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

FORM 10-K

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

For the fiscal year ended December 31, 2024

OR

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

For The Transition Period From To

Commission file number: 001-40523

ELEVATION ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1771427**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
101 Federal Street, Suite 1900, Boston, Massachusetts	**02110**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (716) 371-1125

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

Title of Each Class	Trading Symbol(s)	Name Of Each Exchange On Which Registered
Common stock, par value $0.0001 per share	**ELEV**	**The Nasdaq Stock Market LLC**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 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 (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

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

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $135.2 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date). As of February 28, 2025, there were 59,215,795 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

Documents Incorporated by Reference

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2025 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2024. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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Throughout this Annual Report on Form 10-K (the "Annual Report"), the "Company", "Elevation", "Elevation Oncology", "we", "us", and "our", except where the context requires otherwise, refer to Elevation Oncology, Inc. and its consolidated subsidiary, and "our Board of Directors" refers to the Board of Directors of Elevation Oncology, Inc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "predict," "potential" and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk factors" and elsewhere in this filing. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this Annual Report include, among other things, statements about:

- our ability to develop, obtain regulatory approval and commercialize our product candidates, including EO-3021 and EO-1022;
- the timing of our preclinical studies and clinical trials for our product candidates, including EO-3021 and EO-1022;
- our ability to establish and maintain collaborations, including with CSPC Pharmaceutical Group Limited (collectively with its affiliates, "CSPC"), our licensor and partner for EO-3021, and with Synaffix B.V. ("Synaffix"), whose technology platform we are using in developing EO-1022;
- estimates of our addressable market and market growth;
- our expectations regarding demand for, and market acceptance of, our product candidates, including EO-3021 and EO-1022;
- our ability to compete effectively with existing competitors and new market entrants;
- the potential effects of extensive government regulations relating to our industry;
- our ability to obtain, maintain, and protect and enforce intellectual property and proprietary rights;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to maintain secure, efficient and uninterrupted operation of our information technology systems from security breaches, cyberattacks, loss or leakage of data and other disruptions;
- our ability to expand our pipeline of product candidates;
- our ability to attract and retain key management and technical personnel;
- general economic, market and geopolitical conditions, including fluctuating interest rates, potential tariffs, market volatility and inflation, and the impact of geopolitical tensions with China and ongoing regional military conflicts;
- our ability to maintain the listing of our common stock on the Nasdaq Global Select Market and the potential liquidity and trading of our common stock; and
- our expectations regarding expenses, future revenue, capital requirements and our needs for additional financing.

The forward-looking statements made in this filing relate only to events or information as of the date on which the statements are made in this Annual Report. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations, except as required by law. We intend the forward-looking statements contained in this Annual Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

PART I

Item 1. Business

Overview

We are an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs. We are leveraging our antibody-drug conjugate ("ADC") expertise to advance a novel pipeline, initially targeting two validated targets in oncology, Claudin 18.2 and HER3.

Our lead product candidate, EO-3021 (also known as SYSA1801 or CPO102), is an ADC comprised of a fully human anti-Claudin 18.2 immunoglobulin G1 ("IgG1") monoclonal antibody ("mAb") site-specifically conjugated with a cleavable linker to the cytotoxic monomethyl auristatin E ("MMAE") payload. Claudin 18.2 is overexpressed in several types of cancers, including gastric, esophageal, pancreatic, ovarian and lung. EO-3021 is currently being evaluated in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab, a PD-1 inhibitor, and ramucirumab, a VEGFR2 inhibitor, in patients with advanced, unresectable or metastatic gastric/gastroesophageal junction ("GEJ") solid tumors.

In August 2024, we reported promising initial monotherapy data from the dose escalation portion of our ongoing Phase 1 clinical trial of EO-3021. This data demonstrated competitive efficacy, with a 42.8% confirmed objective response rate ("ORR") in a biomarker-enriched population, and a differentiated safety profile, including minimal hematological toxicity and hepatotoxicity, and no peripheral neuropathy/hypoesthesia. We expect to report additional monotherapy safety and efficacy data from the dose escalation and expansion portions of the clinical trial in the second quarter of 2025.

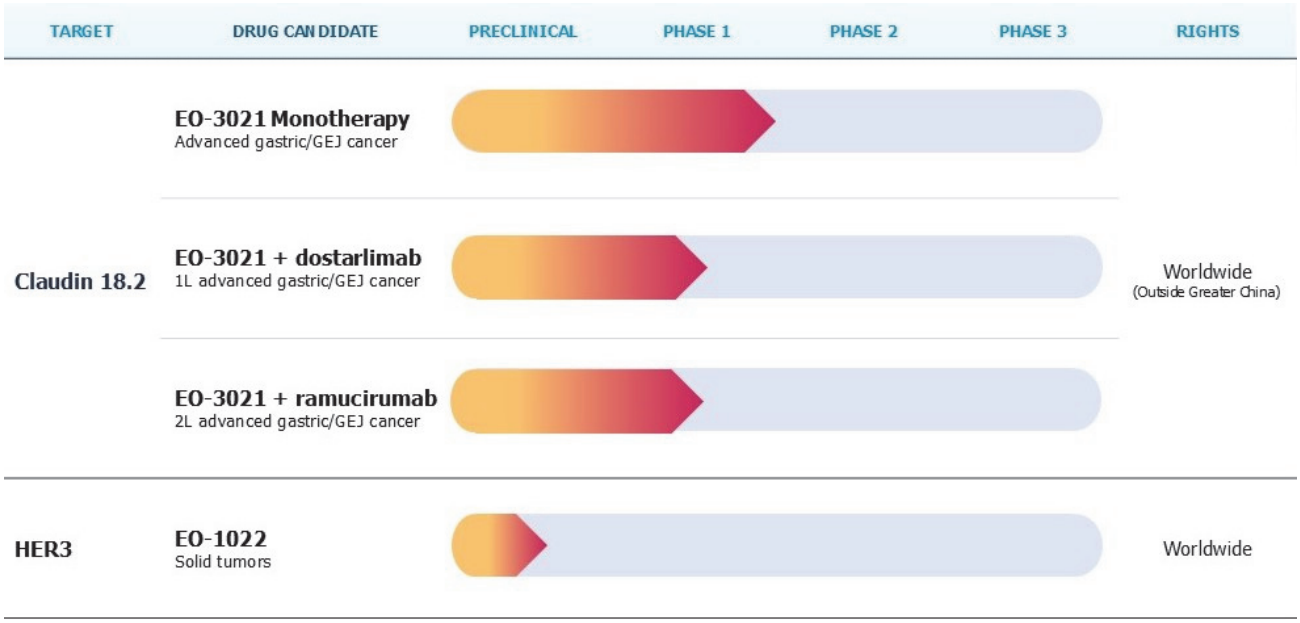
Based on the initial clinical data, we are focusing the clinical development of EO-3021 on the first- and second-line treatment of advanced gastric/GEJ cancer, where EO-3021's key attributes can potentially provide differentiated benefits and address unmet needs in both patient outcomes and safety. In December 2024, we announced preclinical proof-of-concept data indicating the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors. We expect to report initial data from the combination cohorts of the clinical trial in the fourth quarter of 2025 or the first quarter of 2026.

We have an active Investigational New Drug ("IND") application for EO-3021 with the U.S. Food and Drug Administration (the "FDA"). EO-3021 was granted orphan drug designation by the FDA for the treatment of gastric cancer (including GEJ cancer) in November 2020 and for the treatment of pancreatic cancer in May 2021. Additionally, in September 2024, EO-3021 was granted Fast Track designation by the FDA for the treatment of patients with advanced or metastatic gastric/GEJ cancer expressing Claudin 18.2 that has progressed on or after prior therapy.

We currently retain worldwide development and commercialization rights for EO-3021 outside Greater China (the People's Republic of China, Hong Kong, Macau and Taiwan).

Our second product candidate, EO-1022, is a potentially differentiated HER3 ADC being developed for the treatment of patients with HER3-expressing solid tumors, including breast cancer, non-small cell lung cancer and other solid tumors. EO-1022 is an ADC containing seribantumab, a fully human immunoglobulin G2 ("IgG2") anti-HER3 mAb, and an MMAE payload, with glycan site-specific conjugation. In April 2024, we announced preclinical proof-of-concept data for our HER3 ADC program using a non-site-specific conjugation ADC. We expect to present preclinical data for EO-1022 in the second quarter of 2025 and to submit an IND application for EO-1022 in 2026.

Our pipeline is shown below:



We have an experienced management team with expertise in ADC and oncology drug discovery and development, as well as a proven track record to discover and develop novel cancer therapies for patients with significant unmet medical needs. Additionally, we are backed by a group of renowned scientific advisors and partners that bring clinical and operational expertise to help optimize execution.

Our Strategy

Our goal is to deliver safe and effective selective cancer therapies for patient populations with significant unmet medical needs. Key elements of our strategy include:

- ***Rapidly advance our lead product candidate, EO-3021, an ADC targeting Claudin 18.2, through clinical development.*** We are currently evaluating EO-3021 in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab in the first-line setting and ramucirumab in the second-line setting of advanced gastric/GEJ cancer treatment. We expect to report additional monotherapy safety and efficacy data from the dose escalation and expansion portions of the clinical trial in the second quarter of 2025. We expect to report initial data from the combination cohorts of the clinical trial in the fourth quarter of 2025 or the first quarter of 2026.

- ***Rapidly advance our second product candidate, EO-1022, a potentially differentiated ADC targeting HER3, through preclinical development.*** We expect to present preclinical data for EO-1022 in the second quarter of 2025 and submit an IND application for EO-1022 in 2026.

- ***Evaluate strategic opportunities to potentially accelerate development timelines and enhance the commercial potential of our product candidates globally***. We intend to leverage our ADC expertise to advance a novel pipeline. We plan to commercialize our product candidates in key markets, either alone or with strategic partners, and maximize the worldwide commercial potential of our programs.

Our Lead Product Candidate: EO-3021

EO-3021 is an ADC designed to target Claudin 18.2, which can selectively deliver a cytotoxic payload directly to cancer cells expressing Claudin 18.2. We believe Claudin 18.2 is overexpressed in a majority of gastric and GEJ cancers and is a clinically validated biomarker, with one Claudin 18.2 mAb (zolbetuximab) approved to be used in combination with chemotherapy for the first-line treatment of advanced gastric/GEJ adenocarcinoma that is Claudin 18.2 positive. We believe an ADC approach could maximize the reach and benefit of Claudin 18.2-targeting therapy, as an ADC harnesses

both the specificity of the antibody and the cytotoxicity of the payload to potentially improve both efficacy and safety over standard of care.

We believe EO-3021 has the potential to be a differentiated Claudin 18.2 ADC, due to its competitive anti-tumor activity and differentiated safety profile. EO-3021 features site-specific conjugation at glutamine (Q295), which has been shown to increase ADC stability and minimize free payload compared to cysteine conjugation. Our initial clinical data showed competitive anti-tumor activity of 42.8% confirmed ORR in a biomarker-enriched patient population in advanced gastric/GEJ cancer, minimal payload-associated toxicities and limited overlapping toxicities with standard-of-care agents used in earlier lines of therapy. Therefore, we believe EO-3021 could be an active, more combinable Claudin 18.2 ADC to address unmet needs in the earlier lines of therapy for the treatment of advanced gastric/GEJ cancer.

In July 2022, we licensed the worldwide exclusive rights, outside Greater China, from a subsidiary of CSPC Pharmaceutical Group Limited (collectively with its affiliates, "CSPC") to develop and commercialize products containing EO-3021 for the treatment of cancer.

We are evaluating EO-3021 in combination with dostarlimab, a PD-1 inhibitor, in the first-line setting and ramucirumab, a VEGFR2 inhibitor, in the second-line setting for the treatment of advanced gastric/GEJ cancer. We will sponsor and conduct all clinical development of both combinations and will assume all costs associated with the study.

We believe high unmet needs in first-line and second-line advanced gastric/GEJ cancer provide compelling market opportunities. Based on published studies, we believe approximately 60% of patients living with gastric/GEJ cancer have tumors expressing Claudin 18.2 in at least 20% of tumor cells at immunohistochemistry ("IHC") 2+/3+. The incidence of gastric/GEJ cancer in the United States, Japan, France, Germany and the United Kingdom in 2024 has been estimated to be approximately 178,000.

Monotherapy Data from our Ongoing Phase 1 Clinical Trial

In August 2024, we reported initial monotherapy data from the dose escalation portion of our ongoing Phase 1 clinical trial of EO-3021. As of the data cutoff date of June 10, 2024, 32 patients had been treated in the dose escalation portion of the trial at four dose levels (ranging from 1.0 mg/kg to 2.9 mg/kg administered intravenously ("IV") every three weeks ("Q3W")), including 26 patients with gastric/GEJ cancer. The median age was 65 years (ranging from 45 to 83) and the median number of prior lines of therapy was three (ranging from one to seven).

Initial safety data were as follows:

- As of the data cutoff date of June 10, 2024, EO-3021 was observed to be generally well-tolerated. No Grade 4 or 5 treatment-related adverse events were reported, and less than 10% of patients discontinued EO-3021 due to adverse events. No neutropenia or peripheral neuropathy/hypoesthesia, both known toxicities associated with MMAE, were observed in the safety population of 32 patients treated with EO-3021.

- Across all grades, the most common treatment-emergent adverse events (reported in ≥20% of patients) were nausea (56%), decreased appetite (47%), fatigue (41%) and diarrhea (28%). Four dose-limiting toxicities (one each of Grade 3 fatigue, encephalopathy, worsening decreased appetite, and Grade 2 decreased appetite requiring a dose reduction at Cycle 2) were observed at the 2.9 mg/kg dose level, leading to the decision to select the 2.0 mg/kg and 2.5 mg/kg Q3W doses for evaluation in the dose expansion portion of the Phase 1 trial.

Initial efficacy data in gastric/GEJ cancer were as follows:

- As of the data cutoff date of June 10, 2024, 15 patients with gastric/GEJ cancer were evaluable for efficacy with measurable disease, at least one post-baseline scan, and available Claudin 18.2 IHC results. Seven of these 15 patients (47%) had tumors with Claudin 18.2 expression in ≥20% of tumor cells at IHC 2+/3+. Claudin 18.2 expression was determined retrospectively using a Claudin 18.2-specific IHC assay.

- In seven patients with Claudin 18.2 in ≥20% of tumor cells at IHC 2+/3+, the ORR was 42.8% (three confirmed partial responses, one of which was confirmed following the June 10, 2024, data cutoff) and the disease control rate ("DCR") was 71.4%, including two patients with stable disease ("SD").

