first commercial sale of the licensed product in such country.

We may terminate the Stanford Agreement, on a licensed product-by-licensed product basis, at any time for any reason by providing at least 60 days' written notice to Stanford. Stanford may terminate the Stanford Agreement if we are in breach of any provision of the Stanford Agreement and fail to remedy such breach within 60 days after written notice of such breach by Stanford. In addition, Stanford has the right to terminate the Stanford Agreement, on a licensed product-by-licensed product basis, if we are not

diligently developing and commercializing such licensed product under certain conditions or if we fail to achieve specified development milestones for such licensed product by certain dates, subject to our extension rights.

Other Third-Party Agreements

We have entered into license agreements with third parties related to the development and commercialization of our product candidates, including evorpacept, and SIRPα antibodies which we are exploring in our research program. In consideration of the foregoing, we have agreed to customary payment terms in these agreements, including certain milestone payments upon the achievement of clinical and commercial milestones and low single-digit royalties. See further details in Note 13 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Commercialization

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Manufacturing and Supply

We do not own or operate and do not intend to establish our own manufacturing facilities. We rely on, and will continue to rely on, CMOs for both drug substance and drug product. Evorpacept and ALX2004 bulk drug substance and finished drug product are produced in accordance with current good manufacturing practices, or cGMPs.

Our existing supply of evorpacept and ALX2004 is sufficient to complete our clinical trials through the first quarter of 2026. We plan to manufacture additional supplies with our existing CMOs to produce evorpacept and ALX2004 drug product sufficient to complete the ongoing and planned clinical trials described in this document. We first entered into an engagement with KBI Biopharma, Inc. in 2015 for evorpacept analytical method development, formulation development, bulk drug manufacturing, release and stability testing. We first entered into an engagement with Patheon Biologics LLC in 2022 for evorpacept bulk drug manufacturing and release testing. We first entered into a drug product manufacturing agreement with Lyophilization Services of New England, Inc. (now PCI Pharma Services) in 2016 for evorpacept drug product used in clinical trials. We subsequently entered into a drug product manufacturing agreement with Patheon UK Limited in 2022 for drug product production of evorpacept drug product used in clinical trials. We first entered into an engagement with WuXi Biologics and WuXi XDC in 2023 for ALX2004 analytical method development, formulation development, bulk drug manufacturing, drug product manufacturing, release and stability testing, used in clinical trials.

Competition

The development and commercialization of new product candidates is highly competitive. We face competition with respect to evorpacept and ALX2004, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immune-oncology therapies for the treatment of cancer. There are other companies working to develop immuno-oncology therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Newly approved therapeutics could change the treatment paradigm or standard of care, which could negatively impact the design of our clinical trials and the prospects of our product candidates.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, including with respect to the targeting of the CD47 pathway, targeting EGFR as an ADC target and others are based on entirely different approaches. We are aware that Adagene, Akesobio, Bio-Thera Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Byondis, Centessa, Conjupro Biotherapeutics, CTTQ (SinoBiological), Daiichi Sankyo, Exelixis, GenSci, Gilead Sciences (through its acquisition of Forty Seven), Hanchor Bio, Hisun, Hutchmed, I-Mab, Ichnos, ImmuneOncia Therapeutics, ImmuneOnco Biopharma, Innovent, Kahr, LaNova, Lightchain Bioscience, Mabwell Therapeutics, Mabworks, Novimmune, OSE Immunotherapeutics, Pfizer (through its acquisition of Trillium Therapeutics), Phanes, Pyxis Oncology (through its acquisition of Apexigen), Shandong New Time, Shattuck Labs, Sorrento Therapeutics, Sumgen, SunHo Pharmaceutical, TG Therapeutics, Waterstone, and Zai Lab, among others, are developing or have begun development of drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. We are also aware that AstraZeneca, BioNTech, Bristol Myers Squibb with Systimmune, CSPC, and Henlius, among others, are developing or have begun development of antibody drug conjugates targeting EGFR. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if evorpacept, ALX2004 and/or any of our other future product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology 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, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

Government Regulation

In the United States, the FDA, regulates biologic products under the Food, Drug, and Cosmetic Act, or FDCA, and Public Health Service Act, or PHSA. Biologic products and substances 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.

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

U.S. Biologics Regulation

Any future product candidates must be approved by the FDA through the BLA process before they may be legally marketed in the United States.

The process generally involves the following:

- Completion of extensive preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation.
- Submission to the FDA of an investigational new drug, or IND, application, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made.
- Approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced.
- Performance of adequate and well-controlled human clinical trials in accordance with the applicable IND regulations, good clinical practice, or GCP, requirements to establish the safety and effectiveness of the proposed biologic product candidate for its intended purpose.
- Compliance with PREA, BPCA and FDARA regarding development of certain molecularly targeted oncology drugs for pediatric use.
- Preparation of and submission to the FDA of a BLA.
- A determination by the FDA within 60 days of its receipt of a BLA to file the application for review.
- Satisfactory completion of any FDA audit of selected clinical trial sites that generated the data in support of the BLA.
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency.
- Satisfactory completion of an FDA Advisory Committee review, if applicable.
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.
- If necessary, FDA review and approval of the combination partner NDA/BLA to address any cross-labeling requirements to permit commercial marketing of the combination product for the particular indications for use in the United States.
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical and Clinical Development

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 require substantial time, effort and financial resources, and we cannot be certain that any approvals for any future product candidates will be granted on a timely basis, or at all.

The preclinical developmental stage generally involves laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, including pharmacology, PK, toxicokinetic and metabolism studies, that support subsequent clinical testing in humans. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new biopharmaceutical product to humans.

The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises any concerns or questions about the proposed clinical trial(s) and places the trial(s) on clinical hold. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the trial until completed. Regulatory authorities, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and 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, the clinical data are relevant to the US patient population in terms of medical practice, standard of care, and patient population definition, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. For biologics being studied in oncology indications, the investigational product is initially introduced into patients with a broader range of malignancies, and may later focus on the target disease or condition. These trials are generally designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, to identify possible side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks and additional information on PK and PD. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, purity and potency for an intended use, and generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. These trials usually include comparisons with placebo and/or other comparator treatments.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 trials may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must 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 candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process often includes multiple FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically 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 compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its biopharmaceutical substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our business and competitive advantage.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Management Strategy (REMS) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for Fast Track designation if they are intended to treat patients with a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat patients with a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a Fast Track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating patients with serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The Food and Drug Omnibus Reform Act 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.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat patients with a rare disease or condition, which is 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 for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In a 2021 court case, the court expanded the scope of orphan drug exclusivity by finding that orphan drug exclusivity applies to all uses or indications within an entire disease or condition. This position was in contrast to the FDA's longstanding view which ties the scope of orphan drug exclusivity to the uses or indications for which a drug is approved, and thus 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. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations.

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, such as market exclusivities, which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may lead to new policies, changes in the regulations, or disruptions to the normal operations of federal agencies, any of which may impact our clinical development plans.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to facility registration, biopharmaceutical product listing, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a supplement submission, which may require the development of additional preclinical studies, clinical trials, data and/or assays, such as comparability protocols.

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 a product, complete withdrawal of the product from the market or product recalls.
- Fines, warning letters or holds on post-approval clinical trials.
- Refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals.
- Product seizure or detention, or refusal of the FDA to permit the import or export of products.
- Consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs.
- Mandated modification of promotional materials and labeling and the issuance of corrective information.
- The issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product.
- Injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA approved reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Additionally, prescribing physicians are free to specify "Do Not Substitute" in prescriptions, which would prohibit pharmacists from substituting a branded biologic product for a biosimilar product.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and impact of the BPCIA are subject to uncertainty.

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 Clinical Trials Regulation EU No 536/2014, which entered into force in January 2022 with a transition period and aims at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. From January 31, 2025, or the end of the transition period, any trials approved under the Clinical Trials Directive that continue running will need to comply with the Clinical Trials Regulation, and their sponsors must enter information on the trials in the Clinical Trials Information System.

In the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union (excluding Croatia), Norway, 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.

Other U.S Healthcare Laws and Compliance Requirements

Biopharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Research, manufacturing, sales, promotion and other activities following product approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the U.S. Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Department of Justice, 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 also must comply with state and federal fraud and abuse laws, false claims laws, transparency laws, government price reporting and health information privacy and security laws. These laws include the following:

- 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. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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 civil False Claims Act, or FCA. In addition, the intent standard under the federal Anti-Kickback Statute was amended by the ACA to eliminate the need to prove specific intent and actual knowledge to establish an Anti-Kickback Statute violation.
- The federal civil and criminal false claims, including the 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.
- The civil monetary penalties laws 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 offering or transferring 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, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- The distribution of pharmaceutical products is subject to additional requirements and regulations, 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. For example, 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 Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.
- Analogous state and foreign laws and regulations, such as state anti-kickback, anti-referral and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology or pharmaceutical companies to comply with the biotechnology or pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report certain information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require biotechnology companies to report information on the pricing of certain drug products, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, 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, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government programs such as Medicare or Medicaid, managed care plans, private health insurers and other organizations. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors may attempt to control costs by limiting coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication, and by limiting the amount of reimbursement for particular procedures or drug treatments. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. The Medicare and Medicaid programs are often used as models by private payors and other governmental payors to develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the product or will provide coverage at an adequate reimbursement rate.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Third-party payors are increasingly challenging the price and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products to obtain third-party payor coverage, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Other Healthcare Laws

U.S. Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, a new licensure framework for follow on biologic products, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Bipartisan Budget Act of 2018, or BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. However, on April 27, 2020, the U.S. Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. There have been legislative and judicial efforts to repeal, replace, or change some or all of the ACA, including measures taken during the Trump administration. In June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Trump administration will impact the ACA, our business, financial condition and results of operations.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which will stay in effect through 2032, unless additional congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. For example, under the American Rescue Plan Act of 2021, Medicaid statutory rebates are no longer capped at 100% of the 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 seven 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 legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current U.S. presidential administration on us and the pharmaceutical industry as a whole is unclear. Various industry stakeholders 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 and future regulations, healthcare measures and agency rules by the government 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 after obtaining regulatory approval for any of our products. FDA has authorized the state of Florida to develop a drug importation program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate, if approved, is prescribed or used.

Employees and Human Capital Resources

As of December 31, 2025, we had 43 employees, 11 of whom hold Ph.D. or M.D. degrees and 29 of whom were engaged in research and development activities. None of our employees are represented by a labor union and we believe we maintain good relations with our employees. We rely on skilled, innovative, and passionate employees to conduct our research, development and business activities. Our employees are united by our goal of developing therapies that help patients fight cancer. Developing a diverse, equitable and inclusive culture is essential to our success and we are committed to building a workplace where all individuals feel welcomed and valued.

The biopharmaceutical industry is highly competitive and recruiting and retaining employees is critical to the continued success of our business. 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. We also offer a collaborative work environment, flexible or remote work arrangements, ongoing professional development opportunities, career advancement opportunities, and a culture that values diversity and inclusion.

Corporate Information

Our predecessor company, ALX Oncology Limited, an Irish private company limited by shares, was initially incorporated in Ireland on March 13, 2015 under the name Alexo Therapeutics Limited and changed its name to ALX Oncology Limited on October 11, 2018. We were then incorporated in Delaware on April 1, 2020 under the name ALX Oncology Holdings Inc. We present the information included in this Annual Report on Form 10-K as that of ALX Oncology Holdings Inc. unless such information refers to a date prior to April 1, 2020, in which case it reflects that of our predecessor company.

Our principal executive offices are located at 323 Allerton Avenue, South San Francisco, California, 94080. Our telephone number is 650-466-7125. Our website address is alxoncology.com.

We use ALX Oncology and other marks as trademarks in the United States and other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and amendments to reports filed pursuant to Sections 13(a), and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) are filed with the U.S. Securities and Exchange Commission (SEC). We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information 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. Such documents and other information filed by us with the SEC are available free of charge on the Investor section of our website (ir.alxoncology.com) when such reports are available on the SEC's website.

Investors and others should note that we may announce material information to the public through filings with the SEC, our website (alxoncology.com), press releases, public conference calls, and public webcasts. We encourage our investors and others to review the information disclosed through such channels as such information could be deemed to be material information. Please note that this list may be updated from time to time.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained elsewhere in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factors Summary

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. These risks include, but are not limited to, the following:

- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future;
- We will require substantial additional capital to finance our operations, such capital may not be available to us when needed or may only be available on terms that are unfavorable to us;
- We have a limited operating history, have no products approved for commercial sale, and have not generated any revenue from product sales, licenses or collaborations;
- We are substantially dependent on the success of our lead product candidate, evorpacept, also known as ALX 148, which is in clinical development and which has not completed a pivotal trial;
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration, or FDA, or other comparable foreign regulatory authorities;
- Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, efficacy and potency of our product candidates or provide the basis for marketing approval;
- Our product candidates may cause significant adverse events or other undesirable side effects when used alone or in combination with other treatments;
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue;
- If we are unable to obtain, maintain and enforce patent protection and other intellectual property for our product candidates and related technology, our business could be materially harmed;
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy;
- We rely on third-party manufacturers for clinical supplies of our product candidates;
- The levels of our debt and compliance with the terms of our loan agreement could restrict our ability to operate our business;
- Macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, U.S. federal government shutdowns, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic, could adversely impact our business including our ongoing and planned clinical trials and preclinical research;
- The price of our stock may be volatile, and you could lose all or part of your investment; and
- If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in our financial reports.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue from product sales, licenses or collaborations to date and have financed our operations principally through public offerings of our common stock and private placements of our convertible preferred stock. Our net losses were $101.7 million, $134.9 million and $160.8 million for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $722.8 million. We have devoted substantially all of our resources and efforts to research and development. Our product candidates, evorpacept and ALX2004, are in early-stage clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for evorpacept and ALX2004 and advance our other programs. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We have incurred and expect to continue to incur additional costs associated with operating as a public company and compliance with legal, accounting and other regulatory requirements. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. 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 drug development programs or future commercialization efforts. Further, any decline in our stock price or perceived potential decline in our stock price that may be associated with stock market volatility generally, may negatively impact our ability to raise capital.

As of December 31, 2025, we had cash, cash equivalents and investments of $48.3 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and investments and net proceeds of $140.3 million raised in our registered offering that closed in February 2026 (the February 2026 Offering) will be sufficient to fund our operations through the first half of 2028. Our estimate as to how long we expect our existing cash, cash equivalents, investments and funds available from our term loan will be sufficient to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, such as periods of a rising rate of inflation or economic downturns, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash, cash equivalents and investments to advance the clinical development of evorpacept and ALX2004, as well as for working capital and other general corporate purposes. This may include additional preclinical research, clinical development, hiring additional personnel, capital expenditures, the potential acquisition of businesses or assets and the costs of operating as a public company, as well as for working capital and other general corporate purposes. Advancing the development of evorpacept and ALX2004, and our other programs will require a significant amount of capital. Our current cash, cash equivalents and investments on hand, may not be sufficient to fund all of the actions that are necessary to complete the development of evorpacept and ALX2004, or our other programs.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Our ability to raise additional funds may be adversely impacted by market perceptions of our ability to maintain our listing on the Nasdaq. Other than the loan and security agreement, or Loan Agreement, we entered into with Oxford Finance LLC, Oxford Finance Credit Fund II LP and Silicon Valley Bank, or SVB, collectively, the Lenders, in the fourth quarter of 2022 and most recently amended in December 2023, we do not have any committed external source of funds. Under the Loan Agreement, $25.0 million is available for us to draw down at the Lenders' sole discretion as of December 31, 2025. SVB was closed in March 2023, and the FDIC was appointed as receiver to SVB. The FDIC created Silicon Valley Bridge Bank, or SVBB, as successor to SVB, which was acquired by First Citizens Bank, and is now operated as a division of First Citizens Bank, or SVB-First Citizens. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, a stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect one's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. For example, our Loan Agreement restricts our ability to incur additional indebtedness without the consent of the Lenders. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. 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.

Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We were incorporated and commenced operations in 2015, have no products approved for commercial sale and have not generated any revenue from product sales, licenses or collaborations. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates and conducting preclinical and clinical trials of our product candidates, including Phase 1 and Phase 2 clinical trials of evorpacept and Phase 1 clinical trials of ALX2004. We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenue from any product sales, licenses or collaborations and do not expect to generate any revenue from the sale of product candidates in the foreseeable future. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our product candidates evorpacept and ALX2004, and our other future product candidates;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of evorpacept, ALX2004 and our other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for evorpacept, ALX2004 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;

- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of evorpacept and ALX2004, and any future product candidates as viable treatment options by patients, the medical community and third-party payors;
- obtaining favorable coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidate; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and/or continue our operations.

The terms of our Loan Agreement require us to meet certain operating and financial covenants, place restrictions on our operating and financial flexibility, and may subject us to default.

In October 2022, we entered into the Loan Agreement, most recently amended in December 2023, under which we have borrowed $10.0 million. Under the Loan Agreement, $25.0 million is available for us to draw at the Lenders' sole discretion as of December 31, 2025. The proceeds of the loans may be used by us for working capital and to fund our general business requirements.

The term loans under the Loan Agreement mature on October 1, 2027. We began to make principal payments in equal monthly installments beginning on December 1, 2025. The term loans accrue interest at a floating rate as described elsewhere in this report, and interest is payable monthly in arrears. The term loans once repaid or prepaid may not be reborrowed. The term loans may be prepaid in full or in part in increments of $10.0 million, with various prepayment premiums. Upon the earlier of prepayment or maturity of any term loan, we are required to pay a fee of 6.0% of the original principal amount of such funded term loan, and a contingency fee may apply in connection with a prepayment of such term loan under certain circumstances. We are also obligated to pay other customary fees for a loan facility of this type and size.

The term loans under the Loan Agreement are secured by substantially all of our assets, except our intellectual property, which is the subject of a negative pledge, and will be guaranteed by our future subsidiaries, subject to certain limitations.

The Loan Agreement contains customary affirmative and negative covenants, including covenants limiting our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on our capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

If we default under the Loan Agreement, the Lenders will be able to declare all obligations immediately due and payable and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The events of default under the Loan Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of our obligations under the Loan Agreement, the termination of the Lenders' commitments, a 5.0% increase in the applicable rate of interest and the exercise by the Lender of other rights and remedies provided for under the Loan Agreement. Any declaration by the Lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, evorpacept, or our second product candidate, ALX2004, which are both in clinical development and have not completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize evorpacept or ALX2004 in one or more indications, or we experience significant delays in doing so, we may never generate any revenue or become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our product candidates evorpacept and ALX2004, in our ongoing clinical trials. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of evorpacept in one or more of these indications, such as gastric/gastroesophageal junction, or GEJ, carcinoma, breast cancer, NHL or multiple myeloma. We cannot be certain that evorpacept will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, testing, manufacturing, safety, efficacy and potency, labeling, approval, sale, marketing and distribution of evorpacept is, and will remain, subject to comprehensive regulation by the FDA and comparable foreign regulatory authorities. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize evorpacept, ALX2004 or any of our future product candidates, would materially harm our business, financial condition and results of operations. We are not permitted to market or promote evorpacept, ALX2004 or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. If we do not receive marketing approvals for evorpacept or ALX2004, we may not be able to continue our operations.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. The clinical trials of our product candidates may not produce positive results or demonstrate adequate safety, purity and efficacy and potency to the satisfaction of regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy/potency of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. For example, in April 2025, we announced that topline data from our Phase 2 ASPEN-03 and ASPEN-04 clinical trials did not meet the primary endpoints, and we will no longer pursue evorpacept in combination with pembrolizumab in head and neck squamous cell carcinoma (HNSCC). The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain approval of their drugs.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety, purity and efficacy and potency to the satisfaction of the FDA or comparable international regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. In addition, the FDA or any comparable international regulatory authorities may conclude that the results from our clinical trials are insufficient to support any accelerated approval that we may seek with respect to evorpacept, ALX2004 or any of our future product candidates in general or with respect to any specific indications. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Additionally, in March 2023, the 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 providing a more robust efficacy and safety assessment, among other recommendations. To the extent the FDA requires us to collect additional data or to conduct additional clinical trials in accordance with the new guidance, including with respect to our single-arm ASPEN-09-Breast study in HER2-positive breast cancer, our clinical timelines may be delayed.

Clinical trials of our product candidates are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety, purity and efficacy and potency of our product candidates or provide the basis for marketing approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials (including initiation of any pediatric study) to demonstrate their safety, purity and efficacy and potency. Clinical trials are expensive and difficult to design and implement. Clinical trials can take many years to complete, and their ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. For example, in April 2025, we announced that topline data from our Phase 2 ASPEN-03 and ASPEN-04 clinical trials did not meet the primary endpoints, and we will no longer pursue evorpacept in combination with pembrolizumab in HNSCC. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe, pure and effective or potent for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

We do not know whether our future clinical trials will begin or enroll subjects on time or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- adding necessary new clinical trial sites;
- recruiting suitable subjects to participate in a trial;
- noncompliance with clinical trial protocols;
- investigational site or trial subjects withdrawing or dropping out of clinical trials at a higher rate than anticipated; and
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results or interval changes to standards of care for the treatment of specific tumor types that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of subjects required for clinical trials is larger than anticipated, enrollment in these clinical trials is slower than anticipated or subjects dropping out of these clinical trials at a higher rate than anticipated;
- delays in clinical trials due to outbreaks or public health crises, such as the COVID-19 pandemic, that impact both trial site operations, subject selection and participation;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates are greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- any development and approval of FDA or other comparable foreign regulatory authorities required companion diagnostics necessary for use with our product candidates; and
- regulators revising the requirements for approving our product candidates.

As a result of any of these delays or other circumstances, we may incur unplanned costs, not obtain or be delayed in obtaining marketing approval, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have our drug removed from the market after obtaining marketing approval.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate safety and efficacy sufficient to obtain marketing approval of our product candidates or to market our drugs after any such approval.

We have experienced and, if we continue to experience delays or difficulties in the enrollment of subjects in clinical trials and/or retention of subjects in clinical trials in the future, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or comparable international regulatory authorities. Subject enrollment is a significant factor in the timing of clinical trials. In particular, because certain of our clinical trials of evorpacept and ALX2004 are focused on indications with small patient populations, our ability to enroll eligible subjects may be limited or may result in slower enrollment than we anticipate.

In the past, clinical trial enrollment and data collection has been adversely impacted by staff shortages, site closures, travel limitations and physical distancing requirements and personal safety concerns resulting from and associated with the COVID-19 pandemic.

Subject enrollment may also be affected if new standards of care become widely available or our competitors have ongoing competing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. In addition, regulatory requirements governing clinical trials have changed and may continue to change in the future. The timing of our clinical trials depends on our ability to recruit subjects to participate in our studies and changes to regulatory requirements, if any, governing clinical trials may impede our ability to enroll subjects. Subject enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy or potency of current or newly approved drugs for the disease under investigation and other changes in standard of care that could make our clinical trials less attractive, including the drugs or other product candidates we use in our combination studies;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials by us and the clinical trial sites;
- patient referral practices of physicians;
- the ability to monitor subjects adequately during and after the clinical trial;
- proximity of clinical trial sites to prospective subjects;
- risk of subjects enrolled in clinical trials dropping out before completion;
- inability or delay in enrollment of subjects due to a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic;
- an inability to appropriately enroll an ethnically and racially diverse patient population representative of the target patient population;
- non-compliance with regulatory requirements; and
- subjects experiencing severe or unexpected adverse effects related to our product candidates.