- In eight patients with Claudin 18.2 in <20% of tumor cells at IHC 2+/3+, the ORR was 0% and the DCR was 50%, including four patients with SD.

Preclinical Data Indicating Combination Potential

In December 2024, we announced preclinical proof-of-concept data indicating the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors. The *in vivo* data from preclinical studies evaluating the anti-tumor activity of EO-3021 with a VEGFR2 or PD-1 inhibitor showed:

- treatment with EO-3021 and DC101, a surrogate of the VEGFR2 inhibitor ramucirumab, exhibited statistically superior tumor growth inhibition ("TGI") compared to treatment with either EO-3021 or DC101 alone (TGI: 88.2% for EO-3021 in combination with DC101, compared to 20.1% for EO-3021 and 59.2% for DC101 alone); and

- treatment with EO-3021 and a PD-1 inhibitor exhibited statistically superior TGI compared to treatment with either EO-3021 or a PD-1 inhibitor alone (TGI: 79.9% for EO-3021 in combination with a PD-1 inhibitor, compared to 33.8% for EO-3021 and 25.0% for a PD-1 inhibitor alone). 92% (11/12) of mice treated with the combination of EO-3021 and a PD-1 inhibitor achieved a complete response ("CR"), compared to 50% (6/12) of mice treated with EO-3021 monotherapy and 17% (2/12) of mice treated with a PD-1 inhibitor alone.

Clinical Development Plan

We have an active IND for EO-3021 with the FDA, and we are evaluating EO-3021 in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab, a PD-1 inhibitor, and ramucirumab, a VEGFR2 inhibitor, in patients with advanced, unresectable or metastatic gastric/GEJ solid tumors. We believe our initial monotherapy data suggested the potential for competitive efficacy and a differentiated safety profile, including minimal hematological toxicity and hepatotoxicity, and no peripheral neuropathy/hypoesthesia.

Based on these data, we are focusing the clinical development of EO-3021 on the first- and second-line treatment of advanced gastric/GEJ cancer, where EO-3021's key attributes can potentially provide differentiated benefits and address unmet needs in both patient outcomes and safety.

In the monotherapy dose escalation part of our Phase 1 trial, we enrolled patients in increasing dose levels, including 1.0, 2.0, 2.5 and 2.9 mg/kg IV Q3W. The primary objective in dose escalation was to evaluate the safety and tolerability of EO-3021. In the ongoing dose expansion part of our Phase 1 trial, we are exploring two doses of EO-3021: 2.0 mg/kg IV Q3W and 2.5 mg/kg IV Q3W. These doses were selected with the goal of further characterizing EO-3021 in order to select an optimized dose for further clinical development. The primary objective in dose expansion is to evaluate preliminary anti-tumor activity of EO-3021. We have implemented prospective Claudin 18.2 expression testing as part of the patient screening process in the dose expansion portion of the Phase 1 trial, focusing enrollment on patients with a minimum of 25% of tumor cells at IHC 1+/2+/3+.

Patient dosing is ongoing in the combination portion of our Phase 1 trial. The combination cohorts are evaluating EO-3021 in combination with dostarlimab in the first-line setting and with ramucirumab in the second-line setting. By combining EO-3021 and dostarlimab, an immune checkpoint inhibitor, we aim to deliver synergistic benefit, potentially offering patients improved outcomes beyond those seen with the existing combination of immunotherapy and chemotherapy. The combination of an immunotherapy and chemotherapy agent is the standard of care for the treatment of gastric/GEJ cancer in the front-line setting. With the EO-3021 and ramucirumab combination, we aim to deliver improved tolerability and synergistic anti-tumor activity compared to the approved combination of ramucirumab and paclitaxel. The combination of ramucirumab and paclitaxel is the standard of care for the treatment of second-line gastric/GEJ cancer.

Structure and Mechanism of Action

Claudin 18.2 is a compelling ADC therapeutic target that is part of a family of tight junction membrane proteins. Expression of Claudin 18.2 in normal tissues is restricted to the gastric mucosa and typically has minimal overlap with HER2 or PD-L1 expression. During malignant transformation, the tight junctions may become disrupted, exposing

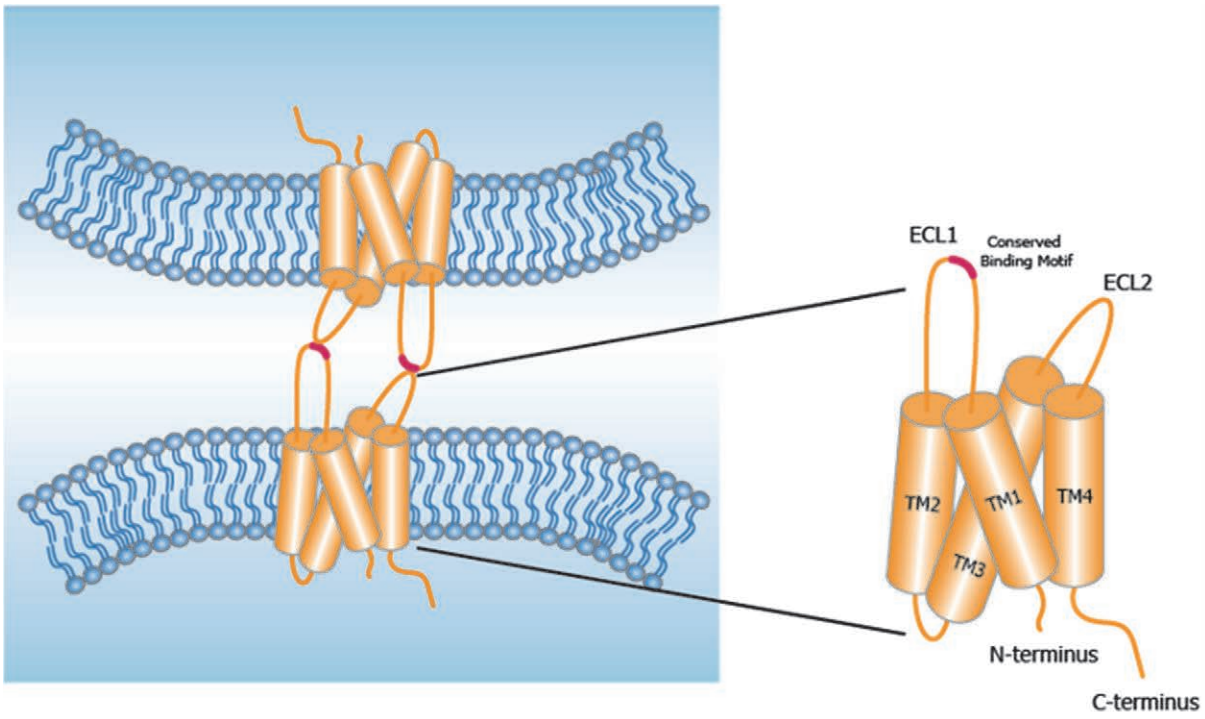
Claudin 18.2 and allowing them to be accessible by Claudin 18.2-targeting agents. Claudin 18.2 is overexpressed in several types of cancers, including gastric, esophageal, pancreatic, ovarian and lung.

EO-3021 consists of a fully human IgG1 mAb that targets Claudin 18.2 and is site-specifically conjugated to the MMAE payload via a cleavable linker with a drug-to-antibody ratio ("DAR") of 2. Site-specific conjugation at glutamine (Q295) increases ADC stability and has been shown to minimize free MMAE compared to cysteine conjugation.

EO-3021 is designed to bind to Claudin 18.2 on the cell surface and is internalized, upon which the linker is cleaved in the lysosome to release the MMAE payload, a potent anti-mitotic agent. This results in microtubule disruption, inhibiting cell division and promoting cancer cell death via apoptosis. Additionally, a bystander effect may occur, in which MMAE diffuses out of targeted cancer cells and into neighboring cancer cells, promoting neighboring cancer cell death via apoptosis. MMAE has been clinically validated as an effective anti-tumor payload and is the cytotoxic component of several FDA-approved ADCs.

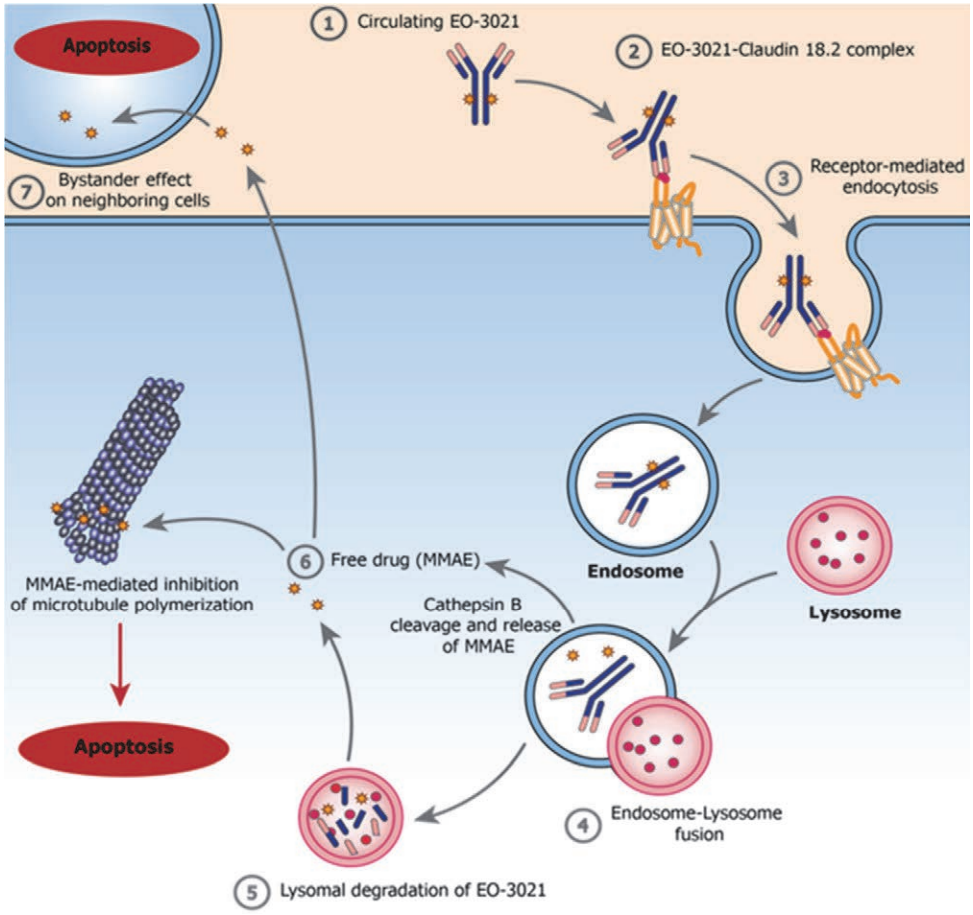
The structure of Claudin 18.2 is shown in Figure 1 below, and the mechanism of action of EO-3021 is shown in Figure 2 below:

Figure 1



Structure of Claudin 18.2. Claudin 18.2 is a tight junction membrane protein with four transmembrane structural domains (TM1, TM2, TM3 and TM4), two extracellular loops (ECL1 and ELC2) and the NH2 and COOH ends (N-terminus and C-terminus, respectively) located intracellularly.

Figure 2



Mechanism of Action of EO-3021. The IgG1 mAb of EO-3021 binds to Claudin 18.2, and this initiates internalization of the EO-3021-Claudin 18.2 complex. Lysosomal cleavage of the linker releases free MMAE into the cancer cell, which results in microtubule disruption, inhibiting cell division and promoting cancer cell death via apoptosis. A bystander effect may occur, in which free MMAE promotes neighboring cancer cell death.

Our Second Product Candidate: EO-1022

We are developing EO-1022, a potentially differentiated HER3 ADC for the treatment of patients with HER3-expressing solid tumors, including breast cancer and non-small cell lung cancer. EO-1022 combines seribantumab, a fully human IgG2 anti-HER3 mAb, and an MMAE payload with glycan site-specific conjugation. It is designed to leverage seribantumab's desirable HER3 internalization properties and the latest site-specific ADC technology to treat patients living with solid tumors that express HER3.

In April 2024, we announced preclinical proof-of-concept data for our HER3 ADC program using a non-site-specific conjugated seribantumab ADC with an MMAE payload (HER3-ADC1). The *in vitro* and *in vivo* data from preclinical studies showed:

- HER3-ADC1 binding to cancer cells, endocytosis, MMAE release and inhibition of proliferation were dependent on HER3 expression;

- in cytotoxicity assays, HER3-ADC1 displayed HER3-dependent cell killing and outperformed a benchmark HER3 ADC with a deruxtecan payload, which is currently in clinical development; and

- in a patient-derived xenograft (PDX) model of pancreatic cancer with high HER3 expression, HER3-ADC1 induced tumor regression, whereas an isotype-MMAE control and a benchmark HER3 ADC with a deruxtecan payload had only a modest effect.

In September 2024, we entered into a license agreement with Synaffix B.V. ("Synaffix"), giving us global access to Syanffix's clinical stage, site-specific ADC technology platform, which we are using to develop EO-1022. If we successfully develop and commercialize EO-1022, we would potentially be obligated to pay Synaffix up to $365.5 million in development, regulatory and commercial milestones and tiered royalties in the low to mid-single digit percentages on net sales.

We expect to present preclinical data for EO-1022 in the second quarter of 2025 and to file an IND application for EO-1022 in 2026.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

Until we have completed the first Phase 2 clinical trial for EO-3021 in the United States, CSPC will supply EO-3021 for clinical investigation purposes in the United States as we request, but only to the extent necessary to conduct such clinical trial, at no cost to us.

We generally expect to rely on third parties for the manufacturing of any companion or complementary diagnostics we may develop.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

We compete directly with companies that focus on oncology and companies dedicating their resources to cancer therapies. With the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available and new therapeutic candidates are clinically developed or approved therapies are explored for new indications. Any candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and established presence in the market than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion or complementary diagnostics in guiding the

use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and patient convenience. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

There are a number of biological and biotechnology companies that currently are pursuing the development of selective cancer therapies for patients with significant unmet medical needs. In particular, we expect that EO-3021 will compete against other ADCs targeting Claudin 18.2. Several such candidates are currently in clinical development, including those of Antengene, AstraZeneca, Chia Tai Tianqing Pharmaceutical, Evopoint Biosciences, Innovent Biologics, LaNova Medicines, Merck KGaA/Jiangsu Hengrui, RemeGen, Shanghai Junshi Bioscience, Sichuan Kelun-Biotech Biopharmaceutical, SystImmune and TORL Biotherapeutics. We may face further competition from companies pursuing the development of product candidates that target Claudin 18.2 through other modalities. For example, Astellas Pharma has received regulatory approval for a mAb targeting Claudin 18.2 in combination with chemotherapy for the first-line treatment of advanced gastric/GEJ adenocarcinoma that is Claudin 18.2 positive. Additional companies developing product candidates that target Claudin 18.2 include Beijing Mabworks Biotech, CARsgen Therapeutics, Flame Biosciences, FutureGen Biopharmaceutical, Jiangsu Aosaikang Pharmaceutical, Legend Biotech, NovaRock Biotherapeutics, Shanghai Longyao Biotechnology, Transcenta Holding, Triumvira Immunologics, Zai Lab and others. Development efforts with respect to, and clinical trial results of, these potentially competitive product candidates may be unsuccessful, which could result in a negative perception of product candidates targeting Claudin 18.2 in general, which could in turn negatively impact the regulatory approval process for EO-3021.