Our inability to enroll a sufficient number of subjects in our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our drugs.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Further, interim, topline and preliminary data include certain assumptions, estimations, calculations and conclusions as part of our analyses of data available at that time, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. 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 subject enrollment continues and more subject data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. Some may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If evorpacept, ALX2004 or any of our other product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, in ALX-Oncology-sponsored clinical trials, the most common adverse events of any grade associated with evorpacept (frequency ≥20%) are fatigue, anemia, nausea, diarrhea, constipation, and neutrophil count decrease. These events have been reported across the program in patients administered evorpacept as a single agent, in combination with pembrolizumab, trastuzumab, rituximab, azacitidine, or enfortumab vedotin and as a multiproduct regimen in combination with pembrolizumab, platinum, and 5 FU, or in combination with trastuzumab, ramucirumab, and paclitaxel, or in combination with azacitidine + venetoclax. Such side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any adverse events as a result of evorpacept or any of our future product candidates, including in combination with therapy, may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

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

The development and commercialization of new product candidates is highly competitive. We face competition with respect to evorpacept and ALX2004, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology therapies for the treatment of cancer. There are other companies working to develop immuno-oncology therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Newly approved therapeutics could change the treatment paradigm or standard of care, which could negatively impact the design of our clinical trials and the prospects of our product candidates.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approaches, including with respect to the targeting of the CD47 pathway, targeting epidermal growth factor receptor (EGFR) as an antibody-drug conjugate target, and others are based on entirely different approaches. We are aware that Adagene, Akesobio, Bio-Thera Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Byondis, Centessa, Conjupro Biotherapeutics, CTTQ (SinoBiological), Daiichi Sankyo, Exelixis, GenSci, Gilead Sciences (through its acquisition of Forty Seven), Hanchor Bio, Hisun, Hutchmed, I-Mab, Ichnos, ImmuneOncia Therapeutics, ImmuneOnco Biopharma, Innovent, Kahr, LaNova, Lightchain Bioscience, Mabwell Therapeutics, Mabworks, Novimmune, OSE Immunotherapeutics, Pfizer (through its acquisition of Trillium Therapeutics), Phanes, Pyxis Oncology (through its acquisition of Apexigen), Shandong New Time, Shattuck Labs, Sorrento Therapeutics, Sumgen, SunHo Pharmaceutical, TG Therapeutics, Waterstone, and Zai Lab, among others, are developing or have begun development of drugs targeting the CD47 pathway that may have utility for the treatment of indications that we are targeting. We are also aware that AstraZeneca, BioNTech, Bristol Myers Squibb with Systimmune, CSPC, and Henlius, among others, are developing or have begun development of antibody drug conjugates (ADCs) targeting EGFR. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if evorpacept, ALX2004 and/or any of our other future product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology 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, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Even after approval, our manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our approved products 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 on-going compliance with current good manufacturing practices, or cGMPs, and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Regulatory approvals may contain significant limitations related to use restrictions for specific target population subsets, *e.g.*, based on biomarker analyses or age groups, warnings, precautions or contraindications, or may include costly and burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition for approval of our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk mitigation tools.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a contract supplier, vendor, or facility where the product is manufactured or processed, a regulatory agency may impose restrictions on that product, the manufacturing facility or contractor, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, European Medicines Agency (EMA) and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions or enforcement actions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any of these sanctions, enforcement actions or penalties described above may inhibit our ability to commercialize our product candidates, even if approved, and generate revenue.

We contract with third parties for the manufacture of our product candidates for preclinical development and clinical trials, and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our drugs if any of our product candidates receive marketing approval. No assurance can be given that long-term, scalable manufacturers can be identified or that they can make clinical and commercial supplies of our product candidates that meet the product specifications of previously manufactured batches, or are of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. Such third-party manufacturers may also be subject to delays due to circumstances outside of their control for a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic, that could shut down or cause limited staffing of their facilities. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. If they are unable to do so, it could have a material adverse impact on our business.

The facilities used by contract manufacturers to manufacture our product candidates must be approved by the FDA or any applicable foreign regulatory authority pursuant to inspections that may be conducted after we submit our marketing applications to the FDA or any such foreign regulatory authority. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any applicable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact, including causing substantial delay in, our ability to develop, obtain regulatory approval for or market our product candidates. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

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

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or commercial drug supply after marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

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

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. We have previously encountered challenges in the production of a drug substance batch, and as a result incurred additional costs to address and rectify the manufacturing process. Also, as product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing, suppliers and formulation, are altered in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the modified manufacturing, materials or process. This could delay completion of clinical trials, require the conduct of additional clinical trials, such as bridging studies to demonstrate the product is substantially equivalent to product used during earlier clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Development of product candidates in combination with other therapies could expose us to additional risks. Lack of third-party combination drugs may materially and adversely affect demand for our product candidates.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Further, to the extent the regulatory authorities require concurrent updates to the drug labeling of an approved drug product to include the combination use to allow approval of one of our product candidates, we will need to coordinate with the third-party manufacturer regarding such combination labeling changes, which could delay or impact the approval of our product candidate. Changes in standard of care and treatment paradigm can materially and adversely affect our business and results of operations, including the design of our clinical trials. 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 are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our product candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. In addition, we currently use, and plan to use in the future, third-party drugs in our development and clinical trials as controls for our studies, such as conducting Phase 2/3 clinical trials of evorpacept in combination with trastuzumab for gastric/GEJ carcinoma. As a result, the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. For instance, we entered into clinical trial collaboration and supply agreements with Eli Lilly, pursuant to which our collaboration counterparties will supply doses of ramucirumab for use in certain clinical trials. If the agreement with Eli Lilly is terminated before the trial is completed, we may need to find another source of ramucirumab in order to continue our trial.

If other pharmaceutical companies discontinue these drugs for combination therapies in the future, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs at all or in a timely manner and on a cost-effective basis. Use of new combination drugs with our approved product candidates will require further regulatory approval before we can promote such new combination therapies. As a result, demand for our product candidates may be lowered, which would in turn materially and adversely affect our business and results of operations.

We may not be able to obtain regulatory approval for our product candidates or commercialize any product candidates that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with the third parties that conduct the activities related to our clinical trials on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll subjects on a timely basis or otherwise conduct our clinical trials as planned. In addition, there is no guarantee that these third parties will devote adequate time and resources to our clinical trials or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. For example, these third parties may be adversely impacted by outbreaks and public health crises, such as the COVID-19 pandemic. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA or other regulatory agencies. Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCPs, regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the FDA or foreign regulatory authority may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA or foreign regulatory authority could determine that any of our clinical trials fail or have failed to comply with applicable cGCPs.

Our business also may be implicated if any of our CROs violates fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our third-party clinical trial sites terminate for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer the care of those subjects to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop and license future product candidates would be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new CRO partner, and the terms of any additional arrangements that we establish may not be favorable to us. Switching or adding CROs or other service providers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or service provider commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative arrangements, the resulting delays and potential inability to find suitable replacements could materially and adversely impact our business.

Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.

Even if the FDA and applicable foreign regulatory authorities approve the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use our product candidates. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of evorpacept and ALX2004 and any other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of evorpacept, ALX2004, and our other product candidates to treat cancer or other applicable targeted diseases, as compared with other available drugs, treatments or therapies;

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the approval of other new therapies for the same indications;
- the prevalence and severity of any adverse side effects associated with evorpacept, ALX2004, and our other product candidates;
- limitations or warnings contained in the labeling approved for evorpacept, ALX2004, or our other product candidates by the FDA or foreign regulatory authorities;
- availability of alternative treatments and the potential and perceived advantages of our product candidates over alternative treatments;
- the size of the target patient population and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength and effectiveness of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost-effectiveness in relation to alternative treatments;
- relative convenience and ease of administration;
- our ability to obtain sufficient third-party coverage or reimbursement by government, insurers or third-party payors, and the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that the FDA or any foreign regulatory authority may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

Adverse events in clinical trials for our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for evorpacept, ALX2004 or any other product candidate that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry generally could also result in greater governmental regulation and stricter labeling requirements.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and/or third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval.

We currently have no marketing and sales organization and we have never commercialized a product candidate. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own medical affairs, sales, marketing and supply capabilities or outsource these activities to a third party.

If any of our product candidates ultimately receives regulatory approval, we may choose to establish an internal marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. We have no internal sales, marketing or distribution capabilities.

The market opportunities for the product candidates we develop, if approved, may be limited to certain smaller patient subsets.

There is no guarantee that the product candidates we develop, even if approved, would be approved for the currently proposed indications. We may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk. Regulators, like the FDA, may require us to narrow our indications to smaller patient subsets, and the number of patients in such subsets may turn out to be lower than expected. If this were to occur, it could have a material adverse effect on our business.

Our current and future product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe, pure, potent or effective for use by the target patient population for any indication.

Our product candidates, evorpacept and ALX2004, are at an early stage of clinical development and not all adverse effects can be predicted or anticipated. Unforeseen side effects from evorpacept, ALX2004, or any of our future product candidates may arise at any time during clinical development or, if approved by regulatory authorities, after the approved drug product has been marketed. Any undesirable or unacceptable side effects of evorpacept, ALX2004, or our future product candidates could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable international regulatory authorities, or result in marketing approval from the FDA or comparable international regulatory authorities with restrictive label warnings or for limited patient populations. Ultimately, such side effects could result in product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, including changing the dose and/or schedule of administration, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future product candidates.

Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve and maintain acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy and potency or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain and maintain coverage and adequate reimbursement for a product;
- our ability to generate revenue and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

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

The FDA strictly regulates manufacturers' promotional claims of drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the FDA-approved labeling. The FDA, the Department of Justice, the Inspector General of the Department of Health and Human Services, or HHS, among other government agencies, actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including 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.

Risks Related to Government Regulation

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review with respect to our drugs, which will result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed, or subject to certain conditions of approval and may contain requirements for potentially costly post-approval trials and surveillance to monitor the safety, purity and efficacy/potency of the marketed product. For any approved drug, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with 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 the drug;
- withdrawal of the drug from the market or voluntary or mandatory product recalls;
- adverse publicity, fines, warning letters or holds on clinical trials;
- refusal by the FDA or any other applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- drug product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the policies of the FDA or other comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or impact any already approved drugs. 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 more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. Further, changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may lead to new policies and changes in the regulations that can increase our compliance costs or delay our clinical development and timelines. 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, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, which could lead to our inability to generate product revenue. 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.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. 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 product candidates in those countries. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for or obtained regulatory approval for any product candidate and it is possible that we may never obtain regulatory approval for evorpacept or ALX2004, or any other product candidates we seek to develop in the future. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

- the FDA or comparable international regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable international regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective 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 potency and safety in the full population for which we seek approval;
- the FDA or comparable international regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, New Drug Application or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable international regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable international regulatory 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 international foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and potency and approval standards. 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.

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, ability to hire and retain key personnel and accept the payment of user fees, government shutdowns, return-to-office policy and other policies and executive actions under the current U.S. presidential administration, including as a result of budget delays or other circumstances like the COVID-19 pandemic, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

Further, under the new leadership at the HHS, reorganization of that department, departure of senior leadership at the FDA and other agencies under HHS, mass layoffs at HHS, government shutdown, and a lapse in U.S. government appropriations may impact operations at the FDA as well as other federal agencies, which can materially delay our timelines. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. These new policies are also expected to lead to fewer agency guidance documents that could result in interference with FDA programs or lead to delays or refusals to approve products. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. It is unclear how our industry and our clinical programs will be impacted by policies or regulations implemented under the current presidential administration and the new FDA commissioner or other executive orders. To the extent the agency reorganization and other agency changes lead to disruptions in the FDA's operations, our interactions, correspondence, and regulatory review processes with the FDA may be delayed.

While we have received certain FDA Fast Track designations, such Fast Track designations may not lead to a faster development or regulatory review or approval process, and do not increase the likelihood that the drug will receive marketing approval.

The FDA granted Fast Track designation for evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-overexpressing advanced gastric or GEJ adenocarcinoma with disease progression on or after prior trastuzumab, and fluoropyrimidine or platinum-containing chemotherapy in January 2020. If a product candidate is intended for the treatment of a serious condition and preclinical or clinical data demonstrate the potential to address unmet medical need for such condition, a sponsor may apply for FDA Fast Track designation. Even though we received these Fast Track designations for evorpacept, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

While we have received certain orphan drug designations from the FDA and the European Commission, we may be unable to maintain the benefits associated with such orphan drug designation. If we decide to seek orphan drug designation for additional indications for our product candidates in the future, we may be unsuccessful.

Under the Orphan Drug Act, the FDA may designate a product candidate 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 January 2022, the FDA's Office of Orphan Products Development granted Orphan Drug Designation, ODD, to evorpacept for treatment for gastric/GEJ cancer. We may seek ODD for certain additional indications for our product candidates in the future. ODD neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process. Generally, if a product candidate with ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity that precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing product candidates approved in those indications by the FDA for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. However, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture a sufficient supply of our product. In response to recent litigation, the FDA clarified in a January 2023 notice that the FDA 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. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations. Changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

In June 2023, the European Commission granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer. In the European Union approved orphan medicines are granted 10 years of market exclusivity, which can be extended to 12 years if a pediatric investigation plan is completed. The market exclusivity period can be shortened if the approved orphan drug becomes commercially successful. An orphan designation can also be revoked if, for example, the prevalence of the condition increased to more than 5 per 10,000 individuals of the total population, if additional therapies are introduced after the initial designation and have improved the morbidity or mortality of a condition so that it is no longer chronically debilitating and/or life-threatening, or if we are unable to demonstrate significant benefit over existing authorized products. We can provide no assurance that we will be able to maintain all the benefits associated with the designation or that we will be successful in commercializing our product if approved.

Current and future legislation may increase the difficulty and cost for us to commercialize our products, if approved, and affect the prices we may obtain. We may face difficulties from changes to current regulations and future legislation.

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. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA and other federal agencies, which could lead to uncertainties in the industry and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. 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.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. 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 drugs, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our drugs;

- 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively ACA, was enacted in 2010 and includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA continues to impact the U.S. pharmaceutical industry. Since its enactment, there have been judicial, executive 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures of the current U.S. presidential administration will impact the ACA. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2032, with the exception of temporary suspension under COVID-19 relief legislation.

There also has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their drugs, which has resulted in several U.S. 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, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Programs rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have 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. Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. 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 seven 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, Centers for Medicare & Medicaid Services, or CMS, selected 10 high-cost Medicare Part D drugs in 2023 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. Various industry stakeholders, including 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. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. The One Big Beautiful Bill Act, which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or that increase generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as other legislative, executive, and administrative actions and agency rules

implemented by the current U.S. presidential administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

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. FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved drug product. Any denial in coverage or reduction in reimbursement from Medicare or other government funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future product candidates. In addition to continuing pressure on prices, price controls and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future product candidates, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such product candidates and third-party payors' reimbursement policies might adversely affect our ability to sell any future product candidates profitably.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay the commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower-priced cross-border sales, our profitability will be negatively affected.

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, 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.

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.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through our prescribers, consultants, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate are described in the following paragraphs:

- The U.S. federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. Moreover, the ACA provides that the government may assert that a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or FCA.
- The federal civil and criminal false claims, including the civil 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 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 offering or transferring 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 Health Insurance Portability and Accountability Act, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act and Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, impose certain obligations, including mandatory contractual terms, on covered entities subject to the Final HIPAA Omnibus Rule, *i.e.*, health plans, healthcare clearinghouses and healthcare providers, and their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The U.S. Federal Food, Drug and Cosmetic Act prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.

- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- The distribution of pharmaceutical products is subject to additional requirements and regulations, 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.
- Analogous state laws and regulations impose additional obligations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.
- European and other foreign law equivalents of each of the laws also impose legal requirements, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight, and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

If we, our employees, independent contractors, principal investigators, consultants, vendors or agents acting on our behalf fail to comply with healthcare laws and regulatory requirements, we could be subject to fines, penalties or enforcement actions, or incur costs that could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct as well as risks of noncompliance by contractors or agents acting on our behalf. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of research, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines, exclusion from participation in government-funded healthcare programs, or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involve, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses, we may incur costs and expenses due to injuries to our employees resulting from the use of these materials, as this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Disruptions at the FDA, SEC or other government agencies caused by funding shortages or global health concerns 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, the ability to hire and retain key personnel, return-to-office policies and other executive actions by the current U.S. presidential administration, and changes in the leadership and operations of the FDA. 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. For example, the U.S. government has shut down in the past, forcing regulatory authorities such as the FDA and SEC to furlough employees, and in response to the COVID-19 pandemic, the FDA has postponed certain inspections. If global health concerns or other causes continue to prevent the FDA or other regulatory authorities from conducting their normal operations, such as regular inspections, reviews, or other regulatory activities in a timely manner, or if the FDA and other agencies experience other delays, backlogs or disruptions, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 Foreign Corrupt Practices Act, or 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 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. In addition to our own employees, we 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 penalties 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.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations, including increased tariffs. Governmental regulation of the import or export of our products, including the potential negative impact of tariff increases, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our business. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions. 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.

Data collection under European and U.S. laws is governed by restrictive regulations addressing the collection, use, processing and, in the case of Europe, cross-border transfer, of personal information (i.e., information that relates to an identified or identifiable individual).

We may collect, process, use or transfer personal information from individuals located in the European Economic Area, or EEA, Switzerland and the United Kingdom in connection with our business, including in connection with conducting clinical trials in these regions.

Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA or the United Kingdom or Switzerland. The collection and use of personal information (which includes health data) in the EEA is governed, in part, by the provisions of the General Data Protection Regulation (EU) 2016/679, or the GDPR, or its UK equivalent, the UK General Data Protection Regulation, or, together with the UK's Data Protection Act 2018, the UK GDPR, or the new Swiss Federal Act on Data Protection, or FADP. These regulations impose requirements relating to having a legal basis for processing personal information and transferring such information outside of the EEA, the United Kingdom and Switzerland, respectively, as applicable, including to the United States, informing concerned individuals about the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information on our behalf, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal information to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping.

Any actual or alleged failure to comply with the GDPR, UK GDPR, FADP, or other data protection laws may result in regulatory inquiries and other proceedings, substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

The GDPR, UK GDPR and FADP also restrict the transfer of personal information outside of the EEA, United Kingdom and Switzerland, respectively, unless appropriate safeguards are in place.

One primary set of safeguards, the Standard Contractual Clauses adopted by the European Commission, has been updated recently. With regard to data transfers outside of the EEA to the United States, in March 2022, the European Union and United States established a new framework for personal information transfers, the EU-U.S. Data Privacy Framework, or the EU-U.S. DPF. A related framework, the Swiss-U.S. Data Privacy Framework, or Swiss-U.S. DPF, also was established, and was the subject of an adequacy decision by the Swiss Federal Council on August 14, 2024. On July 10, 2023, the European Commission adopted an adequacy decision relating to the EU-U.S. DPF. Additionally, a UK Extension to the EU-U.S. DPF, became effective on October 12, 2023. We are evaluating whether to make use of the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF to transfer personal information from the EEA to the United States.

Data protection regulation in the United Kingdom is subject to some uncertainty. Although the European Commission granted "adequacy" status to the United Kingdom in June 2021, and personal information can flow from the European Union to the United Kingdom and back, the United Kingdom may change its policy with respect to the export of personal information to third countries, such as the United States, and the European Commission's adequacy determination for the United Kingdom requires renewal in 2025 and it may be modified or revoked in the interim. The United Kingdom made targeted amendments to the UK GDPR in the UK Data (Use and Access) Act 2025, or DUAA, which was enacted on June 19, 2025. The European Commission has renewed the UK's adequacy decision after assessing the DUAA through December 2031. In addition, in February 2022, the United Kingdom's Information Commissioner's Office issued new Standard Contractual Clauses for the transfer of personal information outside of the United Kingdom. The data transfers enforcement landscape and the longer-term stability of the EU-U.S. DPF and related programs remain uncertain, which could require us to modify our policies and practices and increase our compliance costs.

The EU also has implemented new and revised laws and regulations relating to cybersecurity, including the Network and Information Security Directive II, or NIS2, adopted in 2023, which aims to enhance cybersecurity across critical infrastructure and essential services in the EU. NIS2 provides for all EU member states to have issued implementing legislation by October 2024; however, several EU member states have not finalized their respective legislation and guidance.

We may, therefore, incur liabilities, expenses, costs, and other operational losses under the GDPR, the UK GDPR, the FADP, and applicable laws and regulations of European Union member states in connection with any measures we take to comply with them.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, in 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

Additionally, the California Privacy Rights Act, or the CPRA, was approved by California voters in November 2020. The CPRA modified and augmented the CCPA significantly, effective as of January 1, 2023, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Numerous other states have proposed, and in certain cases enacted similar laws, including comprehensive privacy laws similar to the CCPA enacted in Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia. Other states have proposed, and in certain cases enacted, legislation addressing privacy and cybersecurity in the context of specific subject matter such as biometrics and health-related personal information. The U.S. Department of Justice also has issued rules regarding certain bulk sensitive personal data transfers. As we expand our operations, preclinical studies and clinical trials, these new state laws and other state laws and regulations relating to privacy, data security, and the collection, use, transfer, and other processing of data may increase our compliance costs and potential liability. Laws and regulations relating to these matters are not consistent across jurisdictions, and they may impose conflicting or uncertain obligations. Compliance with these and any other applicable laws and regulations relating to these matters is a rigorous, costly and time-intensive process, and we may be required to put in place additional mechanisms to address new and changing obligations under these laws and regulations. Actual or alleged noncompliance with any such laws and regulations may lead to regulatory investigations, enforcement actions, claims and litigation, and if we fail to comply with any such laws or regulations, we may face significant fines and penalties. Any of these could adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain and maintain patent protection for our product candidates and other research and development discoveries. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development discoveries in a timely manner to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in foreign countries or may fail to effectively prevent third parties from commercializing competitive product candidates.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, and such prior art may affect the scope of any allowable claims or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented or deemed unenforceable and such third parties may gain rights to such patents. We could also become involved in reexamination, *inter partes* review, post-grant review, opposition or derivation proceedings challenging our patent rights or the patent rights of others.

In addition, changes in law may introduce uncertainty in the enforceability or scope of patents we own. If our patents are narrowed, invalidated or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is no prior art that may ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions.

For all of the foregoing reasons, the issuance, validity, enforceability, scope and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the 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 to develop their own products in jurisdictions where we have not obtained patent protection and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be valid 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 proprietary rights generally. Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court, or UPC. Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any court proceedings to enforce our intellectual property rights, and the damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors.