We expect that EO-1022 will compete against other ADCs targeting HER3. Several such candidates are currently in clinical development, including those of Alphamab Oncology, Daiichi Sankyo/Merck, Duality Biologics, Innovent Biologics, Jiangsu Hengrui, MediLink Therapeutics (Suzhou)/BioNTech, Multitude Therapeutics, Shanghai Institute of Biological Products and SystImmune/Bristol Myers Squibb. We may face further competition from companies pursuing the development of product candidates that target HER3 through other modalities. For example, Merus has received regulatory approval for a bispecific antibody (zenocutuzumab) targeting HER2 and HER3. Additional companies developing product candidates that target HER3 include Hummingbird Bioscience, ISU Abxis, Shanghai Institute of Biologic Products, SystImmune and others. Development efforts with respect to, and clinical trial results of, these potentially competitive product candidates may be unsuccessful, which could result in a negative perception of product candidates targeting HER3 in general, which could in turn negatively impact the regulatory approval process for EO-1022.

License, Asset Purchase and Collaboration Agreements

CSPC License Agreement

In July 2022, we entered into a license agreement (the "CSPC License Agreement") with CSPC Megalith Biopharmaceutical Co., Ltd., a subsidiary of CSPC Pharmaceutical Group Limited, pursuant to which CSPC granted to us a worldwide exclusive right and license (outside of Greater China) under certain patents identified in the CSPC License Agreement (the "Licensed Patents") and know-how to develop and commercialize products containing EO-3021 ("Licensed Products") in the treatment of cancer.

Pursuant to the terms of the CSPC License Agreement, we paid to CSPC a one-time, upfront payment of $27.0 million. CSPC will also be eligible to receive up to $148.0 million in potential development and regulatory milestone payments and up to $1.0 billion in potential commercial milestone payments plus royalties on net sales. During the term of the CSPC License Agreement, we are also required to pay to CSPC (i) royalties ranging from mid-single digits through low double digits on net sales of each Licensed Product and (ii) a percentage of non-royalty sublicense income received by us, up to an aggregate of $50.0 million.

We will purchase Licensed Products for any clinical or commercial supply from CSPC under the terms of a supply agreement. Until we have completed the first Phase 2 clinical trial for the first Licensed Product in the United States, CSPC shall supply EO-3021 for clinical purposes as we request, but only to the extent necessary to conduct such clinical trial, at no cost to us.

The CSPC License Agreement will expire automatically upon the expiration of the last royalty term of the last Licensed Product, with each royalty term expiring on a country-by-country basis upon the later of: (i) the expiration or abandonment of the last-to-expire Licensed Patent covering a Licensed Product; (ii) 10 years after the date of first commercial sale in the applicable country; and (iii) expiration of regulatory exclusivity for the Licensed Product in the applicable country.

The CSPC License Agreement may be terminated by us for any reason upon 180 days prior written notice to CSPC. CSPC may terminate the CSPC License Agreement if we or any sublicensee commences an action challenging the Licensed Patents or following the occurrence of certain change of control transactions. Either party may terminate the CSPC License Agreement (i) for an uncured material breach of the CSPC License Agreement by the other party or (ii) if, at any time, the other party undergoes certain bankruptcy, insolvency or dissolution proceedings.

Merrimack Asset Purchase Agreement

In May 2019, we entered into an asset purchase agreement (the "Asset Purchase Agreement") with Merrimack Pharmaceuticals, Inc. (the "previous sponsor"), pursuant to which we acquired the previous sponsor's anti-HER3 antibody programs (the "Acquired Product Candidates"), including seribantumab. Upon closing of the Asset Purchase Agreement in July 2019, we paid the previous sponsor an upfront cash payment of $3.5 million. In addition to the foregoing payment, we may become obligated to pay the previous sponsor up to $54.5 million in additional potential development, regulatory approval and commercial-based milestone payments, consisting of:

- $3.0 million for achievement of the primary endpoint in the first registrational clinical trial of any Acquired Product Candidate;

- up to $16.5 million in total payments for the achievement of various regulatory approval and reimbursement-based milestones in the United States, Europe and Japan; and

- up to $35.0 million in total payments for achieving various cumulative worldwide net sales targets between $100.0 million and $300.0 million for the Acquired Product Candidates.

Dyax Collaboration Agreement

Pursuant to the Asset Purchase Agreement with the previous sponsor, we (i) assumed all of the previous sponsor's obligations and rights under the amended and restated collaboration agreement (the "Dyax Collaboration Agreement"), between the previous sponsor and Dyax Corp. ("Dyax"), which was entered into in January 2007, including an exclusive, worldwide product license to clinically develop or commercialize seribantumab and (ii) agreed to be bound to the terms of a sublicense agreement between the previous sponsor and Dyax entered into in June 2008. Under the Dyax Collaboration Agreement, Dyax used its proprietary phage display technology to identify antibodies that bind to targets of interest to us as therapeutics or diagnostics. Seribantumab was identified through the Dyax Collaboration Agreement. In January 2016, Dyax was acquired by Shire plc, which was subsequently acquired by Takeda Pharmaceutical Company Limited in January 2019.

We may be required to make additional maximum aggregate development and regulatory milestone payments of up to approximately $9.3 million for seribantumab. In addition, Dyax is entitled to tiered mid-single digit royalties based on net sales of seribantumab. Our obligation to pay royalties to Dyax continues on a country-by-country basis until the later of a specified number of years after the first commercial sale of seribantumab in such country and the expiration of the patent rights covering the product in such country. We are obligated to use commercially reasonable efforts to develop and commercialize the antibodies for which we obtain a commercial license.

The Dyax Collaboration Agreement will remain in effect, unless terminated earlier, for so long as we or any of our affiliates or sublicensees continue to develop or commercialize products that remain royalty-bearing under the Dyax Collaboration Agreement. Either party may terminate the Dyax Collaboration Agreement in the event of an uncured

material breach by the other party. We also may terminate the Dyax Collaboration Agreement in its entirety or on a product-by-product basis at any time upon 90 days' prior written notice.

Ligand Commercial License Agreement

Pursuant to the Asset Purchase Agreement with the previous sponsor, we purchased from the previous sponsor all of the right, title and interest in and to the commercial license agreement between the previous sponsor and Selexis SA ("Selexis"), for non-exclusive rights to technology for use in the manufacture of certain biologic products. Under this agreement, we are required to make aggregate milestone payments of up to €0.9 million, per licensed product, and pay royalties of less than one percent on net sales of product, which royalty payments expire in 2026. The obligation to pay royalties with respect to each product sold in a country continues until the expiration of the patent rights covering the product in such country. Either party may terminate the agreement in the event of an uncured material breach by the other party. We also have the right to terminate the agreement at any time upon 60 days' prior written notice. In November of 2021, this agreement was assigned from Selexis to Ligand Pharmaceuticals Incorporated ("Ligand").

Financing Agreements

K2HV Loan and Security Agreement

In July 2022, we entered into a loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC (together with its affiliates, "K2HV", and together with any other lender from time to time party thereto, the "Lenders"), as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $50.0 million principal in term loans (the "Term Loan") consisting of a first tranche of $30.0 million funded at closing and a subsequent second tranche of up to $20.0 million upon our request before March 1, 2025, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. In connection with entering into the Loan Agreement, we also issued to K2HV a warrant to purchase shares of our common stock.

In March 2024, we entered into an amendment to the Loan Agreement with K2HV, pursuant to which: (i) the amortization date of the Term Loan was amended from March 1, 2025 to June 1, 2026; (ii) we issued to K2HV a new warrant to purchase shares of our common stock in exchange for the original warrant ; (iii) upon the Lenders' election to convert any portion of the principal amount of the term loans then outstanding, up to $3.25 million in principal amount, into shares of the our common stock, as described below, designated holders will also receive a warrant to purchase an equal number of shares of our common stock (the "Conversion Warrant"), subject to customary beneficial ownership limitations; and (iv) we paid a customary amendment fee.

The Term Loan will mature on August 1, 2026, with interest-only payments until June 1, 2026, and thereafter interest and principal payments for the remainder of the term. It bears a variable interest rate equal to the greater of (i) 7.95% and (ii) the sum of (A) the prime rate last quoted in *The Wall Street Journal* (or a comparable replacement rate, as determined by the Lenders, if *The Wall Street Journal* ceases to quote such rate) and (B) 3.20%. Upon the final payment under the Loan Agreement, the Lenders are entitled to an end of term charge equal to 6.45% of the aggregate original principal amount of the term loans made pursuant to the Loan Agreement.

We may prepay, at its option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium as follows: 3% of the Loan amounts prepaid if such prepayment occurs in the first year after funding; 2% if such prepayment occurs in the second year after funding; 1% if such prepayment occurs in the third year after funding; and 0% thereafter.

The Lenders may elect at any time following the closing and prior to the full repayment of the term loans to convert any portion of the principal amount of the term loans then outstanding, up to an aggregate of $3.25 million in principal amount, into shares of our common stock and the Conversion Warrant at a conversion price of $2.25 (the effective price per share of common stock sold in the Company's June 2023 offering (see Note 9)), subject to customary 19.99% Nasdaq beneficial ownership limitations. We also granted registration rights to the Lenders with respect to shares received upon such conversion.

Further, the Lenders may elect to invest up to $5.0 million in our future equity financings, provided such investment is limited to no more than 10% of the total amount raised in such equity financing.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. The Loan Agreement also contains covenants requiring that we maintain cash, cash equivalents and marketable securities balance of at least $25.0 million so long as our total market capitalization is less than $250.0 million.

As security for its obligations under the Loan Agreement, the Company granted the Lenders a first priority security interest on substantially all of the Company's assets (other than intellectual property), subject to certain exceptions.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the compositions of matter of our product candidates, their methods of use, and other inventions that are important to our business.

Our success will depend significantly on our ability and our licensors' ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business, to defend and enforce our patents, to preserve the confidentiality of our trade secrets, and to operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop, strengthen, and maintain our proprietary position in the field of selective cancer therapy.

Our wholly-owned patent portfolio includes a patent family with claims directed to antibodies and related compositions covering seribantumab, as well as methods of treating cancer using such antibodies and compositions. The family contains three U.S. patents directed to seribantumab which expire in February 2028 and a fourth U.S. patent which expires in October 2029 (including 614 days of Patent Term Adjustment), subject to any disclaimers or extensions. The family also contains a pending U.S. application, which if issued, would expire in February 2028, subject to any disclaimers or extensions.

In addition, the above-discussed patent family includes granted patents in China, Europe, Hong Kong, Israel, and Japan with claims directed to compositions of matter covering seribantumab and related methods of therapy. These patents expire in February 2028, subject to any disclaimers or extensions.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In the countries in which we file, the patent term is 20 years from the earliest non-provisional filing date, subject to any disclaimers or extensions. The term of a patent in the United States can be adjusted due to any failure of the United States Patent and Trademark Office following certain statutory and regulation deadlines for issuing a patent.

In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for a portion of the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the original expiration of the patent. The protection provided by a patent varies from country to country, and is dependent on the type of patent granted, the scope of the patent claims, and the legal remedies available in a given country.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

Governmental Regulation and Product Approval

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, biological products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, with the exception that the section of the FDC Act that governs the approval of drugs via new drug applications ("NDAs"), does not apply to the approval of biologics. In contrast, biologics are approved for marketing under provisions of the Public Health Service Act (the "PHSA"), via a biologics license application ("BLA"). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as tests of reproductive toxicity and carcinogenicity in animals, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB"), for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides

authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases. In Phase 1, the initial introduction of the drug or biologic into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the biologic. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

These phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug or biologic.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing and distribution of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee. Under an approved BLA, the applicant is also subject to an annual program fee. These fees typically increase annually. A BLA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the BLA includes an indication for other than a rare disease or condition. The FDA has 60 days from its receipt of a BLA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of BLAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the BLA; applications classified as Priority Review are reviewed within six months of the date the FDA files the BLA. A BLA can be classified for Priority Review when the FDA determines the biologic has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the BLA submission.

The FDA may also refer applications for novel biologic products, as well as biologic products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee — typically a panel that includes clinicians, statisticians and other experts — for review, evaluation, and a recommendation as to whether the BLA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice

("cGMP") is satisfactory and the BLA contains data that provide substantial evidence that the drug is safe and effective, or the biologic is safe, pure, potent, and effective, in the respective claimed indication.

After the FDA evaluates the BLA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the BLA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA, or supplement to an approved BLA, before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing original BLAs.

Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs or biologic products that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast Track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Breakthrough Therapy Designation

FDA is also required to expedite the development and review of applications for approval of products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the product candidate. FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either 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. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in most cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The Food and Drug Omnibus Reform Act ("FDORA"), which was enacted in December 2022, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Orphan Drugs

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

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

The first BLA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the BLA application fee.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologic products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made

public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act (the "PREA"), BLAs, or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, the PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act (the "BPCA"), provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to

periodic unannounced inspections by the FDA, during which the agency inspects a biologic product's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), creates an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilars are licensed based on the FDA's findings of safety, purity and potency for a previously FDA-licensed product called a reference product. There must be no differences in route of administration, dosage form and strength to rely on a given reference product, and there must be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency one or more conditions of use for which the reference product is approved. Biosimilarity must be shown through analytical trials, animal trials and at least one clinical trial, absent a waiver from the FDA. A biosimilar product may also meet the higher hurdle of interchangeability such that it can be substituted for a reference product without the intervention of the prescribing health care provider if the sponsor can demonstrate that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The first biosimilar product was approved under the BPCIA in 2015, and the first interchangeable product was approved in 2021. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose some hurdles to biosimilar product implementation, which is still being evaluated by the FDA.