Additionally, the requirements for patentability may differ in certain countries. For example, in certain countries, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition, certain countries in Europe and other countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices require compliance with many procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and implemented wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a higher level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The AIA and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (*e.g.*, via post-grant reviews or *inter partes* reviews). Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Our patents covering one or more of our product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which the patent examiner and we 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 a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patent protection, prosecution, assertion and defense for some of our product candidates may be dependent on third parties.

There may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors, such as with respect to our license agreements. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

If we are unable to protect the confidentiality of our trade secrets and proprietary information or obtain proper assignment of such intellectual property, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets and other proprietary information. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information in part by entering into confidentiality agreements with our employees, consultants, other service providers, including former service provider Tallac Therapeutics, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies in addition to our service provider agreements, such as the Tallac Services Agreement, also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, individuals with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees, consultants, contractors and other service providers, including former service provider Tallac Therapeutics, under such agreements. To the extent that our employees, consultants, contractors or other service providers use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

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 in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, 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 or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced, and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

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

Third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates or biosimilar versions of any approved product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for an invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;
- third parties may initiate opposition or other proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us, including disputes that may arise from our previous reliance on Tallac Therapeutics as the sole provider of our preclinical research services and the intellectual property generated under the Tallac Services Agreement; or
- third parties may seek approval to market biosimilar versions of our future approved products prior to the expiration of relevant patents owned by or licensed to us under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

Any litigation or other proceedings would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved drug. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition and prospects. Any of these outcomes could have a material adverse effect on our business.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation would expose us to the risk described above under "We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time-consuming and unsuccessful."

Our commercial success depends in part on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties.

We are aware of third-party patents and patent applications containing claims in the immuno-oncology field based on scientific approaches that are the same as or similar to our approach, including with respect to the targeting of the CD47 and signal regulatory protein alpha, or SIRPα, pathways, and others that are based on entirely different approaches. These patents and applications could potentially be construed to cover our product candidates and their use. For example, we are aware of U.S. patent 10,907,209 and U.S. patent application 16/118,038 (now abandoned in favor of a divisional application 18/518,353, which has claims that are not related to polypeptides comprising soluble human SIRPα) owned by University Health Network, or UHN, and The Hospital for Sick Children that may encompass certain therapies for the treatment of cancer using polypeptides comprising soluble human SIRPα, as well as related applications in other jurisdictions. This patent and patent application relate to the treatment of cancer with polypeptides comprising soluble human SIRPα. Pfizer, through its acquisition of Trillium Therapeutics, has an exclusive license to the U.S. patent and application. The European counterpart patent (EP 2 429 574) was subject to European Patent Office opposition proceedings, which resulted in the patent being upheld in amended form. Additionally, we are aware of a second European Patent (EP 2 995 315), a divisional of European patent (EP 2 429 574), granted to UHN and The Hospital for Sick Children. This patent relates to the eradication of hematological CD47+ cancer cells and tumors with polypeptides comprising soluble human SIRPα, or a CD47-binding fragment thereof. This patent was upheld as granted by the European Patent Office Opposition Division on November 28, 2025. This decision is currently under appeal. The patent claims of both EP 2 429 574 and EP 2 995 315 could potentially limit our ability to pursue evorpacept in certain indications in certain territories in the EU in the future unless we obtain a license under these patents, these patents are determined to be invalid or unenforceable by the European Patent Office or a national court in one or more relevant territories, these patents are revoked or otherwise limited by the European Patent Office or a national court, or until these patents expire. A license may however not be available on commercially reasonable terms or at all. With respect to U.S. patent 10,907,209, we believe that we do not infringe claims listed in this U.S. patent. Further, with respect to the development of our ALX2004 program, many companies have filed, and continue to file, patent applications related to ADCs and components thereof that are similar to our approach. As the biotechnology industry expands and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that there are not third-party patents or patent applications of which we are aware, but which we do not believe are relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates. These patents may not expire before we receive any marketing approval for our product candidates, and they could delay the commercial launch of one or more future product candidates. If our product candidates were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms or at all, our business, financial condition and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition and results of operations, and we would be exposed to a threat of litigation.

Any litigation resulting from claims of infringement or failure to license patents and proprietary rights of others would expose us to the risk described above under "We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful." Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for product candidates many years before we obtain marketing approval for such product candidates and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with product candidate name approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our rights to develop and commercialize our product candidates may be subject, in part, to the terms and conditions of agreements with others.

Our current agreements do not, and future agreements we may enter into in the future may not, provide exclusive rights to use certain intellectual property and technology retained by a collaborator in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that utilize technology retained by such collaborators to the extent such products are not also covered by our intellectual property.

We may need to obtain additional intellectual property rights from others to advance our research or allow commercialization of product candidates we may develop. We may be unable to obtain additional intellectual property rights at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Furthermore, our current or our future collaborators' patents may be subject to a reservation of rights by one or more third parties. The U.S. government may have certain rights to resulting intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of the government funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in facilities in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in agreements under which we option or license intellectual property rights from collaborators or licensors or otherwise experience disruptions to our business relationships with future collaborators or licensors, we could lose intellectual property rights that are important to our business.

Our current agreements do, and our future agreements may, impose various economic, development, diligence, commercialization and other obligations on us. Such agreements may also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. It might be concluded that we have materially breached our obligations under such agreements and licensors or collaborators might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. Termination of these agreements could cause us to lose the rights to certain patents or other intellectual property, or the underlying patents could fail to provide the intended exclusivity, and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a collaboration agreement, including:

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
- the priority of invention of patented technology.

We may enter into agreements to option or license intellectual property or technology from third parties that are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Moreover, if disputes over intellectual property that we have optioned or licensed prevent or impair our ability to maintain such arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

Risks Related to Our Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 43 employees, including 29 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect we will need additional managerial, scientific, technical, medical, operational, sales, marketing, financial and other personnel. Future growth may impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for evorpacept, ALX2004 and any other future product candidates, while complying with applicable contractual obligations to contractors and other third parties; and
- maintaining and updating our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize evorpacept and ALX2004, and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, which may require our management team to divert its attention away from day-to-day activities of the business and devote a substantial amount of time to the added responsibilities associated with managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on specific independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of evorpacept, ALX2004 and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other qualified outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively maintain our organization by retaining employees or expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize evorpacept and ALX2004, and other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel immuno-oncology approach, and our future success depends on the successful development of our product candidates, evorpacept and ALX2004, and any future product candidates that we develop. There can be no assurance that any development problems we experience in the future related to our novel immuno-oncology approach will not cause significant delays or unanticipated costs or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating 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 life science industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and our scientific, technical, business and medical personnel. The loss of the services provided by any of our executive officers, other key employees and other scientific and medical advisors, our inability to find suitable replacements, and the impacts of any executive officer changes, could result in delays in the development of our product candidates and harm our business. Additionally, layoffs or furloughs, including the previously completed RIF, pausing recruiting efforts, or employee attrition could also create delays in the development of our product candidates, yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees and reduced employee morale, which could all adversely affect our reputation as an employer, making it more difficult for us to hire new employees in the future and harm our business.

We conduct our operations at our facility in the San Francisco Bay Area of California, a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing and sales and marketing personnel, and we face significant competition for experienced personnel. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Additionally, the U.S. has recently experienced historically high levels of inflation and an acute workforce shortage generally, which has created a hyper-competitive wage environment that may increase our operating costs.

Many of the other biotechnology companies that we compete against for qualified personnel have considerably more financial and other resources, different risk profiles and a more extended history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and therefore any declining value in our equity grants could negatively impact our ability to successfully retain existing employees or effectively recruit new employees. 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. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our predecessor company, which after our internal reorganization is now our wholly-owned subsidiary, was an Irish private company limited by shares. Our business is subject to risks associated with conducting business internationally. Some of our subsidiaries and operations, in addition to suppliers, industry partners and clinical study centers, are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we expect to hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks and complexities, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, including changes in tariff and trade policies, employment laws, regulatory requirements and other governmental approvals, permits and licenses, including within the European Union and in the United Kingdom as a result of Brexit;
- our failure to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property, including as a result of potentially relevant third-party patent rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our drugs;
- exposure to foreign currency exchange rate fluctuations;

- political and economic instability, such as the geopolitical unrest and regional economic disruptions caused by Russia's war with Ukraine, and war and instability in Israel and the surrounding region, and including wars, terrorism and political unrest, boycotts, curtailment of trade and other business restrictions;
- natural disasters, such as a fire, an earthquake or a flood, or outbreaks or public health crises, such as the COVID-19 pandemic;
- a security breach or incident or a related breach of our information systems or data;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions, or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

If any of the third parties that we rely on for various operational and administrative aspects of our business fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third-party consultants and contractors to provide specific operational and administrative services, including research and clinical consultation and management. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on cloud-based platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

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 are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. In addition, we have agreed to indemnify various counterparties related to our product candidates against certain liability claims and any agreements or collaborations in the future may include such indemnification obligations. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects or that certain patients should not use our drugs for various reasons.

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.

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 managerial resources, we focus on research programs that we identify for specific indications. 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. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities.

Our spending on current and future research and development programs, such as evorpacept, 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 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. For example, we entered into clinical trial collaborations with our collaborators, including Sanofi, Jazz and the ISTs, to supply evorpacept for clinical trials to advance new combination therapies. We have limited control over the amount and timing of resources that our collaborators dedicate to the development of our products. Any termination or disruption of collaborations could result in delays in the development of products, increases in our costs to develop the products or the termination of development of a product.

We may seek to enter into collaborations, including strategic collaborations, licenses and other similar arrangements related to our product candidates and may not be successful in doing so, and even if we are, we may not be able to maintain or realize the benefits of such relationships. If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans and our business could be adversely affected.

We may seek to enter into collaborations, licenses and other similar arrangements for the development or commercialization of our product candidates, due to strategic advantages to partnering with third parties and capital costs required to develop or commercialize the product candidate in such markets. For instance, we entered into a collaboration agreement with Tallac Therapeutics pursuant to which we expect to jointly develop, manufacture, and commercialize a novel cancer immunotherapy. We may not be successful in our efforts to establish such collaborations for our product candidates because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product are unsatisfactory. We also may not be able to realize the benefit of such collaborations if we are unable to successfully integrate them with our existing operations and company culture. In any such collaborations, we may likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we may enter into.

We face significant competition in seeking appropriate collaborators and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. We also may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our future collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program, or delay its potential commercialization. Further, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. Any of the foregoing factors would likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may acquire businesses or assets and we may not realize the benefits of such acquisitions.

We may acquire businesses or assets or create joint ventures with third parties that we believe may complement our existing product candidates. For example, in October 2021, we acquired ScalmiBio, Inc., or ScalmiBio. We are developing new anti-cancer drug candidates based on ScalmiBio's platform, and the acquisition of ScalmiBio enhanced our internal research and development capabilities. In order to realize the continuing benefits of the ScalmiBio acquisition, we will need to continue to make a substantial investment of time and resources to support research and development efforts. Additionally, we may not be able to realize the benefit of acquiring businesses or assets or joint ventures if we are not able to successfully integrate them with our existing operations and company culture. We may encounter difficulties in developing, manufacturing and marketing any new product candidates resulting from an acquisition, which may delay or prevent us from realizing their expected benefits.

Also, the anticipated benefit of any joint venture or acquisition may not materialize, and any potential or future joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

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

Under the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity by its shareholders holding 5% or more over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, in either case as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2025, we had net operating loss carryforwards of approximately $305.4 million and $69.0 million for U.S. federal and state income tax purposes, respectively. Our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to our company. The federal net operating losses carry forward indefinitely and may only offset 80% of taxable income in periods of future utilization. The state net operating loss carryforwards will begin to expire beginning in 2038. Other limitations may apply under state law. For example, California legislation suspends the use of state net operating losses by taxpayers with net business income or modified adjusted gross income of $1 million or more for tax years beginning on or after January 1, 2024 and before January 1, 2027.

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

We are or may become subject to income and non-income taxes in the United States under federal, state and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, the Organisation for Economic Co-operation and Development, or OECD, has proposed implementing a global minimum tax of 15%, or Pillar Two, which has been implemented into the domestic laws of European Union member countries and is being considered for implementation by other countries. However, on January 5, 2026, the OECD announced a side-by-side elective safe harbor that exempts U.S.-parented multinational businesses from certain provisions of Pillar Two for fiscal years beginning on or after January 1, 2026. Changes in tax laws, regulations, or rulings, changes in interpretations of existing laws and regulations, or changes in accounting principles could negatively and materially affect our financial position, cash flows, and results of operations.

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.

Prior to our initial public offering, no market for shares of our common stock existed. 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 price of our common stock may fall.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. For example, our 2025 Shelf Registration Statement provides for aggregate offerings of up to $364.1 million of the Company's securities inclusive of up to $119.1 million of shares of our common stock through the at-the-market, or ATM, offering. From December 2021 to December 31, 2025, we sold an aggregate of 3,175,681 shares of common stock under our ATM offering. On October 10, 2023, we completed a registered offering (the October 2023 Offering) for the issuance and sale of an aggregate of 8,663,793 shares of common stock at an offering price of $6.38 per share and pre-funded warrants to purchase 1,250,000 shares of common stock at an offering price of $6.379 per pre-funded warrant. On February 2, 2026, we completed the February 2026 Offering for the issuance and sale of an aggregate of 76,979,112 shares of common stock at an offering price of $1.57 per share and pre-funded warrants to purchase 18,574,120 shares of common stock at an offering price of $1.569 per pre-funded warrant. Our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the October 2023 Offering and February 2026 Offering. As of December 31, 2025, no shares underlying the pre-funded warrants had been exercised. If we issue common stock or securities convertible into common stock, our stockholders will experience additional dilution and our stock price may decline.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to those discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, the following factors may cause the market price of our common stock to fluctuate:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or any future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth and development relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of new product candidates or technological innovations by us or our competitors;
- announcements by us, our future strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders including pursuant to the existing primary and secondary shelf registration statements that we have filed with the SEC;
- expiration of market stand-off or lock-up agreements;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market perceptions of our ability to maintain our listing on Nasdaq;

- additions or departures of key personnel;
- announcement of actual or anticipated reduction in force, including the RIF;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, U.S. federal government shutdowns, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of payment or receipt of any future milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- overall fluctuations in U.S. equity markets, general market conditions and market conditions for biotechnology stocks; and
- other factors that may be unanticipated or out of our control.

In addition, the stock market has recently experienced significant volatility, particularly with respect to biotechnology and other life sciences company stocks. The volatility of biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If we are unable to maintain listing of our securities on the Nasdaq Global Select Market or another reputable stock exchange, it may be more difficult for our stockholders to sell their securities.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, it could have a materially adverse effect on our ability to raise additional funds as well as on the price and liquidity of our common stock.

For example, if at any time the bid price of our common stock closes below $1.00 per share for more than 30 consecutive business days, we may be subject to delisting from the Nasdaq Global Select Market. On April 23, 2025, we received a notice from Nasdaq notifying us that we have not been in compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided a compliance period of 180 calendar days from the date of the Notice, or until October 20, 2025, to regain compliance (subject to any additional 180-day compliance period which may be available to us). To regain compliance with Nasdaq's minimum bid price requirement, the closing price per share of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day compliance period, unless the Staff exercises its discretion to extend this ten-business day period. In September 2025, we received written confirmation from the Staff of Nasdaq that we had regained compliance with the minimum bid price requirement, as the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days. However, there can be no assurance that we will be able to maintain compliance with the minimum bid price requirement or other Nasdaq listing standards. To the extent that we are unable to maintain compliance with Nasdaq listing standards, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock and potentially result in even lower bid prices for our common stock.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time. For example, inflationary pressures have increased and we expect will continue to increase costs for our clinical trials;
- our ability to enroll subjects in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for evorpacept and ALX2004, and any of our other product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with evorpacept, ALX2004 and any of our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of evorpacept, ALX2004 or any of our other product candidates;
- the level of demand for evorpacept, ALX2004 and any of our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with evorpacept, ALX2004 and any of our other product candidates;
- our ability to commercialize evorpacept, ALX2004, and any of our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- any increase in interest expense due to an increase in the floating rate under the Loan Agreement as described elsewhere in this Annual Report on Form 10-K;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- a weak or declining economy resulting from adverse macroeconomic conditions such as inflation, interest rate changes, uncertainty in the financial services industry, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, U.S. federal government shutdowns, and any U.S. federal government debt default due to a failure to increase the debt ceiling; and
- the impact of outbreaks or public health crises, such as the COVID-19 pandemic, geopolitical unrest related to Russia's conflict with Ukraine, war and instability in Israel and the surrounding region, and bank failures or instability in the financial services sector on the global economy.

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

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations. Further, 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. 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. In February and April 2025, the current U.S. presidential administration imposed new tariffs on China and China responded with tariffs on select U.S. goods. While we cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, if we are unable to obtain or use services or products from existing service providers, including those of contract development and manufacturing organizations, or if alternative service providers cannot be secured at an acceptable cost or at all, or if such actions cause broader disruption in drug manufacturing and related industries that impact drug product availability or pricing, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, a substantial amount of our common stock in the public market, the market price of our common stock could decline significantly.

Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act.

On October 10, 2023, we completed the October 2023 Offering and on February 2, 2026, we completed the February 2026 Offering. Our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the October 2023 Offering and February 2026 Offering. As of December 31, 2025, no shares underlying the pre-funded warrants had been exercised. Furthermore, we currently have an effective resale shelf registration statement which enables the selling stockholders thereunder, three of our largest stockholders, to sell shares in the public market which could cause our stock price to decline. In addition, any future sales of shares of common stock or other securities under our 2025 Shelf Registration Statement, including pursuant to our ATM facility, could put downward pressure on our stock price. Moreover, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have incurred and will continue to incur significant increased costs and management resources as a result of operating as a public company.

We have incurred and will continue to incur significant legal, accounting, compliance and other expenses as a public company. Our management and other personnel need to devote a substantial amount of time and incur significant expense in connection with compliance initiatives. For example, as a public company, we must maintain additional internal controls and disclosure controls and procedures and have retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

We maintain an enterprise resource planning, or ERP, system, which is designed to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. The ERP system has and will continue to require the investment of significant financial and human resources in order to ensure effective use of the system. Additionally, in the future, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in using an ERP system could adversely affect our internal controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, or SOX, and the related rules and regulations implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time-consuming. We have invested and will continue to invest additional resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. As a public company, we maintain directors' and officers' insurance coverage, which has significantly increased in recent years. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

While we were a large-accelerated filer for fiscal year 2022, we have been a "non-accelerated filer" since fiscal year 2023 and we anticipate we will continue to be one throughout fiscal year 2026. This status could make our common stock less attractive to investors.

Each year, we re-evaluate our SEC filing status. Accordingly, we are a non-accelerated filer, and due to our public float as of June 30, 2025, we anticipate we will be a non-accelerated filer throughout calendar year 2026. This will be re-evaluated each June 30. Pursuant to Section 404(a) of SOX, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, we will not be required to include an attestation report issued by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. If, after our next June 30 re-evaluation, we are no longer a non-accelerated filer, we would be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm and adhere to earlier filing dates based on our determined status beginning with our Form 10-K for the fiscal year. We cannot predict if investors will find our common stock less attractive if we choose to rely on this exemption. If some investors find our common stock less attractive as a result of our non-accelerated filer status, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

Market conditions and changing circumstances could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. For example, in March 2023, SVB, where we maintain certain immaterial accounts, was placed into receivership with the FDIC, and all funds held at SVB were temporarily inaccessible to SVB's customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, or we may lose, some or all of our existing cash, cash equivalents and investments, to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors, employees, and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. In addition, any U.S. federal government debt default due to a failure to increase the debt ceiling may lead to lack of access to our investments in U.S. treasury securities or losses or lower returns on such investments, in addition to broader macroeconomic risk that would follow any such default. Any delay in our ability to access our cash, cash equivalents and investments, or the loss of some or all of such funds, or inability to pay key vendors and others timely, could have a material adverse effect on our operations and cause us to seek additional capital sooner than planned.

We do not anticipate paying cash dividends and, accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, a stockholder's ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect one's rights as a common stockholder. Sales of equity securities may be made under our 2025 Shelf Registration Statement and pursuant to our related ATM facility described therein. Additionally, our stockholders may be further diluted by the exercise of the pre-funded warrants issued in the October 2023 Offering and the February 2026 Offering. As of December 31, 2025, no shares underlying the pre-funded warrants had been exercised. Debt financing, if available, may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Our Loan Agreement with the Lenders restricts our ability to incur additional indebtedness without the consent of the Lenders. If we raise additional funds through partnerships, collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. 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.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

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 will be 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 or the federal district court for the District of 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 ten 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 behalf of us;
- any action asserting a claim of breach of a fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, as either may be amended from time to time; 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 Securities Exchange Act of 1934, as amended, or 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 will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities 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.

If we are unable to maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

In the past, we experienced material weaknesses in our internal control over financial reporting, which have since been remediated for a number of years. If in the future, we have a material weakness in our internal controls over financial reporting, we may not be able to prevent or detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm, if required, may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by our independent registered public accounting firm in connection with Section 404(b) of SOX, as long as such attestation report is required pursuant to such section by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which have since been remediated for a number of years. However, our remediation of previous material weaknesses may not prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

We are required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management are required to assess the effectiveness of these controls annually. We were no longer an "emerging growth company" as of December 31, 2021 and as such, pursuant to Section 404(b) of SOX, our independent registered public accounting firm attested to the effectiveness of our internal control over financial reporting as of December 31, 2021. However, we became a "non-accelerated filer" for fiscal year 2023. While we remain a non-accelerated filer, we will not be required to include an attestation report issued by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. Upon a change in status to an accelerated or large-accelerated filer, our independent registered public accounting firm would be required to attest to the effectiveness of our internal control over financial reporting as of the filing of the Form 10-K of that year. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not and therefore we may be less likely to detect deficiencies in our internal controls over financial reporting in the future and during any fiscal year for which we remain a non-accelerated filer.

We are organized in a holding company structure and we are, and will be, dependent upon the results of operations and cash flows of our subsidiaries and distributions we receive from our subsidiaries.

ALX Oncology Holdings Inc. is a holding company that currently has no material assets other than cash and our ownership of all of the equity issued by ALX Oncology Limited. As such, ALX Oncology Holdings Inc. will have no independent means of generating revenue or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the results of operations and cash flows of ALX Oncology Limited and its consolidated subsidiaries, including any distributions we receive from ALX Oncology Limited. There can be no assurance that our direct and indirect subsidiaries will generate sufficient cash flow to distribute funds to us or that applicable law and contractual restrictions, such as negative covenants in any debt instruments, will permit such distributions. In addition, in the event that the board of directors and stockholders of ALX Oncology Holdings Inc. were to approve a sale of all of our equity in ALX Oncology Limited or any of our other indirect subsidiaries, your equity interest would be in a holding company with no material assets other than those assets and other consideration received in such transaction.

General Risks

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

Our operations, and those of our service providers and suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical or public health crises, such as the COVID-19 pandemic, and other natural or man-made disasters such as the ongoing geopolitical unrest related to Russia's war with Ukraine, war and instability in Israel and the surrounding region, or business interruptions, for which we are partly uninsured. 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.

The majority of our operations including our corporate headquarters are located in the San Francisco Bay Area in California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches or incidents.