A reference product is granted 12 years of data exclusivity from the time of first licensure, or BLA approval, of the reference product and, during that 12 years of data exclusivity, no application for a biosimilar relying on the reference product can be submitted for four years. The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product is eligible for exclusivity, precluding marketing of interchangeable biosimilars referencing the same reference product for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar to be approved, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

FDA Approval and Regulation of Companion and Complementary Diagnostics

If safe and effective use of a product depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, before or at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a new therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication.

The FDA has also introduced the concept of a complementary diagnostic, which the FDA defines as a test that is not required but which provides significant information about the use of a drug. A complementary test can help guide treatment strategy and identify which patients are likely to derive the greatest benefit from therapy, and if approved by the FDA information regarding the IVD will be included in the therapeutic product labeling.

Approval or clearance of the companion or complementary diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion or complementary diagnostics in conjunction with the review of our products will, therefore, likely involve coordination of review by CDER and the FDA's Office of In Vitro Diagnostics and Radiological Health. We may partner with a diagnostic provider to develop a companion or complementary diagnostic for certain of our product candidates. Review and approval of a companion or complementary diagnostic is typically done in parallel with

development of the therapeutic product. However, it is possible that the FDA may permit approval of the companion or complementary diagnostic as a post-marketing commitment following a potential regulatory approval.

Under the FDC Act, *in vitro* diagnostics, including companion or complementary diagnostics, are regulated as medical devices. In the United States, the FDC Act and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval ("PMA approval"). The vast majority of companion and complementary diagnostics require PMA approval.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation (the "QSR"), which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, additional testing and/or restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register their establishments and list their devices with the FDA. A medical device manufacturer's manufacturing processes and the processes of the specification developer and repackager/relabeler (if different from the manufacturer) and initial importer (if manufactured outside of the United States), are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, price transparency and reporting, privacy and cybersecurity laws and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (the "ACA"), amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or ("HITECH"), and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the collection, processing, storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of protected health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not pre-empted by HIPAA or HITECH. For example, at the state level, the California Consumer Privacy Act of 2018 ("CCPA"), imposes obligations on certain businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. In addition, the California Privacy Rights Act of 2020 ("CPRA"), which went into effect in January 2023, imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that is vested with authority to implement and enforce the CCPA and CPRA. Virginia's Consumer Data Protection Act, which took effect in January 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information

revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Other states have also enacted, proposed or are considering proposing data privacy laws.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services ("CMS"), issued a final rule that requires certain manufacturers of prescription drugs to collect and annually report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) physician assistants, certain types of advance practice nurses, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Further, certain states require the posting of information relating to clinical studies and their outcomes. A growing number of states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases and prices of newly launched drugs. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Additionally, we may also be subject to state and foreign laws governing 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.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal, and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices.

Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act (the "IRA") in August 2022, which, among other things, eliminated, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket costs and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also allows the U.S. Department of Health and Human Services ("HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least seven years

(11 years for single-source biologics) are eligible to be selected by CMS 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 products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, 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, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in litigation. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

We expect that additional state and federal healthcare reform measures will be adopted in the future.

Coverage and Reimbursement

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products depends, in part, on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with federal and state government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations. Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products when more established or lower-cost therapeutic alternatives are already available. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Expensive pharmaco-economic studies may need to be conducted in order to demonstrate to payors the medical necessity and cost-effectiveness of product candidates, in addition to the costs required to obtain the FDA approvals. Product candidates may not be considered medically necessary or cost-effective. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a particular reference listed drug in their formularies or otherwise restrict patient access to a reference listed drug when a less costly generic equivalent or other alternative is available. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement

may not be available to enable the maintenance of price levels sufficient to realize an appropriate return on investment in product development. There may also be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. Additionally, we may develop, either by ourselves or with collaborators, companion or complementary diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs products from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Human Capital Resources

As of December 31, 2024, we had 34 full-time employees. Of these employees, five held M.D. and/or Ph.D. degrees, and seven were engaged in research, development and technical operations. From time to time, we also retain independent contractors and consultants to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our incentive share plan is to attract, retain and motivate selected employees, consultants and directors through the granting of incentive share-based compensation awards and cash-based performance bonus awards.

Facilities

We are a remote-first company, meaning that substantially all of our employees work remotely. As a result of this strategy, we do not maintain a corporate headquarters or lease any corporate facilities. We believe that our virtual arrangements are adequate to meet our needs for the immediate future, and that suitable space will be available in the future on commercially reasonable terms, should it be needed.

Legal Proceedings

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

Corporate Information

Our principal executive offices are located at 101 Federal Street, Suite 1900, Boston, Massachusetts 02110 and our telephone number is (716) 371-1125. Our website address is www.elevationoncology.com. Information contained on or accessible through our website is not a part of this Annual Report.

ELEVATION ONCOLOGY and the Elevation Oncology logo are our registered trademarks. Any other trademarks appearing in this Annual Report are the property of their respective holders.

Available Information

The following filings are available through the U.S. Securities and Exchange Commission (the "SEC"), which maintains an Internet site at www.sec.gov, and through our website as soon as reasonably practicable after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15(d) of the Securities Act.

We will make available on our website www.elevationoncology.com, free of charge, copies of these reports and other information as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of the websites referred to above are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider and read carefully all of the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report, before deciding whether to invest in our common stock. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations, net revenue and future prospects. In such event, the trading price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risk Factor Summary

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition and results of operations could be materially harmed and the price of our common stock could significantly decline.

- Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidates.

- We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We have incurred significant operating losses since our inception in 2019 and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

- We are highly dependent on the success of our lead product candidate, EO-3021. We have not completed clinical development or obtained regulatory approval for any product candidate. We may never obtain approval for EO-3021 or any other product candidate.

- If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product or result in significant negative consequences following marketing approval, if any.

- We have, and we may in the future, seek to engage in strategic transactions to acquire or in-license new products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

- The development and commercialization of biological products are subject to extensive regulation, and we may not obtain regulatory approvals for any of our product candidates, on a timely basis or at all.

- If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion or complementary diagnostic tests for our product candidates or any future product candidates that require or

would benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

- Manufacturing biological products is complex and subject to product loss for a variety of reasons. We rely on third parties to manufacture clinical supplies of our product candidates, some of which are based in China, and we intend to rely on third parties to produce commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

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

- We expect to significantly expand our development and regulatory capabilities as we grow our company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

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

- The price of our common stock does not meet the requirements for continued listing on the Nasdaq Global Select Market. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

Risks related to our financial position and need for additional capital

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidates.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. There is no assurance that we will obtain financing from other sources. The uncertainty with respect to our operations and the capital markets generally may make it more challenging to raise additional capital on favorable terms, if at all.

In addition, we expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, seek regulatory approval for, and commercialize our lead product candidate EO-3021 and our second product candidate EO-1022, and potentially add personnel necessary to operate as a commercial-stage public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs, efforts to achieve regulatory approval and preparation for commercialization.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities and expand our regulatory, manufacturing and commercialization activities. Accordingly, we will need to raise substantial additional capital from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to continue to fund our operations and finance the remaining development and commercialization of EO-3021 and EO-1022. The current financing environment in the United States, particularly for biotechnology companies like us, is challenging and we can provide no assurances as to when this will improve. Our business may be impacted by macroeconomic

conditions, including inflation, interest rates and market conditions as well as political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control. These factors may make it challenging to raise additional capital on favorable terms, if at all. A severe or prolonged economic downturn could result in a variety of risks to our business, including in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. For these reasons, among others, we cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders. If adequate financing is not available, we may need to reduce or eliminate our expenditures for research and development of our product candidates, and may be required to suspend development of our product candidates.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We have incurred significant operating losses since our inception in 2019 and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in 2019 and are a clinical-stage biologics company with a limited operating history. We have not yet commercialized any product, nor do we expect to generate revenue from sales of any products for several years, if at all. Consequently, there have been limited operations upon which you can evaluate our business, and predictions about our future success or viability may not be as cancer therapies. For the years ended December 31, 2024 and 2023, we had a net loss of $44.5 million and $45.7 million, respectively. As of December 31, 2024, we had an accumulated deficit of $240.5 million. We expect to continue to incur significant research and development and other expenses related to our ongoing operations, which we anticipate will result in net losses for at least the next several years.

Since our inception, we have focused substantially all of our efforts and financial resources on the licensing, acquisition and clinical development of EO-3021, EO-1022 and seribantumab. To date, we have funded our operations with proceeds from sales of shares of our convertible preferred stock, proceeds from the sale of common stock and warrants, and borrowings under a debt facility. As of December 31, 2024, our cash, cash equivalents and marketable securities were $93.2 million.

We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we seek to advance EO-3021, EO-1022 and other product candidates through clinical and preclinical development. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to incur increasing research and development expenses in connection with our planned clinical trials for EO-3021 and the development of EO-1022 and other product candidates we may choose to pursue. In addition, if we obtain marketing approval for any product candidate, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of such product candidate. Since our initial public offering ("IPO"), we have incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, a product candidate. Our ability to generate revenue and become profitable will depend on a number of factors, including, but not limited to, our ability to:

- initiate and successfully meet our clinical endpoints in our clinical trials for our product candidates;
- initiate and successfully complete all safety, pharmacokinetic and other registrational-enabling studies required to obtain U.S. and foreign marketing approval for our product candidates;
- initiate and complete successful later-stage clinical trials that meet their clinical endpoints;
- submit a BLA for each of our product candidates to the FDA that is filed by the FDA;
- obtain marketing approval for our product candidates;

- establish licenses, collaborations or strategic partnerships that may increase the value of our programs;
- successfully manufacture or contract with others to manufacture our product candidates;
- commercialize our product candidates, if approved, by building a sales force or entering into collaborations with third parties;
- obtain, maintain, protect and defend our intellectual property portfolio;
- achieve market acceptance of our product candidates with the medical community and with third-party payors; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is significantly lower than we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if they are approved.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses we will incur and when, or if, we will be able to achieve profitability. If we decide to or are required by the FDA or regulatory authorities in other jurisdictions to perform studies or clinical trials in addition to those we currently anticipate, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our current and planned clinical trials for, or in the development of, our product candidates, our expenses could increase materially and our potential profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, you should not rely upon the results of any quarterly or annual periods as predictions or indications of future operating performance. We expect our financial condition and operating results to fluctuate from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We require substantial additional funding to pursue our business objectives. If we are unable to raise additional capital when needed or on terms acceptable to us, we could be forced to delay, reduce or terminate our research or drug development programs, any future commercialization efforts or other operations.

Identifying and developing potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and begin selling any approved product. We expect to incur substantial expenses as we advance the clinical development of our product candidates and seek to develop, acquire or in-license additional product candidates. We expect increased expenses as we continue our research and development activities, initiate additional clinical trials and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any product candidate, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we have incurred, and expect to continue to incur, additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all.

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. If we are unable to raise additional capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations. In July 2022, we entered into a sales agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"), and in May 2024, we entered into a new sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") pursuant to which we may offer and sell to or through TD Cowen acting as agent and/or principal, shares of our common stock having aggregate gross proceeds of up to $75.0 million. Under the 2024 Sales Agreement, TD Cowen may sell the shares by any method permitted by law and deemed to be an "at the market" ("ATM") offering as defined in Rule 415 of the Securities Act or in other transactions pursuant to an effective shelf registration statement on Form S-3. However, our ability to raise capital under an ATM facility or other registration statements may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Annual Report on Form 10-K, we are only permitted to utilize a shelf registration statement, including the registration statement under which the ATM facility is operated, subject to Instruction I.B.6 to Form S-3, which is referred to as the "baby shelf" rule. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms. Also in July 2022, we entered into the Loan Agreement with K2HV to provide up to $50.0 million principal amount in term loans.

We believe our cash, cash equivalents and marketable securities of $93.2 million as of December 31, 2024 will enable us to meet our anticipated capital requirements into 2026. Based on current operating plans, we do not expect that this amount will meet our anticipated capital requirements over the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in government regulations. Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our product candidates;
- disruptions or delays in enrollment of our clinical trials;
- the extent to which we develop, in-license or acquire other product candidates or technologies;
- the number and development requirements of future product candidates that we may pursue, and indications for product candidates that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals for our product candidates and any companion or complementary diagnostics that we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;
- the costs associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of our product candidates, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;

- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and

- to the extent we pursue strategic collaborations, including collaborations to commercialize our product candidates or to develop any future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments that we are required to make or are eligible to receive under any such collaborations.

We require additional capital to complete our planned clinical development programs for our current product candidates to obtain regulatory approval. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors over which we may have no or limited control, including financial institutions that may experience insolvency or financial distress. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of our product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. 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 product 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 third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our loan and security agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our Loan Agreement with K2HV is secured by a lien covering substantially all of our personal property, excluding intellectual property.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. The Loan Agreement also contains covenants requiring that we maintain cash, cash equivalents and marketable securities balance of at least $25.0 million so long as our total market capitalization is less than $250.0 million.

The restrictions and covenants in the Loan Agreement, as well as those contained in any future debt financing agreements that we may enter into, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default under the Loan Agreement and any future financing agreements that we may enter into.

Further, the interest rate of the Term Loan issued under the Loan Agreement is based on the published prime rate, a floating rate, subject to a minimum rate set in the Loan Agreement. The Federal Reserve may maintain interest rates at relatively high levels, fail to decrease interest rates in line with market expectations or raise interest rates to combat the effects of inflation. An increase in the prime rate above the set minimum rate would increase our debt service obligations, which could have a negative impact on our cash flow, financial position or operating results, or result in increased borrowing costs in the future.

Risks related to the design and development of our product candidates

We are highly dependent on the success of our lead product candidate, EO-3021. We have not completed clinical development or obtained regulatory approval for any product candidate. We may never obtain approval for EO-3021 or any other product candidate.

Our future success is highly dependent on our ability to obtain regulatory approval for, and then successfully commercialize or identify a strategic partner to commercialize, our lead product candidate, EO-3021. We currently have no products that are approved for sale in any jurisdiction. Our product candidates may not achieve success in their clinical trials or obtain regulatory approval. If we do not obtain regulatory approval for our product candidates and successfully commercialize them in one or more indications or if we experience significant delays in doing so, we may never generate any revenue or become profitable.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our product candidates to the satisfaction of the FDA and other regulatory agencies;
- acceptance of an IND and a BLA by the FDA or other similar clinical trial applications by foreign regulatory authorities for clinical trials for our product candidates;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion or complementary diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities for our product candidates, including the completion of any required post-marketing studies or trials;
- raising additional funds necessary to complete the clinical development of and commercialization of our product candidates;
- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, and protecting and enforcing our rights in our intellectual property portfolio;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if approved, whether alone or in collaboration with third parties;
- acceptance of our products, if approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies available on the market or in development;
- obtaining and maintaining third-party payor coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of any products following regulatory approval.