Despite our implementation of security measures, any of the computer systems and networks belonging to or used by us or our employees and our CROs and other third-party service providers are vulnerable to damage and disruption from computer viruses, ransomware and other malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, as well as security breaches and incidents from inadvertent or intentional actions, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets, which could result in financial, legal, business and reputational harm to us. Any system failure, accident or security breach or incident that causes interruptions in our own or in our CROs' or other third-party service providers' operations could result in a material disruption of our drug discovery and development programs or other aspects of our operations. We may be more susceptible to security breaches and other security incidents while a large percentage of our employees continue to work from home for some portion of time because we and our service providers have less capability to monitor and enforce policies for those employees. Also, ongoing geopolitical unrest and related events such as Russia's war with Ukraine and war and instability in Israel and the surrounding region may subject us and our CROs and other third-party service providers to heightened risks of cyber-attacks and security breaches and incidents, any of which could materially disrupt our drug discovery and development programs or other aspects of our operations.

A system failure or security breach or incident that leads to the loss, corruption or unavailability of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost, corrupted, or unavailable data. In addition, if any disruption or security breach or incident results in loss, destruction, alteration, or unavailability of, or damage or unauthorized access to, our data or applications or unauthorized access to, disclosure, dissemination or other processing of confidential or proprietary information that we or our third-party service providers process, including personal information related to the subjects in our clinical trials, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected and further development of our product candidates may be delayed. Any such disruption, failure or security breach or incident could also cause us to incur additional costs to remedy the damages that arise from such disruption, failure or security breach or incident. Additionally, in the event of any such disruption, failure or security breach or incident, or any perception that one has occurred, we could be exposed to claims, demands, and litigation and governmental investigations and other proceedings, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant liabilities, including fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

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 by SEC rules and regulations. 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 the 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.

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

The market price of our common stock has experienced significant fluctuations in the past year and may be volatile in the future. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management's attention from the business, which could seriously harm our business.

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. We periodically 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 evaluate whether and how to 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 to manage our risk assessment and mitigation processes, including our Chief Accounting Officer (CAO), who serves as our acting Chief Information Security Officer (CISO), as well as external information technology consultants who help manage our information technology systems and our information security.

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

We engage our information technology consultants, including dedicated on-site consultants as well as other third parties, in connection with our risk assessment processes. These partners assist us to help design, implement, monitor, and test our cybersecurity policies and procedures. We also require key third-party service providers to certify that they have the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their 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, which is responsible for monitoring and assessing strategic risk exposure, has delegated primary oversight responsibility for cybersecurity to our audit committee.

Our CAO and acting CISO, who reports to our President, is responsible for the day-to-day management of our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above, with the assistance of and informed by our consultants. Our CAO and acting CISO, who has many years of senior management and operational oversight at emerging technology companies, is informed about and monitors the prevention, detection, mitigation, and remediation of cybersecurity incidents through the day-to-day management of our information technology consultants, which includes engaging with information provided by the consultants, automated monitoring and detection systems, and other tools and processes defined by our cybersecurity policies.

Our CAO and acting CISO provides periodic briefings to our executive officers 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. Our CAO and acting CISO also provides periodic briefings to the board of directors, including the audit committee, on cybersecurity risks and activities.

Item 2. Properties.

Our principal executive office is located in South San Francisco, California. We currently lease 10,000 square feet of office space in South San Francisco, California, under a lease that expires in 2026, and 11,074 square feet of office and laboratory space in Palo Alto, California, under a lease that expires in 2030. We believe that we have sufficient space to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information for Our Common Stock

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "ALXO" since July 17, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 2, 2026, there were 127 holders of record of our common stock. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements and contractual restrictions of then-existing debt instruments and other factors that our board of directors deems relevant.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

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

You should read the following discussion of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis generally addresses 2025 and 2024 items and year-over-year comparisons between 2025 and 2024. Discussions of 2023 items and year-over-year comparisons between 2024 and 2023 that are not included in this Annual Report on Form 10-K can be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 6, 2025. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives. Our clinical pipeline includes two clinical-stage product candidates, the CD47 blocker evorpacept and an epidermal growth factor receptor (EGFR)-targeted antibody drug candidate (ADC) ALX2004. Our lead product candidate, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpacept is currently being evaluated in combination with trastuzumab and chemotherapy in patients with metastatic HER2-positive breast cancer in the Phase 2 ASPEN-09-Breast clinical trial and is also being studied in clinical trials with other targeted anti-cancer antibodies. Cancer cells leverage CD47, a cell surface protein, as a "don't eat me" signal to evade macrophage phagocytosis. We are developing evorpacept to be a next-generation checkpoint inhibitor designed to have a high affinity for CD47 and to avoid the limitations caused by hematologic toxicities inherent in other CD47 blocking approaches. Our second pipeline candidate, ALX2004, is a novel EGFR-targeted antibody-drug conjugate with a differentiated mechanism of action entered into a Phase 1 clinical trial in August 2025.

Evorpacept is a next-generation CD47 blocking therapeutic that we believe has significantly enhanced properties compared to competing CD47 blocking approaches. Evorpacept is a fusion protein that combines a high-affinity CD47 binding domain with a proprietary inactivated Fc domain. The CD47 binding domain of evorpacept is an affinity enhanced extracellular domain of SIRPα, a protein found on myeloid cells such as macrophages, that is the natural receptor to CD47. We have engineered the Fc domain of evorpacept so that it does not provide a pro-phagocytic signal while still maintaining an antibody-like half-life for the molecule. We believe our inactive Fc approach improves tolerability when compared to other CD47 blocking approaches that have an Fc domain that engages activating receptors on macrophages, causing phagocytosis and death of healthy cells in addition to cancer cells.

Evorpacept's design has several additional advantages that we believe will make it broadly applicable to treating a number of oncology indications. Due to the inactive Fc, evorpacept is specifically designed for use in combination with other anti-cancer agents that provide a positive immune-stimulating signal. We believe evorpacept has a favorable tolerability profile that may enable higher dosing levels, increased tumor penetration, and greater combination potential with other leading anti-cancer agents.

We are focused on evorpacept development with the standard-of-care agents that provide a stimulatory signal to the innate immune system. We are combining evorpacept with anti-cancer targeted antibodies with an active Fc domain, where evorpacept enables the Fc-mediated antibody dependent phagocytosis that is impaired by the expression of CD47 on cancer cells.

Data from the randomized ASPEN-06 Phase 2 clinical trial supports the clinical validation of this mechanism of action. ASPEN-06 evaluates the contribution of evorpacept to HERCEPTIN® (trastuzumab) plus standard of care (CYRAMZA® (ramucirumab) + paclitaxel) (Evo-TRP), versus trastuzumab, ramucirumab, and paclitaxel (TRP) in second line or later human epidermal growth factor receptor 2 (HER2)-positive gastric/gastroesophageal junction (GEJ) cancer, where all patients had received an anti-HER2 agent in prior lines of therapy. The full data set was previously presented. Results from a pre-planned exploratory analysis were presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting:

- In a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer, CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression. Retained HER2 expression is defined as patients who are HER-2 positive on a tumor biopsy after receiving a HER2-targeted treatment or by HER2 amplification by circulating tumor DNA (ctDNA). The data was highlighted as part of a poster presentation at the SITC Annual Meeting in November 2025.
    - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% objective response rate (ORR) versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.

- The duration of response (DOR) was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had a median DOR (mDOR) of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. Progression free survival (PFS) and overall survival (OS) data were evaluated in these patients. Treatment with Evo-TRP resulted in a median PFS (mPFS) of 18.4 months versus 7.0 months for TRP, hazard ratio (HR) of 0.39. Treatment with Evo-TRP resulted in a median OS (mOS) of 17 months versus 9.9 months for TRP, HR of 0.70.

Evorpacept has been combined in clinical trials with multiple anti-cancer antibodies in addition to trastuzumab including the CD20-targeted antibody rituximab, the CD38-targeted antibody isatuximab-*irfc*, and the HER2-targeted bispecific antibody zanidatamab. Our earlier ASPEN-01 Phase 1 positive data in combination with rituximab in non-Hodgkin lymphoma (NHL); the Phase 1/2 investigator-sponsored trial (IST) of evorpacept in combination with rituximab and lenalidomide in patients with relapsed refractory B-cell NHL (R/R B-NHL) and subsequently, in patients with newly diagnosed indolent B-cell NHL (iNHL); and the Phase 1b/2 trial of evorpacept with zanidatamab in patients with HER2-positive breast cancer provide additional support for the clinical validation of this mechanism of action and support exploring combinations of evorpacept with other anti-cancer antibodies.

Our second product candidate is ALX2004, a novel EGFR-targeted ADC. ALX2004 was created from our proprietary linker-payload library and fully designed and developed in-house by our scientists. ALX2004 comprises a matuzumab-derived affinity-selected EGFR antibody backbone engineered for optimal activity as an ADC, a proprietary topoisomerase I inhibitor payload with enhanced bystander effect, and a linker with enhanced stability. EGFR is clinically validated as a therapeutic target with several U.S. Food and Drug Administration (FDA)-approved targeted antibodies and small molecules. However, there are currently no approved EGFR-targeted ADCs and early-generation attempts to develop EGFR-targeted ADCs were limited by drug design, on-target off-tumor toxicities and toxicity of older generation payloads.

We are engaged in the following clinical programs, collaborations, and investigator-sponsored trials:

Evorpacept

Combination with the HER2-targeted antibody trastuzumab

- ASPEN-09-Breast – HER2+ Breast Cancer
  - In March 2025, we announced intent to initiate a randomized Phase 2 clinical trial evaluating evorpacept in combination with trastuzumab and chemotherapy for the treatment of patients with HER2-positive metastatic breast cancer after prior treatment with fam-trastuzumab deruxtecan-nxki.
  - In August 2025, we announced that based on the magnitude of benefit in patients with high CD47 expression in HER2-positive gastric cancer, the ASPEN-09-Breast study in HER2-positive breast cancer evaluating evorpacept in combination with trastuzumab and chemotherapy has been amended to a single-arm design in all previously treated HER2 positive patients and will be evaluated by CD47 expression.
  - In January 2026, we announced that the first patient had been dosed in the trial.
- ASPEN-06 – Gastric/GEJ Cancer
  - In January 2020, the FDA granted Fast Track designation for evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of patients with HER2-overexpressing advanced gastric or GEJ adenocarcinoma with disease progression on or after prior trastuzumab and fluoropyrimidine or platinum containing chemotherapy.
  - In January 2022, the FDA's Office of Orphan Products Development granted Orphan Drug Designation (ODD) to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In March 2022, we announced the dosing of the first patient in the multi-center, international ASPEN-06 trial, a randomized Phase 2/3 trial of evorpacept in combination with trastuzumab, ramucirumab and paclitaxel for the treatment of second- and third-line advanced HER2-overexpressing gastric/GEJ cancer, where all patients had received an anti-HER2 agent in prior lines of therapy.
  - In June 2023, the European Commission granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer.
  - In October 2023, we announced positive prespecified interim Phase 2 clinical data from our ASPEN-06 clinical trial. This prespecified interim analysis reported results from 54 randomized patients with second and third line gastric/GEJ cancer, including patients previously treated with fam-trastuzumab deruxtecan-nxki and checkpoint inhibitors. A confirmed ORR of 52% was demonstrated for the Evo-TRP treatment arm compared to 22% for the TRP control arm. An mDOR was not reached for the Evo-TRP treatment arm compared to 7.4 months for the control group. The safety profile of evorpacept was consistent with previous clinical trials and was well-tolerated.

- In July 2024, we announced the topline data from our ASPEN-06 Phase 2 clinical trial. This topline data reported results from 127 randomized patients with second and third line gastric/GEJ cancer and was generally well-balanced across arms based on prespecified stratification factors including line of therapy, prior ENHERTU® use, Asia region, tumor location (GC or GEJ), HER2 expression level, and having HER2-positive disease based upon a tissue biopsy after anti-HER2 treatment. A confirmed ORR of 40.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm. The mDOR was 15.7 months for the Evo-TRP treatment arm and 7.6 months for the TRP control arm in the full trial population. In patients with fresh HER2-positive biopsies (n=48), Evo-TRP demonstrated an ORR of 54.8% compared to 23.1% for the TRP control.
- In January 2025, we presented updated results from the ASPEN-06 Phase 2 clinical trial in an oral presentation at the 2025 American Society of Clinical Oncology Gastrointestinal Cancers Symposium. A confirmed ORR of 41.3% was demonstrated for the Evo-TRP treatment arm compared to 26.6% for the TRP control arm in the intent-to-treat patient population. In patients with confirmed HER2-positive expression as determined by either fresh biopsy or ctDNA HER2-positivity (n=96), the addition of evorpacept to TRP resulted in a 48.9% ORR, an mDOR of 15.7 months and mPFS of 7.5 months, compared to a 24.5% ORR, an mDOR of 9.1 months and mPFS of 6.7 months in the TRP control group, with a PFS HR of 0.64.
- In April 2025, we received guidance from the FDA that the ASPEN-06 Phase 2 trial data evaluating Evo-TRP was not eligible for submission for accelerated approval given the availability of ENHERTU. A Phase 3 versus ENHERTU trial would be needed to pursue a regulatory approval of evorpacept in the second-line setting for HER2-positive gastric and GEJ. Given our disciplined focus and the allocation of our resources, we will not pursue a U.S. registrational path with a Phase 3 trial in gastric cancer and will consider exploring development partnerships to advance this program in gastric cancer.
- In August 2025, we announced topline results from pre-planned exploratory analysis of the ASPEN-06 trial in gastric cancer, where CD47 overexpression was identified as a key predictive biomarker for response and durable benefit.
- In November 2025, we presented a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer in which CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression.
    - In patients with retained HER2-positive and CD47-high gastric cancer (n=43), Evo-TRP had a 65.0% ORR versus 26.1% ORR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer (n=47), Evo-TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
    - The DOR was three times longer in the Evo-TRP arm relative to TRP in these patients. Evo-TRP had an mDOR of 25.5 months versus 8.4 months mDOR for TRP, while patients with retained HER2-positive and CD47-low gastric cancer, had an mDOR of 11.2 months for Evo-TRP compared to 12 months for TRP. PFS and OS data were evaluated in these patients. Treatment with Evo-TRP resulted in an mPFS of 18.4 months versus 7.0 months for TRP, HR of 0.39. Treatment with Evo-TRP resulted in an mOS of 17 months versus 9.9 months for TRP, HR of 0.70.

Combination with the EGFR-targeted antibody cetuximab

- ASPEN-CRC – Colorectal Cancer (CRC)
    - In March 2025, we announced intent to initiate a Phase 1b study evaluating evorpacept in combination with the EGFR-targeted antibody cetuximab and FOLFIRI for the treatment of patients with second-line metastatic CRC.
    - In August 2025, we streamlined evorpacept development program to focus our resources on the ASPEN-09-Breast trial and paused the ASPEN-CRC study announced earlier in March 2025.

Collaborations and Investigator-Sponsored Trials (ISTs)

Combination with the HER2-targeted bispecific, zanidatamab, and HER2-targeted ADC, fam-trastuzumab deruxtecan-nxki

- Jazz Pharmaceuticals plc – Breast Cancer
    - Our collaborator, Jazz Pharmaceuticals plc (Jazz), sponsored and managed the Phase 1b/2 trial of zanidatamab, a HER2-targeted anti-cancer antibody, for the treatment of advanced HER2-expressing breast cancer and other solid tumors in combination with evorpacept (Zanidatamab Trial). We announced the dosing of the first patient in this trial in October 2021.
    - Our initial collaborator for the Zanidatamab Trial was Zymeworks Inc. (Zymeworks), however in a series of transactions commencing in October 2022, Jazz assumed responsibility from Zymeworks for the development and commercialization of zanidatamab in the United States, Europe, Japan and certain other territories, including responsibility for the Zanidatamab Trial.

- In December 2024, Phase 1b/2 data were presented in a poster presentation at the 2024 San Antonio Breast Cancer Symposium (SABCS). The SABCS poster presentation data-cut reported on efficacy findings from all three of the part-two trial cohorts: Cohort 1 (n=21) consisted of patients with HER2-positive breast cancer who had received prior ENHERTU and also a median of six prior systemic therapies in the metastatic setting. Patients were enrolled based on local assessment of tumor samples or central assessment. Of the 21 patients enrolled in Cohort 1, nine were found to be HER2-positive based on central assessment. Cohort 2 (n=15) consisted of patients with HER2-low breast cancer who had received a median of five prior systemic therapies. Cohort 3 (n=8) consisted of patients with other HER2-expressing cancers. Patients in Cohort 1 who were HER2-positive by central assessment (n=9) showed the greatest anti-tumor activity with a confirmed ORR of 55.6% and an mPFS of 7.4 months. Overall, patients in Cohort 1 (n=21) had a confirmed ORR and mPFS of 33.3% and 3.6 months, respectively. Patients in Cohort 2 had a confirmed ORR and mPFS of 20.0% and 1.9 months, respectively. As of the August 2024 data cutoff, median follow-up was 9.6 months, with six patients still on treatment. The mDOR was not reached for Cohort 1 patients (range: 3.6-25.9 months) and was 5.5 months for Cohort 2 patients (range: 3.6-11.0 months), with responses ongoing, including the longest observed response, in each cohort. The combination therapy was well tolerated with a manageable safety profile that was consistent with prior experience of each agent.
- In January 2026, we announced that an exploratory biomarker analysis showed responses in the trial were largely restricted to patients with higher CD47 expression.

Combination with the CD20-targeted antibody rituximab

- MD Anderson Cancer Center – Non-Hodgkin Lymphoma
  - In 2021, an IST of evorpacept was initiated in combination with rituximab and lenalidomide (R^2) for the treatment of patients with indolent and aggressive NHL, sponsored by MD Anderson Cancer Center in Texas. We announced the dosing of the first patient in September 2021.
  - In April 2024, MD Anderson Cancer Center reported clinical data from the ongoing Phase 1/2 IST of evorpacept in combination with R^2 in patients with R/R B-NHL. The new data were presented in an oral presentation at the 2024 American Association for Cancer Research (AACR) Annual Meeting. The Phase 1 part of the clinical trial enrolled a total of 20 patients with indolent (n=18) and aggressive (n=2) R/R B-NHL where all patients had received prior rituximab and 72% had received prior chemoimmunotherapy. Patients received evorpacept 30 mg/kg every two weeks (Q2W) (n=3) or 60 mg/kg every four weeks (Q4W) (n=17) in combination with standard R^2 treatment. The regimen was well tolerated, and there were no dose-limiting toxicities. Patients with indolent R/R B-NHL (n=18) had a best ORR of 94% and a complete response rate of 83%. The mDOR was not reached.
  - In April 2025, final data for the Phase 1 portion of the MD Anderson Cancer Center IST was presented at the 2025 AACR Annual Meeting. In the total population (n=20), after a median follow-up of 28 months (95% CI, 18-28 months) the two-year PFS rate was 69% and two-year OS rate was 84%. The Phase 2 portion of the clinical trial in patients with previously untreated indolent NHL is ongoing and has completed enrollment.
  - In December 2025, data for the Phase 2 portion of this trial, which enrolled patients with untreated indolent NHL was presented at the 2025 American Society of Hematology Annual Meeting. The combination of evorpacept with R^2 generated complete responses in 92% of patients comparing favorably to an approximate 50% historical complete response rate for R^2 alone.

Combination with the CD38-targeted antibody isatuximab-irfc

- Sanofi – Multiple Myeloma
  - In April 2023, we announced a collaboration with Sanofi who will sponsor and manage a Phase 1/2 trial of SARCLISA® (isatuximab-irfc), an anti-cancer antibody, and dexamethasone in combination with evorpacept for the treatment of patients with relapsed or refractory multiple myeloma. We announced the dosing of the first patient in September 2024.
  - In August 2025, we announced that the dose escalation portion of this trial was complete and Sanofi had begun the dose optimization portion of the trial.

Based on our clinical results to date in multiple oncology indications that show encouraging anti-tumor activity and tolerability, our strategy is to pursue evorpacept as a potentially critical component of future oncology treatments in combination with anticancer antibodies.

ALX2004

- In March 2025, we filed an investigational new drug (IND) application for our first ADC program, ALX2004 and in April 2025, the FDA cleared the IND to evaluate ALX2004 in a Phase 1 clinical trial for patients with EGFR-expressing solid tumors.

- In August 2025, we announced the dosing of the first patient in the first-in-human, open-label multi-center Phase 1 clinical trial of ALX2004 for the treatment of advanced or metastatic select EGFR-expressing solid tumors.
- In January 2026, we announced that the trial had begun enrolling patients in the third dose cohort at 4 mg/kg after successfully clearing the second dose cohort. No dose-limiting toxicities were observed in the first two dose cohorts.

Since our founding, we have devoted substantially all of our resources to developing evorpacept, identifying and advancing preclinical programs, including the initiation and advancement of clinical trials of ALX2004, scaling up manufacturing, conducting clinical trials and providing general and administrative support for these operations. We have no products approved for marketing and we have never received any revenue from drug product sales.

From inception through December 31, 2025, we have raised an aggregate of $644.8 million to fund our operations, of which $175.1 million were net proceeds from sales of our convertible preferred stock, $5.8 million were net proceeds from borrowings under a term loan, $169.5 million were net proceeds from our initial public offering, $194.9 million were net proceeds from our registered offering in December 2020, $9.3 million were net proceeds from borrowings under the Loan Agreement (as defined below), $58.9 million were net proceeds from our registered offering in October 2023, and $31.4 million were net proceeds from our at-the-market (ATM) offering. After December 31, 2025, we also raised $140.4 million in net proceeds from our registered offering in February 2026. For more information on the funding of our operations since inception, see section titled "—Liquidity and Capital Resources; Plan of Operations—Funding Requirements" included elsewhere in this Annual Report on Form 10-K.

We have incurred net losses in each year since inception. Our net losses were $101.7 million, $134.9 million and $160.8 million for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $722.8 million. Substantially all of our operating losses are a result of expenses incurred in connection with our research and development programs, primarily evorpacept, and from general and administrative expenses associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance evorpacept through multiple clinical trials in multiple indications;
- pursue regulatory approval of evorpacept in solid tumors and hematological malignancies;
- advance ALX2004 through a first-in-human trial;
- continue preclinical and clinical development efforts;
- obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- manufacture supplies for our preclinical studies and clinical trials; and
- continue to add operational, financial and management information systems to support ongoing operations as a public company.

Nasdaq Minimum Bid Price Compliance

On April 23, 2025, we received a written notice (Notice), from the Listing Qualifications Staff (Staff) of The Nasdaq Stock Market LLC (Nasdaq) notifying us that we had not been in compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market set forth in Nasdaq Listing Rule 5450(a)(1) for a period of 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market, subject to our compliance with the other listing requirements of Nasdaq. In September 2025, we received written confirmation from the Staff of Nasdaq that we had regained compliance with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market, as the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, evorpacept, and the initiation and advancement of ALX2004, which include:

- expenses incurred in connection with preclinical and clinical development, including expenses incurred under collaboration agreements and under agreements with contract research organizations, or CROs;

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expenses for employees engaged in research and development functions;
- expenses related to production of clinical materials, including fees paid to contract manufacturing organizations, or CMOs;
- laboratory, vendor expenses and third-party drugs related to the execution of preclinical studies and clinical trials;
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies; and
- milestone payments related to our ScalmiBio acquisition.