Our ability to successfully complete clinical trials, obtain regulatory approvals and successfully market EO-3021 may also be affected by the timing and results of data of competitors conducting clinical trials evaluating candidates targeting Claudin 18.2, as well as by results from CSPC's ongoing clinical trial of SYSA 1801 (EO-3021) in China.

Many of these factors are beyond our control, and it is possible that none of our product candidates, including EO-3021, will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we experience significant delays or are otherwise unable to successfully commercialize our product candidates, it would materially harm our business.

Drug development is a lengthy and expensive process, and clinical testing is uncertain as to the outcome.

We have initiated a Phase 1 clinical trial of EO-3021 and preclinical studies of EO-1022, and the risk of failure is high for the development of EO-3021, EO-1022 and any of our future product candidates. We are unable to predict when or if our product candidates will prove effective and safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome.

A failure of one or more clinical trials can occur at any stage of testing. The outcomes of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials or of clinical trials of the same product candidates in other indications, and interim or preliminary results of a clinical trial do not necessarily predict final results. There is one approved therapy targeting Claudin 18.2 – a monoclonal antibody ("mAb") (zolbetuximab) to be used in combination with chemotherapy for the first-line treatment of advanced gastric/GEJ adenocarcinoma that is Claudin 18.2 positive – and our Claudin 18.2 ADC approach with EO-3021 may not result in a durable clinical outcome. There is one approved therapy targeting HER3 – a bispecific antibody (zenocutuzumab) – and our HER3 ADC approach with EO-1022 may not result in a durable clinical outcome. In addition, while some results in patients, such as observations of stable disease, may suggest encouraging clinical activity with respect to a product candidate, we expect that stable disease would not be considered to be a sufficient response for regulatory approval purposes. Furthermore, we may observe adverse safety events in later trials that were not observed in prior trials, which would alter the anticipated risk-benefit profile of a product candidate and reduce the likelihood that it receives regulatory approval.

The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. For example, in 2021, the Oncology Center of Excellence within the FDA advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other Oncology Center of Excellence initiatives have included Project FrontRunner, an initiative advanced in 2022 with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options, and Project Equity, an initiative advanced in 2021 to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflect the demographic representation of patients for whom the medical products are intended. More recently, as part of the Food and Drug Omnibus Reform Act ("FDORA"), sponsors will be required to submit Diversity Action Plans ("DAPs") for Phase 3 studies or other pivotal studies of new drugs. DAPs must include the sponsor's goals for enrollment for such studies, disaggregated by age group, sex, and racial and

ethnic demographic characteristics of clinically relevant study populations; the sponsor's rationale for such goals; and an explanation of how the sponsor intends to meet such goals. Actions taken by the new Presidential administration have created significant uncertainty as to whether Project Equity will continue and whether the statutory requirements related to DAPs will be implemented by FDA in the near future. We are considering these and other policy changes as they relate to our programs.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and/or commercialization of our product candidates.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly increase our product development costs. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our product candidates, including:

- regulators, institutional review boards ("IRBs"), or ethics committees ("ECs"), may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA may disagree as to the design or implementation of our clinical trials or with our recommended doses with respect to any of our current or future product candidates;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations ("CROs") and prospective trial sites;
- clinical trials for our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay or halt clinical trials or abandon product development programs;
- lack of adequate funding to continue clinical trials;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients who meet the trial criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- we may experience difficulties in maintaining contact with patients after treatment, resulting in incomplete data;
- we or third-party collaborators may fail to obtain regulatory approval of companion or complementary diagnostic tests, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for various reasons, including a finding by us or by a Data Monitoring Committee for a trial that the participants are being exposed to unacceptable health risks;
- our product candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate the trials;
- the cost of clinical trials may be greater than we anticipate;
- changes to clinical trial protocols; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial or obtain timely marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons, including safety concerns and noncompliance with regulatory requirements. If we are not able to complete successful clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which would limit our future revenues and harm our commercial prospects.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Enrolling patients for our clinical trials requires promptly identifying cancer patients, who in some cases may be required to meet specific biomarker expression cutoffs, and placing these patients in one of our qualified sites in a timely manner. We have implemented prospective Claudin 18.2 expression testing as part of the patient screening process in our ongoing Phase 1 clinical trial of EO-3021. We have relied, and may in the future rely, on several diagnostic partners to conduct initial testing to identify patients that are eligible for our clinical trials. If one or more of these partners encounters delays or is otherwise unable to conduct these tests and identify potential patients, enrollment in our clinical trials may be substantially delayed. In addition, these partners work with several other companies, including our competitors, and may divert resources to collaborations with these other companies, which may detrimentally affect enrollment in our clinical trials. Patient enrollment is also affected by other factors, including:

- the severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of testing mechanisms to screen patients and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing studies or trials with similar eligibility criteria;
- invasive procedures required to enroll patients and to obtain evidence of the product candidates' performance during clinical trials;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;

- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and maintain a sufficient number of patients for 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, which would cause the value of our company to decline, limit our ability to obtain additional financing and delay or limit our ability to obtain regulatory approval for our product candidates.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved product or result in significant negative consequences following marketing approval, if any.

Results of our planned clinical trials of EO-3021 and our other product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, clinical trials evaluating Claudin 18.2 ADCs, including those that use MMAE payloads, such as EO-3021, have reported adverse events of nausea, vomiting, neutropenia, peripheral neuropathy and ocular toxicity. Some patients in our ongoing Phase 1 clinical trial of EO-3021 have experienced keratitis as an adverse event, which has been monitorable with ophthalmic examination, manageable with prophylactic eye drops and dose modification, and reversible. Undesirable side effects could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development, a material percentage of patients in these clinical trials may die during a trial. If we elect to, or are required to, delay, suspend or terminate any clinical trial, whether due to a patient death or otherwise, the commercial prospects of EO-3021 or our other product candidates will be harmed and our ability to generate product revenues will be delayed or eliminated. Any serious adverse events observed in clinical trials could hinder or prevent market acceptance of our product candidates, which would harm our commercial prospects, our financial condition and our reputation.

Moreover, if any of our product candidates is associated with undesirable or unexpected side effects in clinical trials, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, even if it is approved. We may also be required to modify our trial plans based on findings in our clinical trials. Side effects could also affect patient recruitment or the ability of enrolled patients to complete a trial. Many drugs that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling or deny regulatory approval of the product candidate.

It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may decide to or be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a risk evaluation and mitigation strategy ("REMS"), or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- we may be subject to regulatory investigations and government enforcement actions;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Preliminary, topline and interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and is subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data or pre-specified interim analyses from our clinical trials. These updates will be based on an 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. Additionally, pre-specified interim analyses from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Therefore, positive preliminary or interim results in any ongoing clinical trial may not be predictive of such results in the completed study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, any topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Adverse changes between preliminary or 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. See the description of risks under the heading "Risks Related to our Common Stock" for more disclosure related to the risk of volatility in our stock price.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Third parties 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, product candidate or our business.

Additionally, planned clinical trials we conduct may be open-label trials in which both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Open-label clinical trials typically test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

If the preliminary or topline data or results of pre-specified interim analyses that we report differs from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed.

We have, and we may in the future, seek to engage in strategic transactions to acquire or in-license new products, product candidates or technologies, or partner or out-license our product candidates. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures, in-licensing of new products, product candidates or technologies, and partnering or out-licensing our product candidates, that we believe will complement or augment our existing business. For example, in July 2022, we entered into a license agreement pursuant to which CSPC granted us exclusive rights to develop and commercialize EO-3021 worldwide outside of Greater China. If we acquire additional assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including, but not limited to, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and could have a negative impact on the competitiveness of any product candidate that reaches market.

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 and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other future 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 products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may 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 that product candidate.

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

We expect to conduct one or more clinical trials outside the United States. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States is intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of these data alone unless the data is applicable to the U.S. population and U.S. medical practice, including availability of drugs as standard of care, and the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice ("GCP") regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many other regulatory authorities have similar approval requirements. In addition, such trials would be subject to the applicable local laws of the respective jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any comparable regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any comparable regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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.

Risks related to government regulation

The development and commercialization of biological products are subject to extensive regulation, and we may not obtain regulatory approvals for any of our product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety, and other post-marketing information and reports, and other possible activities relating to our product candidates, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Our product candidates must also be approved by comparable regulatory authorities in other jurisdictions prior to commercialization in those jurisdictions.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, there can be no assurance that any of our product candidates will receive regulatory approval in the United States, or other jurisdictions. Most applications for standard review biologic products are reviewed within 10 to 12 months; most applications for priority review biologics are reviewed in six to eight months. Priority review can be applied to biologics

that the FDA determines may offer significant improvement in safety or effectiveness compared to marketed products or where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. In addition, development programs that span many tumor types are relatively novel, and, to date, the FDA has approved only a handful of therapies to treat multiple tumor types based on a common biomarker. We cannot be sure that the FDA will accept our BLA for EO-3021 or our other product candidates. Further, depending upon the results of our planned clinical trials, we may choose to seek Subpart H accelerated approval for a product candidate, which would require completion of a confirmatory trial to validate its clinical benefit. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biologics industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials is susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA:

- may not deem our product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- determines in the case of a BLA seeking accelerated approval that the BLA does not provide evidence that the product candidate represents a meaningful advantage over available therapies for each tumor type;
- determines that the objective response rate ("ORR") and duration of response are not clinically meaningful;
- determines that a tissue agnostic indication is not appropriate, for example, because a consistent anti-tumor effect is not observed across multiple tumor types or the response is too heavily weighted on a specific tumor type;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or specifications;

- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;

- may change approval policies or adopt new regulations; or

- may not file a submission due to, among other reasons, the content or formatting of the submission.

We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidate, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired.

The accelerated approval pathway for any of our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that it will receive marketing approval.

Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon 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. We may seek accelerated approval for a product candidate on the basis of ORR with an acceptable duration of response, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. Whether the ORR we observe in our planned clinical trials will be adequate to support an accelerated approval for any of our product candidates will depend on a number of factors, including the response rate, the durability of the responses, the observed toxicity profile and prior therapies received. This analysis may be complicated by whether there is an available therapy against which to compare our product candidates for certain tumor types based on the patients we enroll.

For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy.

Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. Congress is also considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances. In addition, the Oncology Center of Excellence has announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance.

The enactment of FDORA included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and

requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Moreover, the FDA may withdraw approval of our product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the candidate;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Our failure to obtain marketing approval in jurisdictions outside the United States would prevent our product candidates from being marketed in those jurisdictions, and any approval we are granted for them in the United States would not assure approval in other jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market, which would impair our financial prospects.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

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

Orphan drug designation entitles a party to financial incentives, such as tax advantages and user fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

The FDA has granted orphan drug designation in the United States to EO-3021 for the treatment of gastric cancer (including cancer of gastroesophageal junction) and for the treatment of pancreatic cancer. We may apply for an additional orphan drug designation in the United States or other geographies for EO-3021, EO-1022 or our future product candidates. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. For instance, in the case of a request for orphan drug designation for a tumor agnostic indication, preliminary

findings of a product candidate's treatment effect that is not observed across multiple tumor types or that is too heavily weighted on a specific tumor type may not be sufficient for the FDA to grant a tumor agnostic orphan drug designation. Even if we obtain orphan drug designation for a product candidate in specific indications, we may not be the first to obtain regulatory approval of the product candidate for the orphan-designated indication, due to the uncertainties associated with developing biological products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan 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. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

A Breakthrough Therapy designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

We may seek a Breakthrough Therapy designation for EO-3021, EO-1022 or our future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if the product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process.

The FDA has granted Fast Track designation to EO-3021 for the treatment of patients with advanced or metastatic gastric and gastroesophageal junction cancer expressing Claudin 18.2 that has progressed on or after prior therapy. We may also seek Fast Track designation for EO-1022 or our future product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation for a particular product candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

If we are unable to successfully develop, validate, obtain regulatory approval of and commercialize companion or complementary diagnostic tests for product candidates that require or would benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

A companion diagnostic is a medical device, often an *in vitro* device, which provides information that is essential for the safe and effective use of a corresponding therapeutic drug or biologic product. A companion or complementary diagnostic can be used to identify patients who are most likely to benefit from the therapeutic product.

A companion or complementary diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, the FDA has generally required premarket approval of companion and complementary diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect. However, it is possible that the FDA may permit approval of the companion diagnostic as a post-marketing commitment following a potential regulatory approval.

Development of a companion or complementary diagnostic could include additional meetings with regulatory authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption application. In the case of a companion diagnostic that is designated as "significant risk device," approval of an investigational device exemption by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate.

To be successful in developing, validating, obtaining approval of and commercializing a companion or complementary diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion or complementary diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development, testing, validation and manufacture of companion or complementary diagnostic tests for our therapeutic product candidates that require such tests, the application for and receipt of any required regulatory approvals, and the commercial supply of these companion or complementary diagnostics. If these parties are unable to successfully develop companion or complementary diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials, and may prevent us from initiating a pivotal trial. In addition, the commercial success of any product candidate that requires a companion diagnostic will be tied to and dependent upon the receipt of required regulatory approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. Any failure to do so could materially harm our business, results of operations and financial condition.

Even if we obtain marketing approval for a product candidate, the terms of approvals, ongoing regulation of our products or other post-approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Any product candidates for which we receive accelerated approval from the FDA are required to undergo one or more confirmatory clinical trials. If such a product candidate fails to meet its safety and efficacy endpoints in such confirmatory clinical trials, the regulatory authority may withdraw its conditional approval. There is no assurance that any such product will successfully advance through its confirmatory clinical trial(s). Therefore, even if a product candidate receives accelerated approval from the FDA, such approval may be withdrawn at a later date.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product.

We must also comply with requirements concerning advertising and promotion for our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs or biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to current good manufacturing practices ("cGMPs"), which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturing organizations ("CMOs") will be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, even if we obtain marketing approval for a product candidate, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug and biologic products, including requirements pertaining to their marketing and promotion in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the FDC Act and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- HIPAA prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e.g. public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, protected health information, relating to the privacy, security, and transmission of such protected health information;
- the federal Physician Payments Sunshine Act's transparency requirements under the ACA requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists,

optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians, and their immediate family members. The reported information is made available on a public website; and

- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require biologics companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives. State and non-U.S. laws that also 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may face difficulties from healthcare legislative and regulatory reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, or affect pricing and third-party payment for our product candidates, which could negatively affect our business, financial condition and prospects. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. For example, in 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In 2024, CMS issued a final rule that decreased Medicare reimbursement for physician services by 2.8%, effective January 1, 2025. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies, including payment for companion or complementary diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. In addition, CMS bundles the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and CMS pays for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Further, in 2018, CMS finalized its National Coverage Determination (the "NCD"), for certain diagnostic laboratory tests using next generation sequencing that are approved by the FDA as a companion in vitro diagnostic and used in a cancer with an FDA-approved companion diagnostic indication. Under the NCD, diagnostic tests that gain FDA approval or clearance as an in vitro companion diagnostic will automatically receive full coverage and be available for patients with recurrent, metastatic relapsed, refractory or stages III and IV cancer. Additionally, the NCD extended coverage to repeat testing when the patient has a new primary diagnosis of cancer.