We expense research and development costs as incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered or as services are performed. We record accruals for estimated costs of research, preclinical studies, clinical trials and manufacturing development, which are a significant component of research and development expenses. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

Our research and development expenses consist primarily of costs associated with the development of our lead product candidate, evorpacept, and the initiation and advancement of clinical trials of ALX2004, and include external costs, such as fees paid to consultants, central laboratories, contractors, collaborators, CMOs and CROs in connection with our preclinical and clinical development activities.

Almost all of our research and development expenses to date have been related to the clinical development of our lead product candidate, evorpacept, and the initiation and advancement of clinical trials of ALX2004. We expect to incur significant research and development expenses in the foreseeable future as we continue to invest in research and development activities related to progress on our existing product candidates. As our product candidates advance into later stages of development, we begin to conduct larger clinical trials. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

The successful development of our current and future product candidates is highly uncertain. This is due to numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials;
- our ability to negotiate agreements with clinical trial sites or CROs;
- the number and location of clinical sites included in the trials;
- raising additional funds necessary to complete clinical development of our product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- contracting with third-party manufacturers for clinical supplies of our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio, including, if necessary, litigation; and
- maintaining a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates may significantly impact the costs and timing associated with the development of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and development activities are essential to our business model. There are numerous factors associated with the successful commercialization of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact the success, cost or timing of our clinical development programs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, business development expenses, facilities expenses, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit, accounting and tax-related services, and directors and officers liability insurance premiums. Personnel and related costs consist of salaries, benefits and stock-based compensation expenses. Facilities costs consist of rent and maintenance of facilities.

We anticipate that our general and administrative expenses will decrease as a result of the completed reduction in workforce. Other factors that may affect general administrative expenses include inflationary pressures, higher costs of consulting, legal, tax and regulatory-related services associated with maintaining compliance with stock exchange listing and SEC requirements, audit and investor relations costs, director and officer insurance premiums and other costs associated with being a public company.

Impairment Charge

Impairment charge consists of impairment of long-lived assets.

Interest Income

Our interest income consists primarily of interest income on cash, cash equivalents and investments.

Interest Expense

Our interest expense consists primarily of interest expense on the term loan, amortization of deferred debt issuance costs, and interest related to finance leases.

Other Income (Expense), Net

Our other income (expense), net consists primarily of realized foreign currency transaction gains and losses.

Results of Operations and Net Loss

Comparisons of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Operating expenses:				
Research and development	$ 76,996	$ 116,373	$ (39,377)	-34%
General and administrative	23,850	26,094	(2,244)	-9%
Impairment charge	3,175	—	3,175	100%
Total operating expenses	104,021	142,467	(38,446)	-27%
Loss from operations	(104,021)	(142,467)	38,446	-27%
Interest income	3,964	9,366	(5,402)	-58%
Interest expense	(1,602)	(1,729)	127	-7%
Other income (expense), net	(36)	(20)	(16)	80%
Net loss	$ (101,695)	$ (134,850)	$ 33,155	-25%

Research and Development Expenses

The following table summarizes our research and development (R&D) expenses incurred for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Clinical and development costs	$ 44,418	$ 61,868	$ (17,450)	-28%
Preclinical costs	2,105	6,717	(4,612)	-69%
Personnel and related costs	17,037	23,085	(6,048)	-26%
Stock-based compensation expense	6,205	18,490	(12,285)	-66%
Other research costs	7,231	6,213	1,018	16%
Total research and development expenses	$ 76,996	$ 116,373	$ (39,377)	-34%

R&D expenses decreased by $39.4 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to (i) a decrease of $17.5 million in clinical and development costs due to manufacturing of clinical trial materials, the majority of which was completed in early 2024, to support active clinical trials for our product candidate, evorpacept, (ii) a decrease of $12.3 million in stock-based compensation expense due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange, (iii) a decrease of $6.0 million in personnel and related costs primarily driven by the reduction in workforce in the first quarter of 2025, and (iv) a decrease of $4.6 million in preclinical costs due to pipeline prioritization strategy. These decreases were offset by an increase of $1.0 million in other research costs primarily due to a development milestone payment to ScalmiBio stockholders.

The future trend of our R&D expenses is dependent on our decision-making on which indications to pursue for future clinical development and the costs, timing, and outcomes of any future clinical trials.

General and Administrative Expenses

The following table summarizes our general and administrative (G&A) expenses incurred for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Personnel and related costs	$ 8,672	$ 7,619	$ 1,053	14%
Stock-based compensation expense	6,374	8,603	(2,229)	-26%
Other general and administrative costs	8,804	9,872	(1,068)	-11%
Total general and administrative expenses	$ 23,850	$ 26,094	$ (2,244)	-9%

G&A expenses decreased by $2.2 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to (i) a decrease of $2.2 million in stock-based compensation expense primarily due to terminations from the reduction in workforce as well as modification from the December 2024 option exchange and (ii) a decrease of $1.1 million in other G&A costs such as legal patent fees, corporate consulting fees, and accounting consulting costs. This was offset by an increase of $1.1 million in personnel and related costs primarily driven by severance costs from the reduction in workforce and merit increases.

Impairment Charge

Impairment charge increased by $3.2 million for the year ended December 31, 2025. In May 2025, we made a decision to sublease our leased property in Palo Alto and are actively marketing the leased property for sublease. We recorded long-lived asset impairment charge based on the performed impairment analysis. There was no impairment charge for the year ended December 31, 2024.

Interest Income

Interest income decreased by $5.4 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to lower interest rates as well as lower cash and investment balances during the current year as compared to prior year.

Interest Expense

Interest expense decreased by $0.1 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to lower interest rates.

Other Income (Expense), Net

Other income (expense), net remained flat for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

Since our inception, we have incurred significant operating losses and have not generated any product revenue. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all, subject to regulatory and marketing approval of any of our product candidates. To date, we have funded our operations with proceeds from the sales of shares of our common stock and convertible preferred stock and borrowings under our term loan. As of December 31, 2025, we had cash, cash equivalents and investments of $48.3 million.

Funding Requirements

We have incurred losses and negative cash flows from operations since inception and anticipate that we will continue to incur net losses for the foreseeable future. As of December 31, 2025, we had an accumulated deficit of $722.8 million. We expect to incur significant expenses in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company. Management recognizes the need to raise additional capital to fully implement its business plan. The timing and amount of such future capital requirements are difficult to forecast and will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;
- the timing and outcome of regulatory review of our product candidates;
- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if any of our product candidates are approved, commercial manufacturing;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we obtain marketing approval;
- the legal patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone and royalty payments thereunder;
- our ability to maintain our listing on Nasdaq; and
- macroeconomic conditions and global economic environment, such as inflation, interest rate changes, trade and other global disputes and interruptions, including related to tariffs and trade protection measures, U.S. federal government shutdowns, economic downturns, bank failures or instability in the financial services sector, or geopolitical risks, disasters, and medical or public health crises, such as the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Other than the Loan Agreement, we do not have any committed external source of funds. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

In July 2020, we completed our initial public offering pursuant to a registration statement on Form S-1. In the initial public offering, we issued and sold an aggregate of 9,775,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at a public offering price of $19.00 per share. Net proceeds were approximately $169.5 million, after deducting underwriting discounts and commissions of $13.0 million and offering-related expenses of $3.2 million.

In December 2020, we completed our registered offering pursuant to a registration statement on Form S-1. In this registered offering, we issued and sold an aggregate of 2,737,000 shares of common stock, including the underwriters' exercise in full of their overallotment option, under the registration statement at an offering price of $76.00 per share. Net proceeds were approximately $194.9 million, after deducting underwriting discounts and commissions of $12.5 million and offering-related expenses of $0.7 million.

In December 2021, we entered into a sales agreement (as amended, Sales Agreement) with Cantor Fitzgerald & Co. and Credit Suisse Securities (USA) LLC (Credit Suisse), under which we may offer and sell our common stock, having aggregate gross proceeds of up to $150.0 million, from time to time through them as our sales agents in our ATM offering program. In March 2022, we filed a universal shelf registration statement (2022 Shelf Registration Statement) with the SEC, which was declared effective by the SEC on May 31, 2022. In August 2023, we entered into an amendment to the Sales Agreement to include UBS Securities LLC as an additional sales agent and to remove Credit Suisse as a sales agent.

In October 2022, we entered into the Loan Agreement as described above. Upon closing of the Loan Agreement, we drew $10.0 million. Under the original terms of the Loan Agreement, we had the right to draw an additional $40.0 million through the end of 2023. A further $50.0 million was potentially available to us, $25.0 million upon the achievement of pre-determined development milestones and $25.0 million at the Lenders' sole discretion. For a description of the terms of the Loan Agreement, see "Note 7. Term Loan" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. On May 31, 2023, we entered into a second amendment to the Loan Agreement. The primary purpose of the second amendment was to reduce the percentage of the amount required to be held in our collateral account with SVB-First Citizens from 100% to not less than 50% of the aggregate dollar value of all our collateral accounts.

In March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) to act as receiver. The FDIC created Silicon Valley Bridge Bank, N.A. (SVBB) as successor to SVB. First Citizens BancShares, Inc. (First Citizens Bank) acquired SVBB from the FDIC and operates SVBB as Silicon Valley Bank, a division of First Citizens Bank (SVB-First Citizens). While we have cash in operating accounts with SVB, the majority of our cash, cash equivalents and investments are deposited in custodial accounts held by U.S. Bank for which SVB Asset Management is the investment advisor. There has been no material negative impact to our cash liquidity as a result of the closure of SVB or the subsequent acquisition of SVBB by First Citizens Bank. Under the Loan Agreement, 50% of the funding comes from SVB, one of the three Lenders. Given the SVBB acquisition by First Citizens Bank, SVB-First Citizens will continue to fulfill SVB's obligations under the Loan Agreement.

In October 2023, we completed a registered offering pursuant to the 2022 Shelf Registration Statement. In this registered offering, we issued and sold an aggregate of 8,663,793 shares of common stock, including the underwriters' exercise in full of their overallotment option of 1,293,103 shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,250,000 shares of common stock at an offering price of $6.38 per share and $6.379 per pre-funded warrant. Net proceeds were approximately $58.9 million, after deducting underwriting discounts and commissions of $3.8 million and offering-related expenses of $0.6 million. As of December 31, 2025, no shares underlying the pre-funded warrants had been exercised.

In December 2023, we entered into a third amendment to the Loan Agreement. The primary purpose of the third amendment was to (i) extend the draw period for the first tranche loans from December 31, 2023 to June 30, 2024, (ii) add as a condition for the funding of any first tranche loans after the effective date of the amendment, the requirement that the Phase 2 portion of the ASPEN-06 study in gastric/GEJ cancer either remains ongoing or the achievement of a milestone related to the development of the ASPEN-06 study, and (iii) add a contingency fee in the amount of $0.6 million to the Lenders if the Company prepays any of the loans under the Loan Agreement other than in connection with refinancing of the Loan Agreement with the Lenders and their affiliates.

We decided not to draw down on any portion of the $40.0 million available to us under the Loan Agreement by the deadline of June 30, 2024. As a result of this decision, the $40.0 million was added to the $25.0 million available upon the achievement of pre-determined development milestones for a total of $65.0 million available, split equally between each of the two tranches. We did not achieve all of the requirements needed to gain access to each of the two tranches available upon the achievement of pre-determined development milestones by the deadline of December 31, 2024. As a result, only the $25.0 million tranche available at the Lenders' sole discretion was available to us as of December 31, 2025. The term loans under the Loan Agreement mature on October 1, 2027. We began to make principal payments in equal monthly installments beginning on December 1, 2025.

On March 6, 2025, we filed a shelf registration statement with the SEC that became effective on April 24, 2025 (the 2025 Shelf Registration Statement). The 2025 Shelf Registration Statement replaced the 2022 Shelf Registration Statement and registered the unsold securities from the 2022 Shelf Registration Statement, including those available under the ATM program. From December 2021 to December 31, 2025, we sold an aggregate of 3,175,681 shares of common stock under our Sales Agreement for net proceeds of $31.4 million, after deducting commissions. We may terminate this ATM program and the Sales Agreement at any time, pursuant to its terms.

On February 2, 2026, the Company completed a registered offering and issued an aggregate of 76,979,112 shares of common stock at an offering price of $1.57 per share and pre-funded warrants to purchase 18,574,120 shares of common stock at an offering price of $1.569 per pre-funded warrant. The Company received net proceeds of approximately $140.4 million, after deducting underwriting discounts and commissions of $9.0 million and other offering-related expenses of $0.6 million.

We believe our existing cash, cash equivalents and investments, including net proceeds from the February 2026 offering, will enable us to fund our operating expenses and capital expenditure requirements through the first half of 2028. Additionally, the Company also has the ability to further utilize the ATM program. We have based these estimates on assumptions in which actuals may materially differ, and we could utilize our available capital resources sooner than we expect.

Cash Flows

The following table presents a summary of the net cash flow activity for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2025	**2024**	**2023**
Net cash provided by (used in):			
Operating activities	$ (84,142)	$ (121,912)	$ (130,364)
Investing activities	82,586	86,256	44,657
Financing activities	362	30,817	59,291
Net decrease in cash, cash equivalents and restricted cash	$ (1,194)	$ (4,839)	$ (26,416)

Operating Activities

In the year ended December 31, 2025, net cash used in operating activities of $84.1 million was attributable to a net loss of $101.7 million offset by an increase in net operating assets and liabilities of $0.3 million and non-cash charges of $17.2 million. The change in operating assets and liabilities was primarily driven by an increase in accounts payable and accrued expenses and other current liabilities of $2.3 million, primarily due to timing of invoices and payments, and an increase in other assets of $0.7 million. These increases were partially offset by a decrease in prepaid and other current assets of $0.7 million and a decrease in other non-current liabilities of $1.9 million. Non-cash charges consisted primarily of stock-based compensation expense of $12.6 million, an impairment charge of $3.2 million, non-cash lease costs of $1.7 million, and depreciation and amortization costs of $0.7 million offset by net amortization of premiums and accretion of discounts on investments of $1.2 million.

In the year ended December 31, 2024, net cash used in operating activities of $121.9 million was attributable to a net loss of $134.9 million and a decrease in net operating assets and liabilities of $12.4 million offset by non-cash charges of $25.4 million. The change in operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses and other current liabilities of $17.0 million primarily due to timing of invoices and payments and a decrease in other assets of $7.4 million offset by an increase in prepaid and other current assets of $0.7 million and a decrease in other non-current liabilities of $2.1 million. Non-cash

charges consisted primarily of stock-based compensation expense of $27.1 million, non-cash lease costs of $1.8 million, and depreciation and amortization costs of $0.9 million offset by net amortization of premiums and accretion of discounts on investments of $4.7 million.

Investing Activities

In the year ended December 31, 2025, net cash provided by investing activities of $82.6 million was attributable to cash received for maturities of investments of $134.4 million, offset by purchases of short-term and long-term investments of $51.6 million and purchases of property and equipment of $0.2 million.

In the year ended December 31, 2024, net cash provided by investing activities of $86.3 million was attributable to cash received for maturities of investments of $194.1 million, offset by purchases of short-term and long-term investments of $107.4 million and purchases of property and equipment of $0.4 million.

Financing Activities

In the year ended December 31, 2025, net cash provided by financing activities of $0.4 million was attributable to proceeds from our ATM offering, net of commissions, of $1.7 million, offset by principal payments on finance leases of $0.9 million and principal payments on term loan of $0.4 million.

In the year ended December 31, 2024, net cash provided by financing activities of $30.8 million was attributable to proceeds from our ATM offering, net of commissions, of $29.7 million, proceeds from the exercise of stock options under equity incentive plans of $1.6 million, and proceeds from issuance of common stock pursuant to employee stock purchase plan of $0.4 million, offset by principal payments on finance leases of $0.8 million.

Off-Balance Sheet Arrangements

During the period presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ significantly from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in the notes to our audited consolidated financial statements elsewhere in this Annual Report on Form 10-K. We believe that the following accounting policy reflects the most critical judgments and estimation uncertainty used in the preparation of our consolidated financial results.

Clinical and Contract Manufacturing Accruals

We record accruals for estimated costs of research, preclinical studies and clinical trials, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of our ongoing research and development activities are conducted by third-party service providers, including CROs and contract manufacturing organizations, or CMOs. Our contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. Similarly, our contracts with CMOs generally include pass-through fees such as raw materials and other miscellaneous costs, including shipping. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed but not yet invoiced in accordance with the respective agreements. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services. To assist in our estimates, we rely upon the receipt of timely and accurate reporting from our clinical and non-clinical studies and other third-party vendors.

We make judgments and estimates in determining the accrual balance related to our CMOs at the end of each reporting period based on discussion with internal personnel who work directly and meet regularly with the CMOs. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in reporting amounts that are too high or too low in any particular period. Through December 31, 2025, there have been no material differences from our accrued estimated expenses to the actual clinical trial and manufacturing development expenses. However, variations in the assumptions used to estimate accruals, including, but not limited to, the number of patients enrolled, the rate of patient enrollment, the actual services performed, and related costs may vary from our estimates, resulting in adjustments to clinical trial expense and manufacturing costs in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our financial position and results of our operations.

Recent Accounting Pronouncements

See "Note 2. Significant Accounting Policies" of the Notes to Consolidated Financial Statements in "Item 8. Financial Statements and Supplementary Data" for a full description of recent accounting pronouncements, including the respective expected dates of adoption and estimated effects, if any, on our consolidated financial statements.

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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

As of December 31, 2025, we had cash, cash equivalents and investments of $48.3 million. We generally hold our cash and cash equivalents in interest-bearing bank accounts and money market funds. We have invested primarily in U.S. Treasury securities, U.S. government agency securities, corporate debt securities, commercial paper and asset-backed securities and all our investments are classified as available-for-sale. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents and investments.

As of December 31, 2025, we had borrowings of $9.6 million outstanding under the Loan Agreement. Borrowings under the Loan Agreement bear interest at a floating rate per annum equal to the greater of (i) 1-month term SOFR, and (ii) 2.33%, plus 6.25%. An immediate 10% change in the 1-month term SOFR would not have a material impact on our debt-related obligations, financial position or results of operations.

Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and investments. The Company invests its cash equivalents in highly rated money market funds. The Company's investments consist of debt securities issued by highly rated corporate entities, the U.S. federal government or state and local governments. The Company's exposure to any individual corporate entity is limited by our investment policy. Deposits may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation.

The Company is continuing to monitor any events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally.

During the periods presented, the Company has not experienced any realized losses on its deposits of cash, cash equivalents or investments.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for services with payments denominated in foreign currencies, primarily the euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material impact on our financial results.

Item 8. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
ALX Oncology Holdings Inc.:

Opinion on the Consolidated Financial Statements

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

/s/ KPMG LLP

We have served as the Company's auditor since 2016.

San Francisco, California
March 9, 2026

ALX ONCOLOGY HOLDINGS INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 16,373	$ 17,567
Short-term investments	28,417	110,190
Prepaid expenses and other current assets	5,937	6,595
Total current assets	50,727	134,352
Property and equipment, net	1,200	2,905
Long-term investments	3,494	3,524
Other assets	3,625	6,994
Total assets	$ 59,046	$ 147,775
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,914	$ 4,497
Payable and accrued liabilities due to related party	—	149
Term loan, current	5,217	435
Accrued expenses and other current liabilities	14,422	13,419
Total current liabilities	24,553	18,500
Term loan, non-current	4,532	9,469
Other non-current liabilities	3,980	6,188
Total liabilities	33,065	34,157
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, $0.001 par value; 1,000,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 54,388,022 and 53,052,912 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	54	53
Additional paid-in capital	748,716	734,412
Accumulated other comprehensive income	28	275
Accumulated deficit	(722,817)	(621,122)
Total stockholders' equity	25,981	113,618
Total liabilities and stockholders' equity	$ 59,046	$ 147,775

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

ALX ONCOLOGY HOLDINGS INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2025	**2024**	**2023**
Operating expenses:			
Research and development	$ 76,996	$ 116,373	141,795
General and administrative	23,850	26,094	28,483
Impairment charge	3,175	—	—
Total operating expenses	104,021	142,467	170,278
Loss from operations	(104,021)	(142,467)	(170,278)
Interest income	3,964	9,366	10,649
Interest expense	(1,602)	(1,729)	(1,565)
Other income (expense), net	(36)	(20)	389
Loss before income taxes	(101,695)	(134,850)	(160,805)
Income tax provision	—	—	—
Net loss	$ (101,695)	$ (134,850)	(160,805)
Net loss per share, basic and diluted	$ (1.90)	$ (2.58)	$ (3.74)
Weighted-average shares of common stock used to compute net loss per share, basic and diluted	53,658,399	52,174,904	42,987,767

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

ALX ONCOLOGY HOLDINGS INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Net loss	$ (101,695)	$ (134,850)	$ (160,805)
Other comprehensive gain (loss), net of tax:			
Unrealized gain (loss) on available-for-sale investments	(247)	19	1,101
Total comprehensive loss	$ (101,942)	$ (134,831)	$ (159,704)

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

ALX ONCOLOGY HOLDINGS INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	40,861,386	$ 41	$ 589,735	$ (845)	$ (325,467)	$ 263,464
Issuance of common stock and pre-funded warrants in connection with equity offerings, net of underwriter discounts ($3,795) and issuance costs ($567)	8,663,793	9	58,878	—	—	58,887
Issuance of common stock under equity incentive plans	344,213	—	269	—	—	269
Issuance of common stock under employee stock purchase plan	82,597	—	523	—	—	523
Stock-based compensation	—	—	26,273	—	—	26,273
Unrealized gain on available-for-sale investments	—	—	—	1,101	—	1,101
Net loss	—	—	—	—	(160,805)	(160,805)
Balance as of December 31, 2023	49,951,989	50	675,678	256	(486,272)	189,712
Issuance of common stock under equity incentive plans	810,243	1	1,631	—	—	1,632
Issuance of common stock under employee stock purchase plan	91,138	—	351	—	—	351
Issuance of common stock through ATM offering, net of commissions ($839)	2,199,542	2	29,659	—	—	29,661
Stock-based compensation	—	—	27,093	—	—	27,093
Unrealized gain on available-for-sale investments	—	—	—	19	—	19
Net loss	—	—	—	—	(134,850)	(134,850)
Balance as of December 31, 2024	53,052,912	53	734,412	275	(621,122)	113,618
Issuance of common stock under equity incentive plans	294,454	—	14	—	—	14
Issuance of common stock under employee stock purchase plan	64,517	—	24	—	—	24
Issuance of common stock through ATM offering, net of commissions ($37)	976,139	1	1,687	—	—	1,688
Stock-based compensation	—	—	12,579	—	—	12,579
Unrealized loss on available-for-sale investments	—	—	—	(247)	—	(247)
Net loss	—	—	—	—	(101,695)	(101,695)
Balance as of December 31, 2025	54,388,022	$ 54	$ 748,716	$ 28	$ (722,817)	$ 25,981

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

ALX ONCOLOGY HOLDINGS INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Operating activities			
Net loss	$ (101,695)	$ (134,850)	$ (160,805)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	12,579	27,093	26,273
Depreciation and amortization	706	872	836
Non-cash lease costs	1,719	1,785	1,272
Net accretion of discounts on investments	(1,242)	(4,657)	(6,487)
Accretion of term loan discount and issuance costs	280	265	250
Impairment charge	3,175	—	
Loss on disposal of fixed asset	—	10	—
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	658	(692)	(1,291)
Other assets	(686)	7,375	1,366
Accounts payable	421	(4,024)	458
Payable and accrued liabilities due to related party	(149)	(394)	(1,107)
Accrued expenses and other current liabilities	2,002	(12,624)	11,224
Other non-current liabilities	(1,910)	(2,071)	(2,353)
Net cash used in operating activities	(84,142)	(121,912)	(130,364)
Investing activities			
Purchase of investments	(51,593)	(107,406)	(246,629)
Maturities of investments	134,391	194,109	292,560
Purchase of property and equipment	(212)	(447)	(1,274)
Net cash provided by investing activities	82,586	86,256	44,657
Financing activities			
Proceeds from equity offerings, net of underwriter discounts ($3,795) and issuance costs ($567)	—	—	58,887
Proceeds from ATM offering, net of commissions	1,688	29,661	—
Proceeds from exercise of stock options under equity incentive plan	14	1,632	269
Proceeds from issuance of common stock under employee stock purchase plan	24	351	523
Principal payments on finance leases	(929)	(827)	(388)
Principal payments on term loan	(435)	—	—
Net cash provided by financing activities	362	30,817	59,291
Net decrease in cash, cash equivalents and restricted cash	(1,194)	(4,839)	(26,416)
Cash, cash equivalents and restricted cash at beginning of year	17,633	22,472	48,888
Cash, cash equivalents and restricted cash at end of period	$ 16,439	$ 17,633	$ 22,472
Supplemental disclosure			
Cash paid for interest	$ 1,259	$ 1,387	$ 1,177
Supplemental disclosure of non-cash investing and financing activities			
Purchase of property and equipment in accounts payable and accrued expenses	$ 962	$ 1,158	$ 1,407
Right-of-use asset (modified) acquired under finance leases	$ (182)	$ 1,309	$ 2,600
Reconciliation of cash and cash equivalents and restricted cash:			
Cash and cash equivalents	$ 16,373	$ 17,567	$ 22,406
Restricted cash (included in other assets)	66	66	66
Total cash, cash equivalents and restricted cash	$ 16,439	$ 17,633	$ 22,472

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

(1) ORGANIZATION

Organization

ALX Oncology Holdings Inc., or the Company, was formed as a Delaware corporation on April 1, 2020, or Inception. The Company was formed for the purpose of completing the Company's initial public offering of its common stock and related transactions in order to carry on the business of ALX Oncology Limited. The Company is a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives.

ALX Oncology Holdings Inc. is incorporated in Delaware. ALX Oncology Limited, incorporated in Ireland, is a wholly-owned subsidiary of ALX Oncology Holdings Inc. ALX Oncology Inc., incorporated in Delaware, is a wholly-owned subsidiary of ALX Oncology Limited. All the companies, except for ALX Oncology Holdings Inc., are collectively known as the Subsidiaries.

As of December 31, 2025, the Company has devoted substantially all of its efforts to the formation and financing of the Company, as well as product development, and has not realized product revenues from its planned principal operations. The Company does not have manufacturing facilities and all manufacturing related activities are contracted out to third-party service providers.

The Company expects to incur additional losses in the future to conduct product candidate research and development and to conduct pre-commercialization activities and recognizes that the Company will likely be required to raise additional capital to fully implement its business plan. The Company intends to raise such capital through the sale of additional equity, debt financings and/or strategic alliances with third parties. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms acceptable to the Company. If the Company is unsuccessful in its efforts to raise additional financing, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of its development programs or its future commercialization efforts, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all. The Company believes that the existing capital resources, which includes the capital raised during the February 2026 Offering (see Note 14), will be sufficient to fund the projected operating requirements for at least the next twelve months.

(2) SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and the applicable rules and regulations of the U.S. Securities and Exchange Commission, or SEC.

Principles of Consolidation

All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires the Company 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 periods. On an ongoing basis, the Company evaluates its estimates, including, but not limited to, those related to the estimated useful lives of long-lived assets, clinical and contract manufacturing accruals, fair value of assets and liabilities, fair value of investments, and stock-based compensation. The Company evaluates its estimates and assumptions on an ongoing basis based on historical experience and on various other market-specific and relevant assumptions that the Company believes to be reasonable under the circumstances and adjusts those estimates and assumptions when facts and circumstances change. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company holds its cash and cash equivalents in checking and money market accounts. The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds and U.S. government agency securities that are stated at cost, which approximate fair value.

Investments

Investments consist of money market funds, U.S. Treasury securities, U.S. government agency securities, corporate debt securities, and commercial paper. The Company's investments are classified as available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term investments and long-term investments. The Company determines the appropriate classification of the investments at the time they are purchased and evaluates the appropriateness of such classifications at each balance sheet date. Investments with contractual maturities greater than 12 months are considered long-term investments. The Company has elected to use transaction settlement date as the purchase date of investments.

The Company regularly reviews its investments for declines in estimated fair value below amortized cost. The factors considered in determining whether a credit loss exists include the creditworthiness of the security issuers, the number of investments in an unrealized loss position, the severity and duration of the unrealized losses, and whether it is more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost basis. The cost of investments sold is based on the specific identification method. In circumstances when an unrealized loss is determined to be credit-related, or when the Company intends to sell or is more likely than not required to sell a security before it recovers its amortized cost basis, the difference between the fair value and the amortized cost of the security is recognized within other income (expense), net in the consolidated statements of operations, and an allowance for credit loss is recorded on the consolidated balance sheets. In circumstances when the decline in fair value is non-credit related, the difference is reported in accumulated other comprehensive loss, net of tax, as a separate component of consolidated stockholders' equity.

Concentration of Credit Risk, Credit Losses and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents, and investments. The primary objectives for the Company's investment portfolio are the preservation of capital and the maintenance of liquidity. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments. The Company manages its credit risk by holding its cash, cash equivalents and investments in large financial institutions within the U.S. In addition, the Company's investment policy limits investments to certain types of instruments such as money market funds, debt securities issued by the U.S. government and its agencies, corporate debt securities, commercial paper as well as asset-backed securities, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any realized losses on its deposits of cash, cash equivalents and investments.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers.

The Company's product candidates require approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation of property and equipment is provided using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized on a straight-line basis over the shorter of the term of the lease, or the useful life of the assets. Upon sale or retirement of assets, the cost and related accumulated depreciation or amortization are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations. Maintenance and repairs are charged to the consolidated statements of operations as incurred.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, leases are included in operating or finance lease right-of-use, or ROU, assets; current operating or finance lease liabilities; and non-current operating or finance lease liabilities.

Lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense for operating leases is recognized on a straight-line basis over the lease term. For finance leases, ROU assets are amortized on a straight-line basis over the shorter of the expected useful life or the lease term, and the carrying amount of the lease liability is adjusted to reflect interest, which is recorded in interest expense.

A short-term lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. Fair value is determined using various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary.

Fair Value of Financial Instruments

The fair value of the Company's financial assets and liabilities are determined in accordance with the fair value hierarchy established in Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy of ASC 820 requires an entity to maximize the use of observable inputs when measuring fair value and classifies those inputs into three levels:

Level 1—Observable inputs, such as quoted prices in active markets;

Level 2—Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life; and

Level 3—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

As of December 31, 2025 and 2024, the carrying amount of cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their estimated fair value due to their relatively short maturities. The carrying amount of our non-current debt approximates fair value based on Level 2 inputs since the debt carries a variable interest rate that is tied to the current SOFR rate plus a spread.

The Company classifies money market funds and U.S. treasury securities as Level 1 within the fair value hierarchy as the fair value is based on quoted prices. The Company classifies its investments in U.S. government agency securities, corporate debt securities, commercial paper, and asset-backed securities as Level 2 within the fair value hierarchy as the fair value is estimated by third-party pricing sources using quoted prices for identical or similar instruments in markets that are not active and industry-standard model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes. Where applicable the market approach utilizes prices and information from market transactions for similar or identical assets.

Issuance Costs

Debt issuance costs consist of payments made to secure commitments under certain debt financing arrangements. These amounts are recognized as interest expense over the period of the financing arrangement using the effective interest method. If the financing arrangement is canceled or forfeited, or if the utility of the arrangement to the Company is otherwise compromised, these costs are recognized as interest expense immediately. The Company's consolidated financial statements present debt issuance costs related to a recognized debt liability as a direct reduction from the carrying amount of that debt liability.

Equity issuance costs consist of certain legal, professional, accounting and third-party fees directly associated with in-process equity financings. These amounts are capitalized as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the equity financing. In the event an anticipated offering is terminated or significantly delayed, deferred offering costs will be immediately expensed as part of general and administrative expenses. As of December 31, 2025 and 2024, no deferred offering costs were included as prepaid expenses and other current assets on the consolidated balance sheets, and all offering costs were offset against offering proceeds and reclassified to additional paid-in capital on the consolidated balance sheets.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and external entities on behalf of the Company, such as consultants, central laboratories, contractors, collaborators, contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, in connection with our preclinical and clinical development activities and expenses incurred in connection with license agreements. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and recorded in prepaid expenses and other current assets, and then expensed as the related goods are delivered or the services are performed.

Clinical and Contract Manufacturing Accruals

The Company records accruals for estimated costs of research, preclinical studies and clinical trials, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company's ongoing research and development activities are conducted by third-party service providers, including CROs and CMOs. The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services. To assist in its estimates, the Company relies upon the receipt of timely and accurate reporting from its clinical and non-clinical studies and other third-party vendors.

The Company makes judgments and estimates in determining the accrual balance at the end of each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. Through December 31, 2025, there have been no material differences from the Company's accrued estimated expenses to the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals, including, but not limited to, the number of patients enrolled, the rate of patient enrollment, the actual services performed, and related costs may vary from the Company's estimates, resulting in adjustments to clinical trial expense in future periods.

Stock-based Compensation Expense

The Company incurs stock-based compensation expense primarily from stock options, restricted stock units, or RSUs, and ESPP purchase rights.

The Company estimates the fair value of stock options granted to employees, directors and non-employees and ESPP purchase rights using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return and the estimated fair value of the underlying common stock on the date of grant. The grant-date fair value of RSUs is the fair value of the underlying stock on the award's grant date.

For awards with only service-based vesting conditions, the Company uses the straight-line method to allocate compensation expense to reporting periods over the requisite service period, which is generally the vesting period. For awards that include performance-based vesting conditions, the Company uses the accelerated attribution method to allocate compensation expense on a tranche-by-tranche basis to reporting periods over the requisite service period if and when it becomes probable that the performance condition will be achieved. At each reporting period, the Company will assess the probability of the performance condition being met for each tranche and, as applicable, recognize the cumulative effect of the change in estimate in the period of the change. The Company accounts for the effect of forfeitures as they occur.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company's CODM is its chief executive officer. The Company manages its operations as a single operating segment. All of the Company's long-lived assets are located in the United States. Refer to "Note 3. Segment Reporting" for further information.

Foreign Currency Transactions

The functional currency of the Company's operation and each of its subsidiaries is U.S. dollars. All assets and liabilities denominated in a foreign currency are translated into U.S. dollars at the exchange rate prevailing on the balance sheet date. Expenses are translated at the average exchange rates prevailing during the applicable period. Foreign currency transaction gains and losses are included in the consolidated statements of operations and recorded in other income (expense), net, and were immaterial for the years ended December 31, 2025, 2024 and 2023.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for the period in which the temporary differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the consolidated statements of operations and comprehensive loss in the period that includes the enactment date.

Deferred income taxes comprise the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax reporting purposes, net operating loss carryforwards, and other tax credits measured by applying currently enacted tax laws. A valuation allowance is provided when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, it would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on investments for all periods presented.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration for common stock equivalents. Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company adopted ASU 2023-09 on January 1, 2025 on a retrospective basis. The adoption did not have a material impact on the Company's consolidated financial statements. Refer to "Note 11. Income Taxes" for disclosure related to the adoption of ASU 2023-09.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting - Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03). ASU 2024-03 requires disaggregated disclosure of certain costs and expenses, including purchases of inventory, employee compensation, depreciation and amortization, within relevant income statement captions. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The guidance is applied on a prospective basis with the option for retrospective application. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (ASU 2025-11). ASU 2025-11 clarifies interim disclosure requirements and the applicability of Topic 270. ASU 2025-11 is effective for annual periods beginning after December 15, 2027 and interim periods beginning after December 15, 2028. Early adoption is permitted. The guidance can be applied either on a prospective basis or a retrospective basis to any or all prior periods presented in the financial statements. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements* (ASU 2025-12). ASU 2025-12 aims to make the Codification easier to understand and apply by making changes to the Codification that (1) clarify, (2) correct errors, or (3) make minor improvements. ASU 2025-12 is effective for annual periods beginning after December 15, 2026, including interim periods within those annual periods. Early adoption is permitted. The guidance can be applied on a prospective or retrospective basis. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

(3) SEGMENT REPORTING

The Company manages its operations as a single operating segment. The Company's CODM uses consolidated, single-segment financial information for the purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

The CODM assesses performance and decides how to allocate resources based on the Company's consolidated net loss, including key components of research and development costs and general and administrative costs. These measures are used to monitor budget versus actual results and to evaluate the performance of the segment.

The CODM reviews cash, cash equivalents and investments as a measure of segment assets. As of December 31, 2025 and 2024, the Company's cash, cash equivalents and investments were $48.3 million and $131.3 million, respectively.

The following table presents the significant segment expenses for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Research and development expenses:			
Clinical and development costs	$ 44,418	$ 61,868	$ 99,362
Preclinical costs	2,105	6,717	3,682
Personnel and related costs	17,037	23,085	19,407
Stock-based compensation expense	6,205	18,490	14,665
Other research costs	7,231	6,213	4,679
Total research and development expenses	76,996	116,373	141,795
General and administrative expenses:			
Personnel and related costs	8,672	7,619	7,100
Stock-based compensation expense	6,374	8,603	11,608
Other general and administrative costs	8,804	9,872	9,775
Total general and administrative expenses	23,850	26,094	28,483
Impairment charge:			
Impairment of long-lived assets	3,175	—	—
Total impairment charge	3,175	—	—
Loss from operations	(104,021)	(142,467)	(170,278)
Interest income	3,964	9,366	10,649
Interest expense	(1,602)	(1,729)	(1,565)
Other income (expense), net	(36)	(20)	389
Net loss	$ (101,695)	$ (134,850)	$ (160,805)

(4) FAIR VALUE OF FINANCIAL INSTRUMENTS

The following table presents the Company's financial assets that are measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents					
Money market funds	Level 1	$ 14,682	$ —	$ —	$ 14,682
Short-term investments					
U.S. Treasury securities	Level 1	5,462	5	—	5,467
U.S. government agency securities	Level 2	996	—	—	996
Corporate debt securities	Level 2	19,194	21	—	19,215
Commercial paper	Level 2	2,738	1	—	2,739
Long-term investments					
Corporate debt securities	Level 2	3,493	1	—	3,494
Total		$ 46,565	$ 28	$ —	$ 46,593

	December 31, 2024				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents					
Money market funds	Level 1	$ 15,468	$ —	$ —	$ 15,468
Short-term investments					
U.S. Treasury securities	Level 1	52,167	148	—	52,315
U.S. government agency securities	Level 2	3,101	6	—	3,107
Corporate debt securities	Level 2	52,657	122	—	52,779
Commercial paper	Level 2	1,988	1	—	1,989
Long-term investments					
Corporate debt securities	Level 2	3,526	1	(3)	3,524
Total		$ 128,907	$ 278	$ (3)	$ 129,182

The Company did not have any outstanding financial liabilities to be re-measured on a recurring basis as of December 31, 2025 and 2024.

The fair value of cash equivalents and available-for-sale investments by classification included in the consolidated balance sheets was as follows as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Cash equivalents	$ 14,682	$ 15,468
Short-term investments	28,417	110,190
Long-term investments	3,494	3,524
Total	$ 46,593	$ 129,182

Cash and cash equivalents in the above table excludes bank account cash of $1.7 million and $2.1 million as of December 31, 2025 and 2024, respectively.

The fair value of cash equivalents and available-for-sale investments by contractual maturity was as follows as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Maturing in one year or less	$ 43,099	$ 125,658
Maturing after one year through five years	3,494	3,524
Total	$ 46,593	$ 129,182

The primary objective of the Company's investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

There were no transfers of assets or liabilities between the fair value measurement levels during the years ended December 31, 2025 and 2024 and there were no financial instruments classified as Level 3 as of December 31, 2025 and 2024.

As of December 31, 2025 and 2024, accrued interest receivable related to the Company's investments of $0.3 million and $0.9 million, respectively, was included in prepaid expenses and other current assets on the consolidated balance sheets.

As of December 31, 2025, the unrealized losses for available-for-sale investments were non-credit related and the Company does not intend to sell the investments that were in an unrealized loss position, nor will it be required to sell those investments before recovery of their amortized costs basis, which may be maturity. As of December 31, 2025 and 2024, no allowance for credit losses for the Company's investments was recorded. As of December 31, 2025 and 2024, there were no securities in a continuous net unrealized loss position for more than 12 months. As of December 31, 2025 and 2024, the Company has not recognized any impairment losses on available-for-sale investments.

(5) BALANCE SHEET COMPONENTS

Prepaid Expenses and Other Current Assets

The following table presents the components of prepaid expenses and other current assets as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Prepaid clinical expenses	$ 4,020	$ 3,757
Prepaid expenses	1,069	1,343
Prepaid insurance	530	576
Interest and investment receivables	298	892
Other current assets	20	27
Total prepaid expenses and other current assets	$ 5,937	$ 6,595

Property and Equipment, Net

The following table presents the components of property and equipment, net as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Laboratory equipment	$ 1,844	$ 1,835
Leasehold improvements	709	2,509
Computer hardware and software	461	473
Furniture and fixtures	165	165
Property and equipment, gross	3,179	4,982
Less: accumulated depreciation	(1,979)	(2,077)
Property and equipment, net	$ 1,200	$ 2,905

Depreciation was $0.7 million, $0.9 million, and $0.8 million for years ended December 31, 2025, 2024 and 2023, respectively.

Other Assets

The following table presents the components of other assets, net as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Finance lease right-of-use assets	$ 1,513	$ 2,704
Operating lease right-of-use assets	1,159	4,023
Long-term prepaid clinical expenses	693	—
Other assets	149	200
Long-term prepaid contract manufacturing costs	111	67
Total other assets	$ 3,625	$ 6,994

Impairment of Long-Lived Assets

The Company has determined it operates in a single operating segment and has one reportable segment. The Company reviews for indicators of impairment on a quarterly basis, including changes in how its property is being used.

In May 2025, the Company made a decision to sublease its leased property in Palo Alto. The Company determined that the change in how this building was being used indicated impairment. The Company identified this property as a separate asset group for purposes of long-lived asset impairment assessment. The Company concluded that the carrying value of this property asset group was not recoverable and the estimated fair value of this asset group was below its carrying value. The lower fair value of this asset group was mainly due to the lower estimated sublease income compared to the lease payments in accordance with the initial operating lease agreement and higher discount rate. The Company applied a discounted cash flow method to estimate fair value of its right-of-use asset and leasehold improvements. Based on this analysis, the Company concluded the fair value of the right-of-use asset and leasehold improvements of $1.5 million was lower than its net book value of $4.7 million. The Company recognized a pre-tax long-lived asset impairment charge of $3.2 million on the right-of-use asset and leasehold improvements. For the year ended December 31, 2025, the Company has recognized impairment of $3.2 million on the right-of-use asset and leasehold improvements.

Accrued Expenses and Other Current Liabilities

The following table presents the components of accrued expenses and other current liabilities as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Accrued clinical and nonclinical study costs	$ 6,196	$ 3,858
Accrued compensation and related expenses	4,356	5,306
Other current liabilities	2,323	2,573
Accrued contract manufacturing	1,341	1,479
Accrued property and equipment	206	203
Total accrued expenses and other current liabilities	$ 14,422	$ 13,419

(6) LEASES

In May 2016, the Company entered into a pharmaceutical support services agreement, which included embedded leases that allowed the Company the right to direct the use of certain equipment. The embedded leases commenced in September 2020 and were set to expire in August 2023 with no stated option to extend the term. In May 2023, the Company entered into an addendum to extend the existing lease through May 2026 and lease additional number of certain equipment. In October 2023, the Company entered into an additional addendum to lease an additional number of certain equipment through May 2026. In June 2024, the Company entered into another addendum to extend the existing lease through July 2027 and lease additional number of certain equipment. In August 2025, the Company entered into an additional addendum to terminate a number of certain equipment. The Company classified the leases as finance leases.

In May 2021, the Company entered into a lease agreement for approximately 10,000 square feet of office space located in South San Francisco, California. The lease commenced on June 6, 2021 and expires on August 31, 2026. The lease does not provide an option to extend after it expires. The total lease payments for the life of the lease are approximately $2.0 million. The Company classified the lease as an operating lease.

In February 2022, the Company entered into a lease agreement totaling approximately 11,074 square feet of office and laboratory space located in Palo Alto, California. The lease consists of two premises and expires in February 2030. The lease provides for an option to extend for two years after expiration. The lease for one of the premises commenced in February 2022 and the lease for the second premises commenced in April 2022. The lease provides for an annual base rent of approximately $0.8 million, which increases on an annual basis by 3%. The total lease payments for the life of the lease are approximately $6.9 million. The Company is also responsible for leasehold improvement costs related to the second premises, which totaled to $2.3 million, of which $1.5 million is to be paid with interest at a rate of 7% per annum as additional payments over the life of the lease. The Company classified the lease as an operating lease. Under the terms of the lease agreement, the Company issued a letter of credit to the landlord in the amount of $0.1 million, which is collateralized by a restricted cash deposit of $0.1 million. The restricted cash deposit was included in the other assets on the consolidated balance sheets.

As of December 31, 2025, the ROU assets recorded for operating leases and finance leases were $1.2 million and $1.5 million, respectively. As of December 31, 2024, the ROU assets recorded for operating leases and finance leases were $4.0 million and $2.7 million, respectively. The amounts were included in the other assets on the consolidated balance sheets (see “Note 5. Balance Sheet Components—Other Assets”).

The following table presents the maturities and balance sheet information of the Company's operating and finance lease liabilities as of December 31, 2025 (in thousands, except lease term and discount rate):

	December 31, 2025	
	Operating Leases	Finance Leases
2026	$ 1,187	$ 1,056
2027	912	616
2028	939	—
2029	967	—
2030	163	—
Thereafter	—	—
Total lease payments	4,168	1,672
Less: imputed interest	(706)	(113)
Total lease liabilities	$ 3,462	$ 1,559
Lease liabilities: current [(i)]	$ 901	$ 960
Lease liabilities: non-current [(ii)]	2,561	599
Total lease liabilities	$ 3,462	$ 1,559
Weighted average remaining lease term (in years)	3.9	1.6
Weighted average discount rate	9.5%	8.5%

(i) Current lease liabilities are presented within accrued expenses and other current liabilities on the consolidated balance sheets.
(ii) Non-current lease liabilities are presented within other non-current liabilities on the consolidated balance sheets.