Over the past several years, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Presidential executive orders, 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, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this final rule was delayed by the Inflation Reduction Act (the "IRA") until January 2032. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap has, in some cases, required pharmaceutical manufacturers to pay more in rebates than they have received on the sale of products.

Additionally, several healthcare reform initiatives culminated in the enactment of the IRA in 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS 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 products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent, with an average price reduction of 59.4 percent. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, 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, 20 Part B or D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition are excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while the full economic impact of the IRA is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

At the state level, legislatures are increasingly enacting legislation and implementing 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. In addition, the FDA released a final rule in 2020 providing guidance for states to build and submit importation proposals for drugs from Canada, and the FDA authorized the first such plan in Florida in 2024. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. 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 companion or complementary diagnostics or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Further, in 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

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

In some countries, particularly the countries of the European Union (the "EU"), the pricing of prescription biological products is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of any of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for biological products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. In addition, the withdrawal of the United Kingdom (the "UK") from its membership in the EU, often referred to as "Brexit", has caused uncertainty in the current regulatory framework in Europe and could lead to the UK and EU adopting divergent laws and regulations, including those related to the pricing of prescription biological products, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription biological products, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the UK.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (the "FCPA"), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our third-party contractors are subject to numerous foreign, federal, state and local 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 operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, 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 in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

U.S. and other anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or

private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

There is substantial uncertainty regarding the new U.S. presidential administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.

FDA-regulated industries, such as ours, face substantial uncertainty with regard to the regulatory environment we will face as we proceed with research and development efforts and potentially commercialization efforts following the commencement of a new U.S. presidential administration in January 2025. Some of the new administration's initiatives have manifested in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates and obtain regulatory approvals. There remains general uncertainty regarding future activities by the new administration, which could include the issuance of executive orders, regulations, policies or guidance that adversely affect our business and operations or create a more challenging or costly environment to pursue the development of product candidates. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our business and operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance, there could be a material adverse effect on our business.

Risks related to our reliance on third parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform all of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we expect to be dependent on third parties to conduct our planned preclinical studies and clinical trials of our product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of third parties on whom we rely, to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other biological product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Manufacturing biological products is complex and subject to product loss for a variety of reasons. We rely on third parties to manufacture clinical supplies of our product candidates, some of which are based in China, and we intend to rely on third parties to produce commercial supplies of any approved product. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties, including manufacturers based in China, for the manufacture of our product candidates and future product candidates for clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if a product candidate obtains marketing approval. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates.

Subject to certain exceptions, we are required to acquire our clinical and commercial supply of EO-3021 primarily from CSPC in China. Further, we have entered into clinical supply agreements with Eli Lilly and Company and GSK to supply ramucirumab and dostarlimab, respectively, for combination cohorts in our ongoing Phase 1 clinical trial of EO-3021. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates, products or other supply, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

With rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs that result in increased costs as a result of international transportation of supplies, as well as the costs of materials and products imported into the United States, particularly if these measures occur in regions where we source our product candidates, components or raw materials, such as China. Tariffs, trade restrictions, sanctions, export controls or other restrictive actions imposed by the United States or other countries, including as a result of geopolitical tension, such as a deterioration in the relationship between the United States and China or escalation of ongoing regional military conflicts, could increase the prices of our and our partners' products and product candidates, affect our and our partners' ability to commercialize such products and product candidates, or create adverse tax consequences in the United States or other countries. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the United States. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs, trade restrictions, sanctions, export controls or other restrictive actions by the United States or other countries could materially adversely affect our results of operations and financial condition.

We may be unable to establish any agreements with third-party manufacturers or do so on favorable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing, and data generation to support regulatory applications;
- lack of qualified backup suppliers for those components or materials that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter or other enforcement action by FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

We acquire many key materials for the manufacture of our product candidates on a purchase order basis, and we may not have long-term committed arrangements with respect to any product candidate. We will need to establish one or more agreements with third parties in order to develop and scale up our drug manufacturing process, conduct drug testing and generate data to support one or more regulatory submissions. If we obtain marketing approval for a product candidate, we will need to establish an agreement for commercial manufacture with a third party.

We use a limited number of suppliers for key components of our manufacturing process. Even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our current supplier could result in delays and additional regulatory submissions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve a BLA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third-party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our third-party manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Further, if we make manufacturing or formulation changes to our product candidates or add or change CMOs in the future, the FDA or other regulatory authorities will require a demonstration of the comparability of the new product to the prior product, including potentially through a clinical bridging study.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our product candidates and any products that we may develop may compete with other future product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future CMOs could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substances. If our current CMOs for preclinical and clinical testing cannot perform as agreed, we may be required to replace such CMOs, and we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or we may not be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments or public health epidemics. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates on a select basis. We have not entered into any such collaborations to date. Our likely collaborators for any future collaboration arrangements include large and mid-size biologics companies, regional and national biologics companies and biotechnology companies. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;

- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

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

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

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and

- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described herein would also apply to the activities of any such future collaborators.

Risks related to commercialization of our product candidates

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each such product candidate if it is approved for sale for these indications, acceptance by the medical community, patient access, drug and any related companion or complementary diagnostic pricing and their reimbursement. The total addressable market opportunity for product candidates we may develop may depend upon commercially available next generation sequencing testing.

We may initially seek regulatory approval of our product candidates as therapies for relapsed or refractory patients. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

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

If our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of

acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the acceptance of our product candidates as front-line treatments for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the size of the target patient population;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;
- publicity for our product candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue.

We have never commercialized a product candidate and we currently have no sales or marketing infrastructure and have no experience in the sale, marketing or distribution of biological products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidate and undertaking preclinical studies and clinical trials of our product candidate. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- unfavorable third-party payor coverage and reimbursement in any geography;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Furthermore, developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidate. We may not be able to build an effective sales and marketing organization in the United States, the EU 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 candidate, we may have difficulties generating revenue from them.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidate for which we receive marketing approval.

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 biological products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biologics companies, specialty biologics companies and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide.

There are a number of biological and biotechnology companies that currently are pursuing the development of selective cancer therapies for patients with significant unmet medical needs. In particular, we expect that EO-3021 will compete against other ADCs targeting Claudin 18.2. Several such candidates are currently in clinical development, including those of Antengene, AstraZeneca, Chia Tai Tianqing Pharmaceutical, Evopoint Biosciences, Innovent Biologics, LaNova Medicines, Merck KGaA/Jiangsu Hengrui, RemeGen, Shanghai Junshi Bioscience, Sichuan Kelun-Biotech Biopharmaceutical, SystImmune and TORL Biotherapeutics. We may face further competition from companies pursuing the development of product candidates that target Claudin 18.2 through other modalities. For example, Astellas Pharma has received regulatory approval for a mAb (zolbetuximab) to be used in combination with chemotherapy for the first-line treatment of advanced gastric/GEJ adenocarcinoma that is Claudin 18.2 positive. Additional companies developing product candidates that target Claudin 18.2 include Beijing Mabworks Biotech, CARsgen Therapeutics, Flame Biosciences, FutureGen Biopharmaceutical, Jiangsu Aosaikang Pharmaceutical, Legend Biotech, NovaRock Biotherapeutics, Shanghai Longyao Biotechnology, Transcenta Holding, Triumvira Immunologics, Zai Lab and others. Development efforts with respect to, and clinical trial results of, these potentially competitive product candidates may be unsuccessful, which could result in a negative perception of product candidates targeting Claudin 18.2 in general, which could in turn negatively impact the regulatory approval process for EO-3021.

We expect that EO-1022 will compete against other ADCs targeting HER3.Several such candidates are currently in clinical development, including those of Alphamab Oncology, Daiichi Sankyo/Merck, Duality Biologics, Innovent Biologics, Jiangsu Hengrui, MediLink Therapeutics (Suzhou)/BioNTech, Multitude Therapeutics, Shanghai Institute of Biological Products and SystImmune/Bristol Myers Squibb. We may face further competition from companies pursuing the development of product candidates that target HER3 through other modalities. For example, Merus has received regulatory approval for a bispecific antibody (zenocutuzumab) targeting HER2 and HER3. Additional companies developing product candidates that target HER3 include Hummingbird Bioscience, ISU Abxis, Shanghai Institute of Biologic Products, SystImmune and others. Development efforts with respect to, and clinical trial results of, these potentially competitive product candidates may be unsuccessful, which could result in a negative perception of product candidates targeting HER3 in general, which could in turn negatively impact the regulatory approval process for EO-1022.

Many of the companies against which we are competing or against which we may compete in the future, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products 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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, our product candidates may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as product candidates progress through clinical development.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable labeling than our product candidates. Our competitors also may obtain FDA, foreign regulatory authority, or other marketing or regulatory approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, thereby limiting our potential for commercial success.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. 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 our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, which decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, we may develop, either by ourselves or with collaborators, companion or complementary diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. While we have not yet developed any companion or complementary diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons that are applicable to our product candidates.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, 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.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully

defend ourselves against any claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us could decrease our cash and adversely affect our business and financial condition.

Risks related to employee matters and our operations

We expect to significantly expand our development and regulatory capabilities as we grow our company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, late-stage regulatory affairs, finance, accounting, business operations, public company compliance, communications and other corporate development functions, and, if any of our product candidates receives marketing approval, sales, marketing and distribution. If we acquire additional product candidates or enter into future collaborations, we may need to expand our employee base beyond our current projections, which may include further preclinical research and development or later-stage regulatory operations. To manage our potential growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Further, rapid expansion of our workforce while remaining a virtual company may have a detrimental impact on employee morale and cohesion.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacturing of our product candidates. We cannot assure you that the services of such third-party contract 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 our vendors or consultants 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 our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, we may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the development and management expertise of the principal members of our management, scientific and clinical teams. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and manufacturing strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified finance and accounting personnel will also be critical to our success. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated.

Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are a virtual company and our business depends on the efficient and uninterrupted operation of our information technology systems and those of our third-party CROs, CMOs, or other vendors, contractors or consultants, may fail or suffer security breaches, cyberattacks, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are a virtual company, our business success depends on the security and efficient and uninterrupted operation of our information technology systems, and we may be unable to adequately protect our information technology systems from cyberattacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information, personal health information and sensitive personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, CMOs, vendors, and other contractors and consultants who have access to our confidential information. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, CMOs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third-party service providers, natural disasters, terrorism, war, global pandemics, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, third-party CROs, CMOs, vendors, contractors, consultants, business partners and/or other third parties, or from cyberattacks or supply chain attacks by malicious third parties (including the deployment of harmful malware, ransomware, 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 our system infrastructure, or that of our third-party CROs, CMOs, vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Remote work arrangements generally increase the attack surface available for exploitation, and the risk of a cybersecurity incident occurring, and our investment in risk mitigations against such an incident is generally increasing. For example, there has been an increase in phishing and spam email attacks as well as social engineering attempts from "hackers" hoping to use remote work arrangements to their advantage. We may not be able to anticipate all types of security threats, nor implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Any breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under HIPAA, and other relevant state and federal privacy laws in the United States. If the information technology systems of our third-party CROs, CMOs, vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or security breaches could result in

the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and sensitive personal information), which could result in financial, legal, business and reputational harm to us.

A security breach may cause us to breach customer contracts. Our agreements with certain customers may require us to use industry-standard or reasonable measures to safeguard sensitive personal information or confidential information. A security breach could lead to claims by our customers, their end users, or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with our customers, our customers' end users, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our solutions and/or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our partners, our customers or our customers' end users was disrupted, we could incur significant liability, or our platform, systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We may not have adequate insurance coverage with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. Even claims that ultimately are unsuccessful could result in our expenditure of funds in litigation, divert management's time and other resources, and harm our reputation. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to a cybersecurity breach and related business and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, insurance will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements.

We are subject to stringent and changing laws, regulations, rules, policies, standards, and contractual obligations related to privacy and data security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and other data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The regulatory framework for privacy, data security and data transfers worldwide is rapidly evolving and there has been an increasing focus on privacy and data protection issues with the potential to affect our business and as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. Failure to comply with any of these laws and regulations could result in enforcement actions against us, including fines, public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, data breach notification laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH and other laws. Depending on the facts and circumstances, we could be subject to penalties if we obtain, use, or disclose personal health information maintained by a

HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Additionally, the SEC and many jurisdictions have enacted or may enact laws and regulations requiring companies to disclose or otherwise provide notifications regarding data security breaches. For example, the SEC adopted cybersecurity risk management and disclosure rules, which require the disclosure of information pertaining to cybersecurity incidents and cybersecurity risk management, strategy and governance. In addition, a comprehensive federal privacy bill, which includes a private right of action for violations, has been proposed and is under review by the House of Representatives.

In addition, the state of California enacted the CCPA, which imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA could increase compliance costs and potential liability. In addition, CPRA, which went into effect in 2023, imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that is vested with authority to implement and enforce the CCPA and CPRA. Virginia's Consumer Data Protection Act, which took effect in 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. In addition, Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect in 2023, and Utah enacted the Consumer Privacy Act, which became effective in 2023, and each of these laws may increase the complexity, variation in requirements, restrictions and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, or proposed, or are considering proposing, data privacy laws, which could further complicate compliance efforts, increase our potential liability and adversely affect our business. Additionally, laws, regulations, rules and standards in many foreign jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information, which may impose significant compliance obligations on us. For example, in the EU, the processing of personal data, is governed by the provisions of the General Data Protection Regulation (the "GDPR").

In 2018, the GDPR took effect in the European Economic Area (the "EEA"). The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of natural persons. Among other things, the GDPR imposes strict obligations on the ability to process health-related and other personal data of data subjects in the EEA, including in relation to use, collection, analysis and transfer (including cross-border transfers) of such personal data. The GDPR includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators. The GDPR also includes certain requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, as well as requirements for establishing a lawful basis on which personal data can be processed. In addition, the GDPR increases the scrutiny of cross-border transfers of personal data from clinical trial sites located in the EEA to the other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). Notably, the United States is one such country, although the EU-U.S. Data Privacy Framework ("DPF") has been recognized as adequate under EU law to allow transfers of personal data from the EU (as well as the United Kingdom and Switzerland) to certified companies in the United States. However, the DPF is likely to face legal challenge at the Court of Justice of the European Union which could cause the legal requirements for personal data transfers from the Europe to the United States to become uncertain once again. We will monitor these legal developments and continue to use best practices to follow established European legal standards to conduct cross-border transfer of personal data. Additionally, following the withdrawal by the UK from the EU and the EEA, companies must comply with both the GDPR and the UK GDPR as incorporated into UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. Further, recent legal developments in Europe and the UK have created complexity and compliance uncertainty regarding certain transfers of information from the UK and EEA to the United States. For example, in 2020, the Court of Justice of the EU (the "CJEU"), declared the EU-U.S. Privacy Shield framework (the "Privacy Shield") to be invalid. As a result, Privacy Shield is no longer a valid mechanism for transferring personal data from the EEA to the United States. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature, which seems possible given the rationale behind the CJEU's concerns about U.S. law and practice on government surveillance. The UK GDPR and EU GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

We also may make public statements about our use and disclosure of personal information through our privacy policy and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our policies, certifications, and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our solutions and services and could materially and adversely affect our business, results of operations, financial condition, cash flows and prospects.

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

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, public health epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

Operating as a virtual company, our employees conduct business outside of any leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act (the "TCJA") enacted many significant changes to U.S. tax laws. It is uncertain if and to what extent various states will conform to the TCJA, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax

assets relating to our operations, the taxation of foreign earnings or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under the TCJA, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses may be limited to 80% of current year taxable income (without regard to certain deductions). It is uncertain if and to what extent various states will conform to the TCJA or the CARES Act.

In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Risks related to intellectual property

If we or our licensors are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates may be adversely affected.

Our success depends in large part on our ability and our licensors' ability to protect our proprietary technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the compositions of matter of our product candidates, their methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdictions. It is also possible that we will fail to identify patentable aspects of our product candidates before it is too late to obtain patent protection. Moreover, depending on the terms of any license agreements to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. For example, CSPC has the sole right to control the preparation, filing, prosecution and maintenance of all patents and patent applications within the licensed patents and any jointly owned foreground intellectual property under the CSPC License Agreement.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and

Trademark Office (the "USPTO"), and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our product candidates. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CMOs, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our product candidates or technology, we may not be able to obtain our own patent rights to those product candidates or technology.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of other countries may not protect our rights to

the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic versions or "follow-on" versions of any approved products by submitting NDAs or abbreviated NDAs under Section 505(b)(2) of the FDC Act, respectively, to the FDA during which they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, future patents may be subject to a reservation of rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U.S. government, the government could have certain rights in any resulting patents and technology, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, 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 government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions became effective on March 16, 2013. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our potential collaboration partners' patent applications and the enforcement or defense of our or our future collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time-consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is non-infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable.

In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our product candidates in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our product candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

We and our licensors may not be able to effectively protect or enforce our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents with respect to our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of other countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with our products in such territories and in jurisdictions where we do not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not view favorably the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property and proprietary rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property and proprietary rights in such countries may be inadequate.

If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time-consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other proprietary rights are found to cover our product candidates or any related companion or complementary diagnostics or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

There is a substantial amount of intellectual property litigation in the biotechnology and biological product industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The biological product and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or biologics companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. In addition, we have entered into in the past, and may enter into in the future, sponsored research agreements relating to our product candidates with various academic institutions. Some of these academic institutions may not have intellectual property assignments or similar agreements with their employees and consultants, which may result in claims by or against us related to ownership of any intellectual property. Accordingly, we may be forced to bring claims against third parties or defend claims that they may bring against us to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties, which could require us to obtain a license to such rights. Such a license may not be available on commercially reasonable terms, if at all.

We have entered into agreements with third parties to conduct clinical testing of our product candidates, which provide that improvements to our product candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

We or any of our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or any of our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or any of our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or any of our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The term of our patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, our wholly-owned patent portfolio includes a patent family with claims directed to antibodies and related compositions covering seribantumab, as well as methods of treating cancer using such antibodies and compositions. The family contains three U.S. patents directed to seribantumab which expire in February 2028 and a fourth U.S. patent which expires in October 2029 (including 614 days of Patent Term Adjustment), subject to any disclaimers or extensions. The family also contains a pending U.S. application, which if issued, would expire in February 2028, subject to any disclaimers or extensions. In addition, the above-discussed patent family includes granted patents in China, Europe, Hong Kong, Israel, and Japan with claims directed to compositions of matter covering seribantumab and related methods of therapy. These patents expire in February 2028, subject to any disclaimers or extensions. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for seribantumab, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost to the regulatory review process during which the sponsor was unable to commercially market its new product. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug is eligible for the extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. We may rely on our licensors, such as CSPC, to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any

licensed patents and patent applications. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. We seek to protect our trade secrets and proprietary know-how in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, CMOs, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent 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 other third party, our business, financial condition, results of operations and prospects could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our and our licensors' intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products similar to any product candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future;

- we, or any licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;

- we, or any licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;

- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our common stock

The market price of our common stock is likely to continue to be highly volatile, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the price initially paid for the stock. The market price for our common stock may be influenced by many factors, including the other risks described in this filing and the following:

- our ability to continue as a going concern;

- enrollment or results of clinical trials of our product candidates, or those of our competitors, licensors or collaborators, or changes in the development status of our product candidates;

- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;

- the success of competitive products or technologies;

- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;

- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;

- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;

- the success of our efforts to acquire or in-license additional technologies, products or product candidates;

- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;

- market conditions in the biologics and biotechnology sectors;

- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;

- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;

- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- political instability, including the prospect or occurrence of a federal government shutdown;
- natural disasters and other calamities; and
- general economic, market and geopolitical conditions, including fluctuating interest rates, potential tariffs, market volatility and inflation, and the impact of geopolitical tensions with China and ongoing regional military conflicts.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. 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.

In the past, securities class action litigation has often been brought against public companies following declines in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

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, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. The holders of a significant portion of our outstanding common stock have rights, subject to some 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 our stockholders.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock, even if our business is doing well.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in June 2023, we closed an underwritten public offering of (i) 17,810,000 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 4,440,000 shares of common stock and (ii) accompanying warrants to purchase one share of common stock for each share of common stock or pre-funded warrant sold. As of December 31, 2024, all of the pre-funded warrants have been exercised and common warrants for 200,000 shares have been exercised. This public offering and subsequent transactions may have an additional impact on the price of our common stock. Additionally, in 2024, we sold 11,625,295 shares of our common stock pursuant to the 2022 Sales Agreement with Cowen under our then-at-the-market offering facility. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

Based on the beneficial ownership of our common stock as of December 31, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially hold a substantial percentage of our outstanding voting stock. As a result, these stockholders, if acting together, have significant control over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" or "smaller reporting companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an "emerging growth company," we are only required to provide two years of audited financial statements.

We could be an "emerging growth company" until December 31, 2026, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an "emerging growth company" as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an "emerging growth company" immediately. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, if our revenues remain less than $100.0 million, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our

common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

There is no public market for our purchase warrants.

There is no public trading market for the purchase warrants we issued in June 2023, and we do not expect a market to develop. In addition, we do not intend to apply to list the purchase warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Global Select Market. Without an active market, the liquidity of the purchase warrants will be limited.

Additionally, each holder of a purchase warrant will not be entitled to exercise any portion of any purchase warrant which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the purchase warrant, as applicable, unless such percentage is increased upon at least 61 days' prior notice.

Anti-takeover provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management and, therefore, decrease the trading price of our common stock.

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our Board of Directors (the "Board") or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified Board so that not all members of our Board are elected at one time;
- permit only the Board to establish the number of directors and fill vacancies on the Board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our Board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

- prohibit cumulative voting; and

- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law (the "DGCL"), may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Any provision of our 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.

The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may result in increased costs for investors to bring a claim. Further, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America, to the fullest extent permitted by law, shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act("Federal Forum Provision"). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court.

Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and

other employees. If a court were to find either exclusive-forum provision in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting, compliance and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an "emerging growth company," we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Select Market.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

The price of our common stock does not meet the requirements for continued listing on the Nasdaq Global Select Market. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

In September 2024, we received notice from the Listing Qualifications staff of the Nasdaq Stock Market LLC that the price of our common stock does not meet the requirements for continued listing on the Nasdaq Global Select Market. If

we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of the Nasdaq Global Select Market require, among other things, that the minimum bid price of a listed company's stock be at or above $1.00. If the closing minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. We cannot provide any guarantee that we will regain compliance during the grace period or be able to maintain compliance with Nasdaq's listing requirements in the future. If we are not able to regain compliance during the grace period, or any extension of the grace period for which we may be eligible, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

General risk factors

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

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 have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. However, 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 will be met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make required related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

Failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting and the market price of our common stock could decline.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Select Market. Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control

over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an EGC. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective.

In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Furthermore, in connection with the future attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stockholders could lose confidence in our reporting and the market price of our common stock could decline. In addition, we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities.

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

The market price of our common stock may be volatile. The stock market in general, and pharmaceutical and biologics companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. 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 and other types of litigation in the future. Securities litigation against us and other litigation proceedings could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of all our stakeholders and especially preventing any breach, loss or compromise of clinical trial participant personal data. We are a virtual company, and our business depends on the efficient and uninterrupted operation of our information technology systems and those of our third-party CROs, CMOs and other vendors, contractors and consultants. Our Board is actively involved in oversight of our risk management program, and cybersecurity represents an important component of our overall approach to enterprise risk management ("ERM"). Our cybersecurity policies, standards, processes and practices are fully integrated into our ERM program and are based on recognized frameworks established by the Center for Internet Security Controls Framework and other applicable industry standards, with quarterly review and adjustment of safeguards for continuous improvement. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of our overall ERM approach, our cybersecurity program is focused on the following key areas:

- ***Governance:*** As discussed in further detail under "Governance" below, our Board's oversight of cybersecurity risk management is supported by our audit committee, which regularly interacts with our ERM function, our head of information technology and members of management.

- ***Collaborative Approach:*** We have implemented a comprehensive, cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

- ***Technical Safeguards:*** We deploy technical safeguards that are designed to protect our information systems from cybersecurity threats, including multifactor authentication, mobile device management, email filtering, firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

- ***Incident Response and Recovery Planning:*** We have established and maintain comprehensive incident response and recovery plans to address our response to a cybersecurity incident, and such plans are tested and evaluated on a regular basis. This includes continuous security operations center monitoring of our systems and accounts. Furthermore, we maintain cyber liability insurance as an additional safeguard against a potential loss due to a cybersecurity incident.

- ***Third-Party Risk Management:*** We maintain a comprehensive, risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

- ***Education and Awareness:*** We provide regular, mandatory training for personnel regarding cybersecurity threats as a means to equip our employees with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices. We also perform regular phishing campaigns among our employees and provide convenient solutions for our employees to report suspicious messages.

We engage in the periodic assessment and testing of our policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, such as vulnerability management of both virtual network and physical laptops, regular security operations center reviews, regular Center for Internet Security scorecard reviews, user account audits of both employees and third parties and information technology general controls reviews. We also engage third parties to perform assessments on our cybersecurity measures to enable continuous improvement and adherence to best practices. The results of such assessments, audits and reviews are reported to the Audit Committee, and we adjust our cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

Governance

Our Board, in coordination with our audit committee, oversees our risk management process. The audit committee receives regular presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, the threat environment, technological trends and information security considerations arising with respect to our peers and third parties. The Board and the audit committee will also receive prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been resolved. The audit committee regularly discusses our approach to cybersecurity risk management with our management team.

Our information technology personnel, in coordination with our management team, work collaboratively across the Company to implement a program designed to protect our information systems from cybersecurity threats and to promptly

respond to any cybersecurity incidents in accordance with our incident response and recovery plans. Through ongoing communications with our entire employee basis and appropriate third party contractors, our head of information technology and management monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time, and will report such threats and incidents to the Audit Committee when appropriate.

Our head of information technology has over a decade of information technology experience in the biopharmaceutical industry and oversees our cybersecurity program. He has experience developing and leading cybersecurity programs, including evaluating and implementing tools and technologies that enable defense and response capabilities, and developing critical cybersecurity procedures and training and awareness programs.

Although we are subject to ongoing and evolving cybersecurity threats, we are not aware of any material cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to affect us, including our business strategy, results of operations or financial condition.

Item 2. Properties

Not applicable.

Item 3. Legal Proceedings

At each reporting date, we evaluate whether or not a potential loss amount or a potential range of losses is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. We expense as incurred the costs related to such legal proceedings. We are not a party to any material legal matters or claims and did not have contingency reserves established for any litigation liabilities as of December 31, 2024.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock trades under the symbol "ELEV" on The Nasdaq Stock Market and has been publicly traded since June 25, 2021. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 28, 2025, there were approximately 9 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available fund and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board and will depend on our financial condition, operation results, capital requirements, general business conditions and other factors that the Board may deem relevant.

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs. We are leveraging our antibody-drug conjugate ("ADC") expertise to advance a novel pipeline, initially targeting two validated targets in oncology, Claudin 18.2 and HER3.

Our Lead Product Candidate: EO-3021

Our lead product candidate, EO-3021 (also known as SYSA1801 or CPO102), is an ADC comprised of a fully human anti-Claudin 18.2 immunoglobulin G1 ("IgG1") monoclonal antibody ("mAb") site-specifically conjugated with a cleavable linker to the cytotoxic monomethyl auristatin E ("MMAE") payload. Claudin 18.2 is overexpressed in several types of cancers, including gastric, esophageal, pancreatic, ovarian and lung. EO-3021 is currently being evaluated in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab, a PD-1 inhibitor, and ramucirumab, a VEGFR2 inhibitor, in patients with advanced, unresectable or metastatic gastric/gastroesophageal junction ("GEJ") solid tumors.

In August 2024, we reported promising initial monotherapy data from the dose escalation portion of our ongoing Phase 1 clinical trial of EO-3021. This data demonstrated competitive efficacy, with a 42.8% confirmed objective response rate ("ORR") in a biomarker-enriched population, and a differentiated safety profile, including minimal hematological toxicity and hepatotoxicity, and no peripheral neuropathy/hypoesthesia. We expect to report additional monotherapy safety and efficacy data from the dose escalation and expansion portions of the clinical trial in the second quarter of 2025.