The following table presents the components of lease costs for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 1,042	$ 1,244	$ 1,263
Variable lease cost and other, net [(i)]	516	560	461
Short-term lease cost	—	14	17
Finance lease cost:			
Amortization of right-of-use assets	1,009	962	493
Interest	190	220	44
Total lease costs	$ 2,757	$ 3,000	$ 2,278

(i) The variable lease cost and other, net is comprised primarily of common area maintenance charges for the operating lease, which are dependent on usage. These costs are classified as operating lease expense due to the election to not separate lease and non-lease components. These costs were not included within the measurement of the Company's operating lease ROU assets and operating lease liabilities.

The following table presents the supplemental cash flow disclosures for cash paid for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 1,305	$ 1,267	$ 1,241
Operating cash flows from finance leases	$ 199	$ 205	$ 20
Financing cash flows from finance leases	$ 929	$ 827	$ 388
Right-of-use asset (modified) acquired under leases			
Finance leases	$ (182)	$ 1,309	$ 2,600

(7) TERM LOAN

Oxford Finance and Silicon Valley Bank Loan

In October 2022, the Company entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, Oxford Finance Credit Fund II LP, and Silicon Valley Bank, or Lenders, for a secured term loan facility of up to $100.0 million. Pursuant to the Loan Agreement, the Company drew an initial loan of $10.0 million. Under the original terms of the Loan Agreement, the Company had the right to draw an additional $40.0 million through the end of December 2023. The Loan Agreement provides for an additional $50.0 million over three tranches, with $12.5 million available in each of two tranches based upon the achievement of milestones related to the development of evorpacept and one preclinical product candidate, and $25.0 million at the Lenders' sole discretion. The proceeds of the loans may be used by the Company for working capital and to fund its general business requirements.

Borrowings under the Loan Agreement bear interest at a floating rate per annum equal to the greater of (i) 1-month term Secured Overnight Financing Rate, or SOFR, and (ii) 2.33%, plus 6.25%. The minimum per annum interest rate is 8.58%. Interest on the term loans is payable monthly in arrears. The Company began making interest payments beginning on December 1, 2022 and principal payments in equal monthly installments beginning on December 1, 2025. The term loans mature on October 1, 2027.

The term loans may be prepaid in full or in part, in increments of $10.0 million, with various prepayment premiums. Upon the earlier prepayment or maturity of any term loan, the Company is required to pay a final payment fee of 6.0% of the original principal amount of such funded term loan. The final payment will be accreted to the final payment amount as interest expense using the effective interest method over the term of the loan through maturity date. The term loans once repaid or prepaid may not be reborrowed. The Company is also obligated to pay other customary fees for a loan facility of this size and type.

The term loans under the Loan Agreement are secured by substantially all of the Company's assets, except the Company's intellectual property, which is the subject of a negative pledge, and will be guaranteed by the Company's future subsidiaries, subject to certain limitations. The Company and its subsidiary, ALX Oncology Limited, have guaranteed the obligations under the Loan Agreement. The Loan Agreement contains customary affirmative and negative covenants, including covenants limiting the ability of the Company to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on its capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

The Loan Agreement contains customary events of default, which include, but are not limited to payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of our obligations under the Loan Agreement, the termination of the Lenders' commitments, a 5.0% increase in the applicable rate of interest and the exercise by the Lender of other rights and remedies provided for under the Loan Agreement.

The Company received net proceeds from issuance of the term loan of $9.3 million after deducting debt issuance costs of approximately $0.7 million. Debt issuance costs were recorded as debt discount on the term loan, offsetting term loan, non-current on the consolidated balance sheets. The debt discount will be amortized over the term of the loan as interest expense using the effective interest method. During the years ended December 31, 2025, 2024 and 2023, interest expense incurred in connection with the Loan Agreement was $1.3 million, $1.2 million, and $1.1 million, respectively.

The Company determined that certain loan features were embedded derivatives requiring bifurcation and separate accounting. Those embedded derivatives were bundled together as a single, compound embedded derivative and then bifurcated and accounted for separately from the host contract. As of December 31, 2025, the value of the embedded derivative is not material, but could become material in future periods if an event of default became more probable than is currently estimated. As of December 31, 2025, we were in compliance with all financial reporting covenants under the Loan Agreement.

In March 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, to act as receiver. The FDIC created Silicon Valley Bridge Bank, N.A., or SVBB, as successor to SVB. First Citizens BancShares, Inc., or First Citizens Bank, acquired SVBB from the FDIC and operates SVBB as Silicon Valley Bank, a division of First Citizens Bank, or SVB-First Citizens. Under the Loan Agreement, 50% of the funding comes from SVB, one of the three Lenders. Given the SVBB acquisition by First Citizens Bank, SVB-First Citizens will continue to fulfill SVB's obligations under the Loan Agreement.

In May 2023, we entered into a second amendment to the Loan Agreement. The primary purpose of the second amendment was to reduce the percentage of the amount required to be held in our collateral account with SVB-First Citizens from 100% to not less than 50% of the aggregate dollar value of all our collateral accounts.

In December 2023, we entered into a third amendment to the Loan Agreement. The primary purpose of the third amendment was to (i) extend the draw period for the first tranche loans from December 31, 2023 to June 30, 2024, (ii) add as a condition for the

funding of any first tranche loans after the effective date of the amendment, the requirement that the Phase 2 portion of the ASPEN-06 study in gastric/GEJ cancer either remains ongoing or the achievement of a milestone related to the development of the ASPEN-06 study, and (iii) add a contingency fee in the amount of $0.6 million to the Lenders if the Company prepays any of the loans under the Loan Agreement other than in connection with refinancing of the Loan Agreement with the Lenders and their affiliates.

The Company decided not to draw down on any portion of the $40.0 million available under the Loan Agreement by the deadline of June 30, 2024 and did not achieve all of the requirements needed to gain access to each of the two tranches available upon the achievement of pre-determined development milestones by the deadline of December 31, 2024. As a result, only the $25.0 million tranche available at the Lenders' sole discretion was available as of December 31, 2025.

As of December 31, 2025, the future maturities under the Loan Agreement are as follows (in thousands):

	December 31, 2025
2026	$ 5,217
2027	4,948
2028	—
2029	—
2030	—
Total future maturities	10,165
Less: current portion of term loan	(5,217)
Total term loan, net of current portion	4,948
Less: unamortized debt issuance costs	(324)
Less: unaccreted final payment costs	(92)
Term loan, non-current, net	$ 4,532

(8) STOCKHOLDERS' EQUITY

On July 21, 2020, the Company's amended and restated certificate of incorporation became effective, authorizing 1,000,000,000 shares of common stock, $0.001 par value per share, and 100,000,000 shares of undesignated preferred stock, $0.001 par value per share. As of December 31, 2025 and 2024, the Company had 54,388,022 and 53,052,912 shares of common stock outstanding, respectively.

Common Stock

In July 2020, the Company consummated its initial public offering and issued 9,775,000 shares of common stock for net proceeds of approximately $169.5 million, after deducting underwriting discounts and commissions of $13.0 million and offering-related expenses of $3.2 million. Upon the closing of the initial public offering, all shares of convertible preferred stock outstanding and accrued cumulative dividends were automatically converted into 23,934,533 shares of common stock.

In December 2020, the Company consummated its registered offering and issued 2,737,000 shares of common stock for net proceeds of approximately $194.9 million, after deducting underwriting discounts and commissions of $12.5 million and offering-related expenses of $0.7 million.

In October 2023, the Company completed a registered offering and issued an aggregate of 8,663,793 shares of common stock, including the underwriters' exercise in full of their overallotment option of 1,293,103 shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,250,000 shares of common stock at an offering price of $6.38 per share and $6.379 per pre-funded warrant. Net proceeds were approximately $58.9 million, after deducting underwriting discounts and commissions of $3.8 million and offering-related expenses of $0.6 million.

Common stock reserved for future issuance as of December 31, 2025 consists of the following:

	December 31, 2025
Stock options issued and outstanding	12,878,187
RSUs issued and outstanding	240,433
PSUs issued and outstanding	57,750
Stock options authorized for future issuance	2,578,855
Employee Stock Purchase Plan shares authorized for future issuance	1,440,263
Pre-funded warrants issued and outstanding	1,250,000
Total	18,445,488

At-the-Market Equity Offering

In December 2021, the Company entered into a sales agreement with Cantor Fitzgerald & Co. and Credit Suisse Securities (USA) LLC (Sales Agreement), under which it may offer and sell shares of the Company's common stock, having aggregate gross proceeds of up to $150.0 million, from time to time through them as the Company's sales agents in its at-the-market equity offering program (ATM Offering). In August 2023, the Company entered into an amendment to the Sales Agreement to include UBS Securities LLC as an additional sales agent and to remove Credit Suisse as a sales agent. As of December 31, 2025, the Company had issued approximately 3,175,681 shares of common stock pursuant to the Sales Agreement for net proceeds of $31.4 million. The Company may terminate this ATM program at any time, pursuant to its terms.

Pre-Funded Warrants

As part of the October 2023 Offering, the Company issued pre-funded warrants to certain investors to purchase 1,250,000 shares of common stock in a registered offering at an offering price of $6.379 per pre-funded warrant. Each pre-funded warrant entitles the holder to purchase one share of common stock at an exercise price of $0.001 per share.

The pre-funded warrants to purchase shares of common stock are exercisable at any time after their original issuance. However, the pre-funded warrants include a separate provision whereby the exercisability of the pre-funded warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 9.99% of the Company's common stock. This threshold is subject to the warrant holder's rights under the pre-funded warrants to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the warrant holder to the Company. The pre-funded warrants will expire on the date the warrants are exercised in full.

The pre-funded warrants were classified as equity and accounted for as a component of additional paid-in capital. The pre-funded warrants were classified as equity because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding that their offering price approximated their fair value, and allocated the aggregate net proceeds from the offering proportionately to the common stock and pre-funded warrants, including approximately $7.4 million allocated to the pre-funded warrants and recorded as a component of additional paid-in capital on the consolidated balance sheets.

As of December 31, 2025, no shares underlying the pre-funded warrants had been exercised. All of the outstanding pre-funded warrants are included in the weighted-average number of shares of common stock used to calculate basic net loss per share attributable to common stockholders (see "Note 12. Net Loss Per Share Attributable to Common Stockholders").

(9) STOCK-BASED COMPENSATION

Equity Incentive Plans

2020 Equity Incentive Plan

On April 1, 2020, the board of directors (the Board) approved a new equity incentive plan, or the 2020 Equity Incentive Plan, that replaced the Company's existing equity compensation plan, 2015 Share Award Scheme. The 2020 Equity Incentive Plan permitted the issuance of up to 4,379,139 shares of the Company's common stock pursuant to awards granted under it, and authorized the award of stock options, restricted stock awards, stock appreciation rights and RSUs to employees, directors, and consultants.

Amended and Restated 2020 Equity Incentive Plan

In July 2020, the Company adopted the Amended and Restated 2020 Equity Incentive Plan, or the 2020 Plan. The 2020 Plan replaced the Company's 2020 Equity Incentive Plan and a total of 7,874,862 shares were reserved under the 2020 Plan. Unless the Board provides otherwise, beginning on January 1, 2021, the maximum number of shares which shall be made available for issuance under the 2020 Plan will automatically increase on the first day in January of each calendar year (i.e., the first day of our fiscal year) by an amount equal to the least of:

- 4,000,000 shares;
- four percent of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year; or
- such number of shares as our board of directors may determine no later than the last day of our immediately preceding fiscal year.

The terms of the stock option agreements, including vesting requirements, are determined by the Board, subject to the provisions of the 2020 Plan. The term of the options generally expire, upon the earliest of (i) termination of continuous service for

cause (ii) three months after the termination of continuous service for reasons other than cause, death or disability (iii) twelve months after the termination of continuous service due to disability (iv) eighteen months after the employee's death if the employee died during the period of continuous service (v) expiration date in the grant notice or (vi) the day before the tenth anniversary of the date of grant. The per share exercise price of the incentive stock options must equal at least the fair market value of a share underlying such options on the date of grant.

All awards that are canceled, forfeited or expired are returned to the 2020 Plan and are available for grant in conjunction with the issuance of new awards. Stock options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over an agreed service period, usually four years. Certain stock options granted under the 2020 Plan provide option holders the right to elect to exercise unvested options in exchange for common stock. Such unvested common stock is subject to a repurchase right held by the Company at the original issuance price in the event the optionee's service to the Company is terminated either voluntarily or involuntarily. The right lapses as the underlying repurchase right expires. These repurchase terms are considered to be a forfeiture provision. The cash received from employees for exercise of unvested options is treated as a refundable deposit and is classified as a liability on the consolidated balance sheets. At December 31, 2025, there was no such unvested early exercised options and related liability.

2025 Inducement Equity Incentive Plan

In January 2025, the Company adopted the 2025 Inducement Equity Incentive Plan, or the 2025 Plan. The 2025 Plan provides for the granting of equity-based awards, including non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units and performance shares. A total of 1,500,000 shares were reserved under the 2025 Plan.

The terms of the stock option agreements, including vesting requirements, are determined by the Board, subject to the provisions of the 2025 Plan. The term of the options generally expire, upon the earliest of (i) termination of continuous service for cause (ii) three months after the termination of continuous service for reasons other than cause, death or disability (iii) six months after the termination of continuous service due to disability (iv) six months after the employee's death if the employee died during the period of continuous service (v) expiration date in the grant notice or (vi) the day before the tenth anniversary of the date of grant. The per share exercise price of the incentive stock options must equal at least the fair market value of a share underlying such options on the date of grant.

All awards that are canceled, forfeited or expired are returned to the 2025 Plan and are available for grant in conjunction with the issuance of new awards. Stock options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over an agreed service period, usually four years.

Shares Available for Grant

The following table provides a summary of shares available for grant under the 2020 Plan and 2025 Plan:

	Total
Shares available for grant at December 31, 2024	642,557
Authorized	3,622,116
Granted	(7,394,675)
Canceled/forfeited	5,708,857
Shares available for grant at December 31, 2025	2,578,855

Stock Option Exchange

On December 2, 2024, the Company commenced an offer to exchange eligible options held by eligible employees of the Company for new options (the Exchange Offer). The Exchange Offer expired on December 30, 2024. Under the Exchange Offer, the Company accepted for exchange eligible options to purchase an aggregate of 2,693,873 shares of the Company's common stock, representing 80.3% of the total shares of common stock underlying the eligible options. On December 30, 2024, immediately following the expiration of the Exchange Offer, the exchanged options were canceled and new options to purchase 2,155,095 shares of common stock were granted at an exercise price of $1.66 per share, which was the closing price of the common stock on the Nasdaq Global Select Market on the grant date of the new options. The new options are subject to a new vesting schedule, vesting in equal monthly installments following the new option grant date for the longer of (a) 30 months or (b) the number of months remaining in the vesting schedule on the eligible option grant. Each new option has a maximum term of seven years.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense of $0.6 million for the modified options was calculated using the Black-Scholes option pricing model. The incremental expense and the unamortized expense remaining on the exchanged options as of the modification date are being recognized over the new vesting service period.

Employee Stock Purchase Plan

In July 2020, the Board and stockholders approved the ALX Oncology Holdings Inc. 2020 Employee Stock Purchase Plan, or the ESPP. The ESPP allows eligible employees to have up to 15 percent of their eligible compensation withheld and used to purchase common stock, subject to a maximum of $25,000 worth of stock purchased in a calendar year or no more than 3,000 shares in an offering period, whichever is less. An offering period consists of a six-month purchase period, with a look back feature to our stock price at the commencement of the offering period. Eligible employees can purchase the Company's common stock at the end of the offering period at 85% of the lower of the closing price of our common stock on The Nasdaq Global Select Market on the first and last day of the offering period.

The initial number of shares of common stock available for issuance under the ESPP was 400,000. Unless the Board provides otherwise, beginning on January 1, 2021, the maximum number of shares which shall be made available for sale under the ESPP will automatically increase on the first day in January of each calendar year (i.e., the first day of our fiscal year) during the term of the ESPP by an amount equal to the least of:

- 800,000 shares;
- one percent of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year; or
- such number of shares as our board of directors may determine no later than the last day of our immediately preceding fiscal year.

On January 1, 2025 and 2024, the number of shares available under the ESPP was increased by 530,529 and zero, respectively. As of December 31, 2025, 294,582 shares of common stock have been purchased under the ESPP, and the number of shares of common stock available for issuance under the ESPP was 1,440,263.

Stock Option Activity

The following table provides a summary of stock option activity under the 2020 Plan and 2025 Plan and related information:

	Outstanding Options			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	10,528,751	$ 10.04	6.23	$ 409
Granted	7,394,675	1.37		
Exercised	(14,146)	1.01		
Canceled/forfeited	(5,031,093)	7.51		
Outstanding at December 31, 2025	12,878,187	$ 6.06	6.21	$ 830
Exercisable at December 31, 2025	6,087,380	$ 10.56	3.69	$ 31

The aggregate intrinsic values represent the total pre-tax intrinsic value of options outstanding and exercisable calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of December 31, 2025 and 2024. The total intrinsic value of options exercised during the years ended December 31, 2025, 2024 and 2023 were a nominal amount, $2.6 million and $0.2 million, respectively.

Stock Option Valuation Assumptions

The Company uses the Black-Scholes option pricing model to determine the estimated fair value of stock options at the date of the grant, and stock-based compensation is adjusted for actual forfeitures as they occur. The fair value of each option grant during the years ended December 31, 2025, 2024 and 2023 was estimated with the following assumptions:

	Year Ended December 31,		
	2025	2024	2023
Expected term (in years)	5.2 - 6.1	4.1 - 6.1	5.3 - 6.1
Risk-free interest rate	3.6% - 4.7%	3.5% - 4.7%	3.5% - 4.7%
Expected dividend rate	0%	0%	0%
Expected stock price volatility	93.9% - 99.3%	86.5% - 95.1%	83.6% - 88.6%

Expected Term. The expected term of the options represents the average period the stock options are expected to remain outstanding. As the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term of options granted is derived from the average midpoint between the weighted average vesting and the contractual term, also known as the simplified method. For options granted from the Exchange Offer, the Company used a Monte Carlo simulation to estimate the time it takes for options to return to the money and derived the expected term of options granted from the midpoint between (i) the later of the time it takes to return to the money or the remaining vest term, and (ii) the remaining contractual term.

Risk-Free Interest Rate. The risk-free interest rate is based on the yield of U.S. Treasury notes as of the grant date with terms commensurate with the expected term of the option.

Dividend Yield. The expected dividends assumption is based on the Company's expectation of not paying dividends in the foreseeable future.

Volatility. Since the Company does not have sufficient trading history for its common stock, the expected volatility is based on a combination of the historical volatilities of the common shares of comparable publicly traded companies as well as the historical volatilities of the Company's common shares. The Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the Company's share-based awards. For options granted from the Exchange Offer, the Company used the historical volatilities of the Company's common shares.

Fair Value. Historically, for all periods prior to our initial public offering, the fair value of the shares of common stock underlying our stock option was determined by the Company's Board. Because there was no public market for the Company's common stock, the Board determined fair value of the common stock at the time of grant of the options by considering a number of objective and subjective factors including important developments in the Company's operations, valuations performed by an independent third party, sales of convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock, among other factors the Board deemed relevant to such determination. Since the completion of our initial public offering, the fair value of each share of common stock underlying stock option grants is based on the closing price of our common stock on the Nasdaq Global Select Market as reported on the date of grant.

Restricted Stock Unit Activity

The following table provides a summary of restricted stock unit (RSU) activity under the 2020 Plan and related information:

	Outstanding RSUs	
	Number of RSUs	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2024	1,256,255	$ 12.89
Granted	—	—
Vested	(280,308)	12.29
Canceled/forfeited	(677,764)	13.15
Unvested as of December 31, 2025	298,183	$ 12.89

The total fair value of RSUs vested during the years ended December 31, 2025, 2024 and 2023 was $0.3 million, $2.3 million and $2.8 million, respectively.

Performance-Based Restricted Stock Units

In February 2024, the Company granted 365,000 performance-based restricted stock units, or PSUs, to certain employees under the 2020 Plan. The PSUs are subject to both performance-based and service-based vesting conditions with a fair value based on the closing price of the underlying common stock on the date of grant. Each PSU is split into two tranches with each tranche having performance goals based on the achievement of pre-determined clinical milestones that result in the shares attributable to such tranche being eligible for vesting, subject to the service-based vesting condition. The service-based vesting condition is satisfied on the one-year anniversary of the performance achievement date for each tranche and is subject to the employee's continuous service through such vesting date. Upon vesting, each PSU will automatically convert into one share of the Company's common stock. If the performance condition for a tranche is not met by March 31, 2025, the shares attributable to such tranche will be forfeited.

The Company determined that the performance conditions for one tranche of PSUs was achieved by the March 31, 2025 deadline. As a result, compensation expense of $0.8 million has been recognized related to this tranche of PSUs for the year ended December 31, 2025. The performance conditions for the other tranche of PSUs was not achieved as of March 31, 2025, and therefore, these awards were forfeited.

As of December 31, 2025, there were 57,750 PSUs outstanding and unvested.

Stock-based Compensation Expenses

Stock options granted are measured based on the grant-date fair value estimated using the Black-Scholes option pricing model. The grant-date fair value of RSUs is the fair value of the underlying stock on the award's grant date. Compensation expense is recognized over the vesting period of the applicable awards on a straight-line basis. The weighted-average grant date fair value per share for stock options granted during the years ended December 31, 2025, 2024 and 2023 was $1.07, $4.10 and $4.44, respectively. The weighted-average grant date fair value per share for RSUs granted during the years ended December 31, 2024 and 2023 was $15.59 and $5.86, respectively. There were no RSUs granted during the year ended December 31, 2025.

Stock-based compensation expense includes stock options and RSUs and has been reported in the Company's consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2025	**2024**	**2023**
Research and development	$ 6,205	$ 18,490	$ 14,665
General and administrative	6,374	8,603	11,608
Total	$ 12,579	$ 27,093	$ 26,273

As of December 31, 2025, there was unrecognized share-based compensation expense of $12.6 million, related to unvested stock options which the Company expects to recognize over a weighted-average period of 1.7 years. There was unrecognized share-based compensation expense of $2.1 million, related to unvested RSUs which the Company expects to recognize over a weighted-average period of 1.3 years.

(10) RELATED-PARTY TRANSACTIONS

Tallac Service Agreement

On July 1, 2020, the Company entered into a research and development services agreement, or the Tallac Services Agreement, with Tallac Therapeutics, Inc., or Tallac, a related-party of the Company. The Company's former Chief Scientific Officer was on the Board of Directors of Tallac. In addition, one of the Company's investors was also an investor of Tallac. As such, Tallac was deemed to be a related-party. The Tallac Services Agreement provides that Tallac will provide certain preclinical research services to the Company for a service fee based on the costs incurred by Tallac plus a mark-up equal to 10.0% of such costs. The Tallac Services Agreement has an initial term of four years and is renewed automatically for additional one year terms thereafter. The Company records the payments for the research and development services as research and development, or R&D, costs within the consolidated statements of operations. For the years ended December 31, 2025, 2024 and 2023, the Company recorded zero, a nominal amount and $0.3 million, respectively, as R&D costs in relation to the Tallac Services Agreement. The Tallac Services Agreement was terminated on July 1, 2024.

Tallac Collaboration Agreement

On March 4, 2021, the Company entered into a Collaboration Agreement with Tallac, or the Tallac Collaboration Agreement, to jointly develop, manufacture, and commercialize a novel class of cancer immunotherapy. The collaboration builds on the Company's expertise in developing therapies that block the CD47 checkpoint pathway and expands its immuno-oncology pipeline. The companies will leverage their respective scientific and technical expertise to advance an anti-SIRPα antibody conjugated to a Toll-like receptor 9, or TLR9, agonist for targeted activation of both the innate and adaptive immune systems. The key economic components of the collaboration transaction include that both parties will share equally (a) in the cost and expenses of research and development and (b) any profit or loss.

The Company accounts for R&D costs in accordance with ASC 730, *Research and Development*, which states R&D costs must be charged to expense as incurred. Accordingly, the Company records its internal and third-party costs associated with the collaboration as R&D expenses as incurred. When the Company is entitled to reimbursement of the R&D expenses that it incurs under the collaboration, the Company records those reimbursable amounts as a reduction to R&D expenses. The Company also records as R&D expenses, the portion of Tallac's expenses that the Company is obligated to reimburse, in the period when Tallac incurs such expenses. During the years ended December 31, 2025, 2024 and 2023, the Company recorded $0.1 million, $0.8 million and $1.7 million, respectively, as R&D costs in relation to the Tallac Collaboration Agreement.

The Tallac Collaboration Agreement includes the right to set off clause, as such, the Company records the amount due to or reimbursable from Tallac on a net basis. As of December 31, 2025 and 2024, the Company had accrued expenses of zero and $0.1 million, respectively, related to the Tallac Collaboration Agreement which was presented within the payable and accrued liabilities due to related party on the consolidated balance sheets.

(11) INCOME TAXES

The U.S. domestic and international components of pre-tax loss for the years ending December 31, 2025, 2024 and 2023 are as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
United States	$ (101,198)	$ (134,120)	$ (159,766)
International	(497)	(730)	(1,039)
Loss before income taxes	$ (101,695)	$ (134,850)	$ (160,805)

The federal and state provision (benefit) for income taxes consist of the following (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Current tax expense (benefit):			
US Federal	$ —	$ —	$ —
US State	—	—	—
Foreign	—	—	—
Total current tax expense (benefit)	—	—	—
Deferred tax expense (benefit):			
US Federal	$ —	$ —	$ —
US State	—	—	—
Foreign	—	—	—
Total deferred tax expense (benefit)	—	—	—
Total income tax expense (benefit)			
US Federal	$ —	$ —	$ —
US State	—	—	—
Foreign	—	—	—
Total provision (benefit) for income taxes	$ —	$ —	$ —

The Company has not recorded any income tax expense for the years ended December 31, 2025, 2024 and 2023.

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

A reconciliation of the U.S. federal statutory income tax rate to the effective tax for the years ended December 31, 2025, 2024 and 2023 are as follows (in thousands):

	Year Ended December 31,					
	2025		2024		2023	
At federal statutory income tax rate	$ (21,356)	21.0%	$ (28,318)	21.0%	$ (33,769)	21.0%
State income taxes, net of federal effect	—	0.0%	—	0.0%	—	0.0%
Change in valuation allowance	19,155	-18.8%	31,496	-23.4%	62,964	-39.2%
Nontaxable or nondeductible items						
Stock-based compensation	4,030	-4.0%	1,438	-1.1%	3,619	-2.3%
Nontaxable or nondeductible items	585	-0.6%	51	0.0%	18	0.0%
Changes in tax laws or rates	—	0.0%	—	0.0%	—	0.0%
Tax credits						
Research & development credits	(2,444)	2.4%	(4,668)	3.4%	(7,056)	4.4%
Cross-border tax laws	(74)	0.1%	(101)	0.1%	(175)	0.1%
Worldwide changes in unrecognized tax benefits	—	0.0%	(107)	0.1%	52	0.0%
Foreign tax effects	104	-0.1%	153	-0.1%	218	-0.1%
Other						
Rate benefit of reorganization	—	0.0%	—	0.0%	(25,862)	16.1%
Other	—	0.0%	56	0.0%	(9)	0.0%
Provision (benefit) for income taxes	$ —	0.0%	$ —	0.0%	$ —	0.0%

The Company filed a change in tax status for ALX Oncology Limited in 2023. The reorganization resulted in an increase to capitalized R&D and other deferred tax assets, as well as a corresponding increase in valuation allowance.

State income taxes in California comprise the majority of the state income taxes, net of federal effect category for the years ended December 31, 2025, 2024 and 2023, respectively.

Significant components of the Company's deferred tax assets as of December 31, 2025 and 2024 are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Loss carryforwards	$ 71,139	$ 41,106
Research & other credits	26,968	23,455
Other	5,922	6,999
Accrued expenses	622	1,013
Stock options	6,908	8,380
Lease liabilities	1,055	1,486
Capitalized R&D	37,363	48,392
Fixed assets	266	—
Total deferred tax assets	150,243	130,831
Deferred tax liabilities:		
Fixed assets	—	7
Lease ROU assets	561	1,413
Total deferred tax liabilities	561	1,420
Valuation allowance	(149,682)	(129,411)
Net deferred tax assets	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that the Company's management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, the Company's management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by approximately $20.3 million and $33.1 million for the years ended December 31, 2025 and 2024, respectively.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance	$ 129,411	$ 96,288
Change related to continuing operations	20,271	33,123
Change related to acquisitions	—	—
Change related to OCI	—	—
Ending balance	$ 149,682	$ 129,411

Net operating losses and tax credit carryforwards as of December 31, 2025 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (post December 31, 2017)	$ 305,441	Do Not Expire
Net operating losses, state	$ 68,993	2038-2040
Tax credits, federal	$ 22,797	2039-2045
Tax credits, state	$ 9,000	N/A
Net operating losses, foreign	$ 5,884	N/A

Utilization of the Company's U.S. net operating loss and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitation could result in the expiration of the U.S. net operating loss and credit carryforwards before utilization. To date, the Company has not performed an analysis to determine whether there would be a substantial annual limitation due to a change in ownership.

Unrecognized Tax Benefits

The Company recognizes the tax benefit from uncertain tax positions if it is more likely than not that the tax positions will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefit is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company recognizes interest and penalties related to unrecognized tax benefits in income tax expense. The Company files income tax returns in the U.S. federal and California jurisdiction, which is not currently under exam, and all years since inception are opened to examination.

The unrecognized tax benefits as of December 31, 2025, 2024 and 2023 were $4.7 million, $4.1 million and $3.1 million, respectively. Future changes in the unrecognized tax benefits will not impact the effective tax rate due to the Company's full valuation allowance.

The Company has the following activity relating to unrecognized tax benefits (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Beginning balance	$ 4,110	$ 3,120	$ 1,661
Additions/reversals based on tax positions of prior years	—	—	81
Increases related to current year tax positions	620	1,097	1,409
Settlements	—	—	—
Lapses in statutes of limitations	—	(107)	(31)
Ending balance	$ 4,730	$ 4,110	$ 3,120

During the years ended December 31, 2025, 2024 and 2023, no significant interest or penalties were required to be recognized relating to unrecognized tax benefits.

(12) NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31,		
	2025	2024	2023
Numerator:			
Net loss	$ (101,695)	$ (134,850)	$ (160,805)
Denominator:			
Weighted-average shares of common stock outstanding, basic and diluted	53,658,399	52,174,904	42,987,767
Net loss per share, basic and diluted	$ (1.90)	$ (2.58)	$ (3.74)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods presented as the inclusion of all potential common stock outstanding would have been anti-dilutive.

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share for the years ended December 31, 2025, 2024 and 2023, because including them would have been anti-dilutive:

	Year Ended December 31,		
	2025	2024	2023
Stock options issued and outstanding	12,878,187	10,528,751	8,984,671
RSUs issued and outstanding	240,433	898,755	949,669
PSUs issued and outstanding	57,750	357,500	—
Total	13,176,370	11,785,006	9,934,340

(13) COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2025.

Contingencies

From time to time, the Company may be a party to various claims in the normal course of business. Legal fees and other costs associated with such actions will be expensed as incurred. The Company will assess, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates will be recorded when and if it is determined that a loss related matter is both probable and reasonably estimable. For the years ended December 31, 2025, 2024 and 2023, the Company had no pending or threatened litigation.

License Agreements

In March 2015, the Company entered into a license agreement, or the Stanford Agreement, with the Board of Trustees of the Leland Stanford Junior University, or Stanford, under which the Company obtained a worldwide, royalty-bearing, sublicensable license under certain patents relating to the Company's current product candidates, to develop, manufacture and commercialize products for use in certain licensed fields, the scope of which would include the application of the licensed intellectual property in oncology. The Company paid Stanford a nonrefundable license royalty and reimbursed Stanford for past patent expenses, together totaling less than $0.1 million, and granted Stanford a specified number of shares of common stock of the Company. The Company is required to make milestone payments up to an aggregate of $5.0 million in respect of a specified number of licensed products that successfully satisfy certain clinical and regulatory milestones. The Company recorded the first milestone payment of $0.2 million during the year ended December 31, 2021. There were no milestone payments recorded for the years ended December 31, 2025, 2024 and 2023.

In June 2016, the Company entered into a license agreement with Selexis SA, or Selexis, under which the Company obtained a worldwide, royalty-bearing, sublicensable license under certain patents, know-how and other intellectual property, to use Selexis generated cell lines to manufacture evorpacept, and to make, use and sell licensed product containing such compound in all fields of use. The Company paid Selexis a nominal one-time fee and will pay Selexis an annual maintenance fee. The Company also agreed to pay Selexis milestone payments up to an aggregate of 1.2 million Swiss Francs in respect of all licensed products developed and/or commercialized under the grant that successfully satisfies certain milestone events. The Company recorded a milestone payment of $0.1 million during the year ended December 31, 2021. There were no milestone payments recorded for the years ended December 31, 2025, 2024 and 2023.

In March 2017, the Company entered into an agreement with Crystal Bioscience Inc. (now a subsidiary of OmniAb, Inc.), or Crystal, under which the Company obtained an assignment of certain patents, covering certain SIRPα antibodies. Under this agreement, the Company also received a worldwide, royalty-bearing non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicenses, under certain of Crystal's background patents and know-how necessary to commercialize the rights under the assigned patents. The Company agreed to pay Crystal milestone payments up to $11.1 million in respect of all licensed products developed under the assigned patents, that successfully satisfy certain clinical and regulatory milestones, each milestone being paid only once for all products. The Company recorded the first milestone payment of $0.3 million during the year ended December 31, 2022. There were no milestone payments recorded for the years ended December 31, 2025, 2024 and 2023.

In October 2021, the Company entered into a stock purchase agreement with ScalmiBio, Inc. or ScalmiBio, with plans to develop new anti-cancer drug candidates based on ScalmiBio's platform. Under the terms of the stock purchase agreement, the Company has agreed to pay up to $35.0 million, in aggregate, in certain milestones based on the clinical development of the acquired ScalmiBio technology and has also agreed to pay a low single digit royalty on net sales of any products developed from the ScalmiBio acquired technology for a defined term. The Company has the option to buy-out the royalty payment, prior to the first marketing approval of the developed product. The Company recorded the first milestone payment of $1.0 million during the year ended December 31, 2024 and the second milestone payment of $2.5 million during the year ended December 31, 2025.

In January 2024, the Company entered into a license agreement with WuXi Biologics Ireland, Ltd., or WuXi, under which the Company obtained a worldwide, non-exclusive, non-transferrable, sublicensable license under certain patents, know-how, and other intellectual property, to use WuXi developed cell lines to manufacture, develop, use and sell licensed product containing such compound in all fields of use. The Company agreed to pay WuXi milestone payments up to an aggregate of $3.2 million in respect of all licensed products developed and/or commercialized under the assigned patents that successfully satisfies certain milestone events. The Company recorded the first milestone payment of $0.2 million during the year ended December 31, 2024. There was no milestone payments recorded for the year ended December 31, 2025.

Other Contractual Obligations and Other Commitments

We have other contractual obligations and other commitments from manufacturing and service contracts, which are presented as follows as of December 31, 2025 (in thousands):

	December 31, 2025				
	Total	**2026**	**2027-2028**	**2029-2030**	**Thereafter**
Manufacturing and service contracts	$ 1,247	$ 860	$ 387	$ —	$ —
Total	$ 1,247	$ 860	$ 387	$ —	$ —

In November 2015, the Company entered into a Master Service Agreement, or the MSA, with KBI Biopharma, Inc. relating to formulation development, process development and current good manufacturing practices, or cGMP, manufacturing of evorpacept for use in clinical trials on a project basis. The MSA had an initial term of three years with successive one-year renewal periods, which was extended an additional eight years until November 2026, is cancellable upon notice and is non-exclusive. Statements of work under the MSA commit the Company to certain future purchase obligations of approximately $0.3 million. In addition, the Company has commitments with two other pharmaceutical contract manufacturers, including certain future purchase obligations of approximately $0.8 million. These amounts are based on non-cancellable commitments and forecasts that include estimates of future market demand, quantity discounts and manufacturing efficiencies that may impact timing of purchase.

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

(14) SUBSEQUENT EVENTS

February 2026 Offering

On February 2, 2026, the Company completed a registered offering and issued an aggregate of 76,979,112 shares of common stock at an offering price of $1.57 per share and pre-funded warrants to purchase 18,574,120 shares of common stock at an offering price of $1.569 per pre-funded warrant. The Company received net proceeds of approximately $140.4 million, after deducting underwriting discounts and commissions of $9.0 million and other offering-related expenses of $0.6 million.

Appointment of Chief Medical Officer

On February 25, 2026, the Board of Directors appointed Barbara Klencke, M.D. to the office of Chief Medical Officer on a permanent basis. She has served as interim Chief Medical Officer since September 2025.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures" as of the end of the period covered by this report, pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act.

In connection with that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms as of December 31, 2025. For the purpose of this evaluation, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is accumulated and communicated to management, including our Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f). Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of the end of our 2025 fiscal year, management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework established in the original Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO). Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2025 was effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During our last fiscal quarter, none of our officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" as defined in Regulation S-K Item 408.

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

Not Applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our next Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2025.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item concerning our directors, executive officers, corporate governance, Section 16 reporting compliance and code of business conduct and ethics is incorporated by reference to the Proxy Statement.

Item 11. Executive Compensation.

The information required by this Item regarding executive compensation is incorporated by reference to the Proxy Statement.

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

The information required by this Item regarding security ownership of certain beneficial owners and management and related stockholder matters is incorporated by reference to the Proxy Statement.

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

The information required by this Item regarding certain relationships and related party transactions and director independence is incorporated by reference to the Proxy Statement.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is KPMG LLP, Auditor Firm ID: 185.

The information required by this Item regarding principal accountant fees and services is incorporated by reference to the Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

Financial statement schedules have been omitted as the information required is not applicable or the information is presented in the financial statements or related notes included in Part II, Item 8 of this Annual Report on Form 10-K.

(3) Exhibits

The exhibits listed below are filed as part of this Annual Report on Form 10-K, or are incorporated herein by reference, in each case as indicated below.

Exhibit Index

		INCORPORATED BY REFERENCE				
NUMBER	EXHIBIT TITLE	FORM	FILE NO.	EXHIBIT	FILING DATE	FILED HEREWITH
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39386	3.1	July 21, 2020	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-39386	3.1	June 20, 2023	
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated April 1, 2020.	S-1	333-239490	4.1	June 26, 2020	
4.2	Specimen common stock certificate of the Registrant.	S-1	333-239490	4.2	June 26, 2020	
4.3	Description of Securities.	10-K	001-39386	4.3	March 7, 2024	
4.4	Form of Pre-Funded Warrant.	8-K	001-39386	4.1	October 6, 2023	
4.5	Form of Pre-Funded Warrant.	8-K	001-39386	4.1	January 30, 2026	
10.1#	Loan and Security Agreement, dated as of October 27, 2022, among Oxford Finance LLC, as collateral agent, the lenders from time to time party thereto, ALX Oncology Inc., Alexo Therapeutics International, and Sirpant Therapeutics, each as a borrower, and ALX Oncology Holdings Inc., as guarantor.	8-K	001-39386	10.1	October 31, 2022	
10.1.1	Consent and First Amendment to Loan and Security Agreement, dated as of December 22, 2022.	10-K	001-39386	10.1.1	March 9, 2023	
10.1.2#	Second Amendment to Loan and Security Agreement, dated as of May 31, 2023.	10-Q	001-39386	10.1	August 10, 2023	
10.1.3	Third Amendment to Loan and Security Agreement, dated as of December 22, 2023, among Oxford Finance LLC, as collateral agent, the lenders party thereto, ALX Oncology Inc., as borrower, and ALX Oncology Holdings Inc., as guarantor.	8-K	001-39386	10.1	December 26, 2023	

NUMBER	EXHIBIT TITLE	INCORPORATED BY REFERENCE				FILED HEREWITH
		FORM	FILE NO.	EXHIBIT	FILING DATE	
10.2	Sales Agreement, dated December 17, 2021, by and among ALX Oncology Holdings Inc., Cantor Fitzgerald & Co., and Credit Suisse Securities (USA) LLC.	8-K	001-39386	1.1	December 17, 2021	
10.2.1#	Amendment No. 1 to the Sales Agreement with Cantor and Credit Suisse, dated August 25, 2023.	10-Q	001-39386	10.1	November 13, 2023	
10.3+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-239490	10.1	June 26, 2020	
10.4+	Amended and Restated 2020 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-239490	10.2	July 13, 2020	
10.5+	2025 Inducement Equity Incentive Plan and forms of agreement thereunder.	8-K	001-39386	10.1	January 21, 2026	
10.6+	2020 Employee Stock Purchase Plan.	S-1/A	333-239490	10.3	July 13, 2020	
10.7+^	Confirmatory Employment Letter between the Registrant and Jason Lettmann.	8-K	001-39386	10.1	September 6, 2023	
10.8+	Confirmatory Offer Letter between the Registrant and Harish Shantharam.	10-K	001-39386	10.8	March 6, 2025	
10.9+^	Confirmatory Offer Letter between the Registrant and Shelly Pinto.	10-K	001-39386	10.6	February 28, 2022	
10.10+^	Offer Letter between the Registrant and Barbara Klencke.					X
10.11+	Executive Incentive Compensation Plan.	S-1/A	333-239490	10.9	July 13, 2020	
10.12+	Form of Change in Control and Severance Agreement.					X
10.13	Exclusive (Equity) Agreement between the Registrant and The Board of Trustees of the Leland Stanford Junior University, effective as of March 24, 2015, as amended on April 24, 2015 and May 15, 2015.	S-1	333-239490	10.12	June 26, 2020	
10.14+	Outside Director Compensation Policy.	10-Q	001-39386	10.3	May 8, 2025	
19.1	Insider Trading Policy.	10-K	001-39386	19.1	March 6, 2025	
21.1	List of subsidiaries of Registrant.	10-K	001-39386	21.1	March 6, 2025	
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney.					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

NUMBER	EXHIBIT TITLE	INCORPORATED BY REFERENCE				FILED HEREWITH
		FORM	FILE NO.	EXHIBIT	FILING DATE	
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
97.1	Compensation Recovery Policy.	10-K	001-39386	97.1	March 7, 2024	
101.INS	Inline XBRL Instance Document. - the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and included in exhibit 101)					X

Certain confidential information contained in this document, marked by [***], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential.
^ Certain exhibits and schedules have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted exhibit or schedule to the SEC upon its request.

+ Indicates management contract or compensatory plan.

* 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 the registrant 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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALX ONCOLOGY HOLDINGS INC.

Date: March 9, 2026

By: /s/ Jason Lettmann
Jason Lettmann
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jason Lettmann and Harish Shantharam, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, 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 full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jason Lettmann **Jason Lettmann**	Chief Executive Officer and Director (*Principal Executive Officer*)	March 9, 2026
/s/ Harish Shantharam **Harish Shantharam**	Chief Financial Officer (*Principal Financial Officer*)	March 9, 2026
/s/ Shelly Pinto **Shelly Pinto**	Senior Vice President, Finance and Chief Accounting Officer *(Principal Accounting Officer)*	March 9, 2026
/s/ Corey Goodman **Corey Goodman, Ph.D.**	Chairman of the Board of Directors	March 9, 2026
/s/ Daniel Curran **Daniel Curran, M.D.**	Director	March 9, 2026
/s/ Scott Garland **Scott Garland**	Director	March 9, 2026
/s/ Rekha Hemrajani **Rekha Hemrajani**	Director	March 9, 2026
/s/ Alan Sandler **Alan Sandler, M.D.**	Director	March 9, 2026
/s/ Chris H. Takimoto **Chris H. Takimoto, M.D., Ph.D., FACP**	Director	March 9, 2026

Corporate Directory

Senior Leadership Team

Jason Lettmann
Chief Executive Officer

Barbara Klencke, M.D.
Chief Medical Officer

Jeff Knight
Chief Development & Operating Officer

Harish Shantharam, CFA
Chief Financial Officer

Shelly Wong, CPA
Chief Accounting Officer

Board of Directors

Corey Goodman, Ph.D.
Chairman and Cofounder, ALX Oncology
Managing Partner, venBio Partners

Daniel J. Curran, M.D.
Managing Partner, Mountainfield Venture Partners, LLC
Chief Executive Officer, Timberlyne Therapeutics

Scott Garland
Former Chief Executive Officer, PACT Pharma, Inc.

Rekha Hemrajani
Biotech Board Member

Jason Lettmann
Chief Executive Officer, ALX Oncology

Alan Sandler, M.D.
Chief Development Officer, Revolution Medicines

Chris H. Takimoto, M.D., Ph.D., FACP
Global Chief Medical Officer, START Center for Cancer Research

Corporate Headquarters

ALX Oncology Holdings Inc.
323 Allerton Avenue
South San Francisco, CA 94080

For More Information

Elhan Webb, CFA
Investor Relations Consultant
ewebb@alxoncology.com
Tel: 650.466.7125

Transfer Agent

Computershare Investor Services
P.O. Box 505000
Louisville, KY 40233-5000
Tel: 800.736.3001
www.computershare.com/investor

Common Stock

NASDAQ Global Select Market®: ALXO

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those, express or implied, in these forward-looking statements. Important factors that could impair the value of our assets and business are disclosed in the risk factors contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 9, 2026, and in our Quarterly Reports on Form 10-Q and other documents filed with the SEC from time to time. Except to the extent required by law, we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

ALX ONCOLOGY

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