Based on the initial clinical data, we are focusing the clinical development of EO-3021 on the first- and second-line treatment of advanced gastric/GEJ cancer, where EO-3021's key attributes can potentially provide differentiated benefits and address unmet needs in both patient outcomes and safety. In December 2024, we announced preclinical proof-of-concept data indicating the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors. We expect to report initial data from the combination cohorts of the clinical trial in the fourth quarter of 2025 or the first quarter of 2026.

We have an active Investigational New Drug ("IND") application for EO-3021 with the U.S. Food and Drug Administration (the "FDA"). EO-3021 was granted orphan drug designation by the FDA for the treatment of gastric cancer (including GEJ cancer) in November 2020 and for the treatment of pancreatic cancer in May 2021. Additionally, in September 2024, EO-3021 was granted Fast Track designation by the FDA for the treatment of patients with advanced or metastatic gastric/GEJ cancer expressing Claudin 18.2 that has progressed on or after prior therapy.

In July 2022, we entered into a license agreement with a subsidiary of CSPC Pharmaceutical Group Limited (collectively with its affiliates, "CSPC") to develop and commercialize EO-3021 outside Greater China (the People's Republic of China, Hong Kong, Macau and Taiwan) (the "CSPC License Agreement"). Pursuant to the terms of the CSPC License Agreement, we paid to CSPC a one-time, upfront payment of $27.0 million. CSPC will also be eligible to receive up to $148.0 million in potential development and regulatory milestone payments and up to $1.0 billion in potential commercial milestone payments plus royalties on net sales.

Monotherapy Data from our Ongoing Phase 1 Clinical Trial

In August 2024, we reported initial monotherapy data from the dose escalation portion of our ongoing Phase 1 clinical trial of EO-3021. As of the data cutoff date of June 10, 2024, 32 patients had been treated in the dose escalation portion

of the trial at four dose levels (ranging from 1.0 mg/kg to 2.9 mg/kg administered intravenously ("IV") every three weeks ("Q3W")), including 26 patients with gastric/GEJ cancer. The median age was 65 years (ranging from 45 to 83) and the median number of prior lines of therapy was three (ranging from one to seven).

Initial safety data were as follows:

- As of the data cutoff date of June 10, 2024, EO-3021 was observed to be generally well-tolerated. No Grade 4 or 5 treatment-related adverse events were reported, and less than 10% of patients discontinued EO-3021 due to adverse events. No neutropenia or peripheral neuropathy/hypoesthesia, both known toxicities associated with MMAE, were observed in the safety population of 32 patients treated with EO-3021.Across all grades, the most common treatment-emergent adverse events (reported in ≥20% of patients) were nausea (56%), decreased appetite (47%), fatigue (41%) and diarrhea (28%). Four dose-limiting toxicities (one each of Grade 3 fatigue, encephalopathy, worsening decreased appetite, and Grade 2 decreased appetite requiring a dose reduction at Cycle 2) were observed at the 2.9 mg/kg dose level, leading to the decision to select the 2.0 mg/kg and 2.5 mg/kg Q3W doses for evaluation in the dose expansion portion of the Phase 1 trial.

Initial efficacy data in gastric/GEJ cancer were as follows:

- As of the data cutoff date of June 10, 2024, 15 patients with gastric/GEJ cancer were evaluable for efficacy with measurable disease, at least one post-baseline scan, and available Claudin 18.2 immunohistochemistry ("IHC") results. Seven of these 15 patients (47%) had tumors with Claudin 18.2 expression in ≥20% of tumor cells at IHC 2+/3+. Claudin 18.2 expression was determined retrospectively using a Claudin 18.2-specific IHC assay.

- In seven patients with Claudin 18.2 in ≥20% of tumor cells at IHC 2+/3+, the ORR was 42.8% (three confirmed partial responses, one of which was confirmed following the June 10, 2024, data cutoff) and the disease control rate ("DCR") was 71.4%, including two patients with stable disease ("SD").

- In eight patients with Claudin 18.2 in <20% of tumor cells at IHC 2+/3+, the ORR was 0% and the DCR was 50%, including four patients with SD.

Preclinical Data Indicating Combination Potential

In December 2024, we announced preclinical proof-of-concept data indicating the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors. The *in vivo* data from preclinical studies evaluating the anti-tumor activity of EO-3021 with a VEGFR2 or PD-1 inhibitor showed:

- treatment with EO-3021 and DC101, a surrogate of the VEGFR2 inhibitor ramucirumab, exhibited statistically superior tumor growth inhibition ("TGI") compared to treatment with either EO-3021 or DC101 alone (TGI: 88.2% for EO-3021 in combination with DC101, compared to 20.1% for EO-3021 and 59.2% for DC101 alone); and

- treatment with EO-3021 and a PD-1 inhibitor exhibited statistically superior TGI compared to treatment with either EO-3021 or a PD-1 inhibitor alone (TGI: 79.9% for EO-3021 in combination with a PD-1 inhibitor, compared to 33.8% for EO-3021 and 25.0% for a PD-1 inhibitor alone). 92% (11/12) of mice treated with the combination of EO-3021 and a PD-1 inhibitor achieved a complete response ("CR"), compared to 50% (6/12) of mice treated with EO-3021 monotherapy and 17% (2/12) of mice treated with a PD-1 inhibitor alone.

Clinical Development Plan

We have an active IND for EO-3021 with the FDA, and we are evaluating EO-3021 in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab, a PD-1 inhibitor, and ramucirumab, a VEGFR2 inhibitor, in patients with advanced, unresectable or metastatic gastric/GEJ solid tumors. We believe our initial monotherapy data suggested the potential for competitive efficacy and a differentiated safety profile, including minimal hematological toxicity and hepatotoxicity, and no peripheral neuropathy/hypoesthesia.

Based on these data, we are focusing the clinical development of EO-3021 on the first- and second-line treatment of advanced gastric/GEJ cancer, where EO-3021's key attributes can potentially provide differentiated benefits and address unmet needs in both patient outcomes and safety.

In the monotherapy dose escalation part of our Phase 1 trial, we enrolled patients in increasing dose levels, including 1.0, 2.0, 2.5 and 2.9 mg/kg IV Q3W. The primary objective in dose escalation was to evaluate the safety and tolerability of EO-3021. In the ongoing dose expansion part of our Phase 1 trial, we are exploring two doses of EO-3021: 2.0 mg/kg IV Q3W and 2.5 mg/kg IV Q3W. These doses were selected with the goal of further characterizing EO-3021 in order to select an optimized dose for further clinical development. The primary objective in dose expansion is to evaluate preliminary anti-tumor activity of EO-3021. We have implemented prospective Claudin 18.2 expression testing as part of the patient screening process in the dose expansion portion of the Phase 1 trial, focusing enrollment on patients with a minimum of 25% of tumor cells at IHC 1+/2+/3+.

Patient dosing is ongoing in the combination portion of our Phase 1 trial. The combination cohorts are evaluating EO-3021 in combination with dostarlimab in the first-line setting and with ramucirumab in the second-line setting. By combining EO-3021 and dostarlimab, an immune checkpoint inhibitor, we aim to deliver synergistic benefit, potentially offering patients improved outcomes beyond those seen with the existing combination of immunotherapy and chemotherapy. The combination of an immunotherapy and chemotherapy agent is the standard of care for the treatment of gastric/GEJ cancer in the front-line setting. With the EO-3021 and ramucirumab combination, we aim to deliver improved tolerability and synergistic anti-tumor activity compared to the approved combination of ramucirumab and paclitaxel. The combination of ramucirumab and paclitaxel is the standard of care for the treatment of second-line gastric/GEJ cancer.

Our Second Product Candidate: EO-1022

We are developing EO-1022, a potentially differentiated HER3 ADC for the treatment of patients with HER3-expressing solid tumors, including breast cancer and non-small cell lung cancer. EO-1022 combines seribantumab, a fully human immunoglobulin G2 ("IgG2") anti-HER3 mAb, and an MMAE payload with glycan site-specific conjugation. It is designed to leverage seribantumab's desirable HER3 internalization properties and the latest site-specific ADC technology to treat patients living with solid tumors that express HER3.

In April 2024, we announced preclinical proof-of-concept data for our HER3 ADC program using a non-site-specific conjugated seribantumab ADC with an MMAE payload (HER3-ADC1). The *in vitro* and *in vivo* data from preclinical studies showed:

- HER3-ADC1 binding to cancer cells, endocytosis, MMAE release and inhibition of proliferation were dependent on HER3 expression;
- in cytotoxicity assays, HER3-ADC1 displayed HER3-dependent cell killing and outperformed a benchmark HER3 ADC with a deruxtecan payload, which is currently in clinical development; and
- in a patient-derived xenograft (PDX) model of pancreatic cancer with high HER3 expression, HER3-ADC1 induced tumor regression, whereas an isotype-MMAE control and a benchmark HER3 ADC with a deruxtecan payload had only a modest effect.

In September 2024, we entered into a license agreement with Synaffix B.V. ("Synaffix"), giving us global access to Syanffix's clinical stage, site-specific ADC technology platform, which we are using to develop EO-1022. If we successfully develop and commercialize EO-1022, we would potentially be obligated to pay Synaffix up to $365.5 million in development, regulatory and commercial milestones and tiered royalties in the low to mid-single digit percentages on net sales.

We expect to present preclinical data for EO-1022 in the second quarter of 2025 and to file an IND application for EO-1022 in 2026.

Financial Overview

Since inception, we have incurred significant operating losses annually. We have devoted substantial resources to in-licensing and developing EO-3021, developing EO-1022, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $44.5 million and $45.7 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $240.5 million. These losses have resulted primarily from costs incurred in connection with research and development activities, acquisition, patent investment, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We believe our cash, cash equivalents and marketable securities of $93.2 million as of December 31, 2024 will enable us to meet our anticipated capital requirements into 2026. Based on current operating plans, we do not expect that this amount will meet our anticipated capital requirements over the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will need to raise additional capital in the future to continue developing the drugs in our pipeline and to commercialize any approved drug. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan.

At-the-Market Offerings

During the year ended December 31, 2024, we sold 11,625,295 shares of common stock pursuant to our Sales Agreement entered into in July 2022 (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen") under our then-at-the-market offering facility (the "2022 ATM Facility"), with net proceeds of approximately $44.2 million after deducting issuance costs.

In May 2024, we entered into a sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC ("TD Cowen"), under which we may offer and sell, from time to time, shares of common stock having aggregate gross proceeds of up to $75.0 million (the "2024 ATM Shares") at market prices (the "2024 ATM Facility"). We will pay TD Cowen a commission of up to 3% of the gross proceeds of any sales of the 2024 ATM Shares pursuant to the 2024 Sales Agreement. As of December 31, 2024, we have not sold any 2024 ATM Shares pursuant to the 2024 Sales Agreement.

Financing Agreements

In July 2022, we entered into a loan and security agreement (as amended, the "Loan Agreement") with K2 HealthVentures LLC (together with its affiliates, "K2HV", and together with any other lender from time to time party thereto, the "Lenders"), as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $50.0 million principal in term loans (the "Term Loan") consisting of a first tranche of $30.0 million funded at closing and a subsequent second tranche of up to $20.0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders.

In March 2024, we entered into an amendment to the Loan Agreement with K2HV (the "Loan Agreement Amendment"), pursuant to which: (i) the amortization date of the Term Loan provided under the Loan Agreement was amended from March 1, 2025 to June 1, 2026; (ii) we issued to K2HV an additional warrant to purchase shares of common stock (the "Amendment Warrant"); (iii) upon the Lenders' election to convert any portion of the principal amount of the Term Loan then outstanding, up to $3.25 million in principal amount, into shares of our common stock, as permitted by the Loan Agreement, designated holders will also receive a warrant to purchase an equal number of shares of our common stock, subject to customary beneficial ownership limitations; and (iv) we paid an amendment fee of $0.2 million.

Components of our Results of Operations

Operating Expenses

Research and Development Expenses

Our operating expenses have consisted solely of research and development costs and general and administrative costs. Research and development expenses consist primarily of costs related to our research activities, including the development of our product candidates, and costs incurred for the in-licensing of EO-3021. Our research and development expenses include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities;
- external research and development expenses incurred in connection with the preclinical development of EO-3021 and EO-1022, as well as the preclinical and clinical development of seribantumab, including expenses incurred under agreements with contract research organizations and consultants;
- costs incurred with contract manufacturing organizations that manufacture drug products for use in our preclinical studies and clinical trials of seribantumab;
- fees paid to consultants for services directly related to our product development and regulatory efforts; and
- costs related to compliance with regulatory requirements related to conducting our clinical activity.

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on our behalf. Research and development costs are expensed as incurred. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly.

To date, our research and development expenses have primarily been incurred to advance EO-3021, EO-1022 and seribantumab. We expect that significant additional spending will be required to advance our product candidates through clinical development. These expenses will primarily consist of expenses for the administration of clinical studies as well as manufacturing costs for clinical material supply. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates.

The following table provides a breakout of our research and development expenses by major categories of expense (in thousands):

	Year Ended December 31,		
	2024	2023	Change
EO-3021 clinical program	$ 13,274	$ 6,095	$ 7,179
Seribantumab clinical program	3,692	10,326	(6,634)
Discovery, preclinical, and other unallocated research and development expense	3,356	1,445	1,911
Personnel expenses (including stock-based compensation)	8,275	7,568	707
Total research and development expenses	**$ 28,597**	**$ 25,434**	**$ 3,163**

The successful development and commercialization of EO-3021, EO-1022 or any future product candidates is highly uncertain. The success of EO-3021, EO-1022 or any future product candidate will depend on several factors, including the following:

- successful completion of preclinical studies and timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;

- demonstration of safety, efficacy and acceptable risk-benefit profiles of our product candidates to the satisfaction of the FDA and other regulatory agencies;

- acceptance of an IND and a BLA by the FDA or other similar clinical trial applications by foreign regulatory authorities for clinical trials for our product candidates;

- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion or complementary diagnostics, on a timely basis, or at all;

- receipt and related terms of marketing approvals from applicable regulatory authorities for our product candidates, including the completion of any required post-marketing studies or trials;

- raising additional funds necessary to complete the clinical development of and commercialization of our product candidates;

- successfully identifying and developing, acquiring or in-licensing additional product candidates to expand our pipeline;

- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, and protecting and enforcing our rights in our intellectual property portfolio;

- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if approved, whether alone or in collaboration with third parties;

- acceptance of our products, if approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies available on the market or in development;

- obtaining and maintaining third-party payor coverage and adequate reimbursement; and

- maintaining a continued acceptable safety profile of any products following regulatory approval.

Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services, and insurance costs.

We anticipate that our general and administrative expenses will increase in the future as we support our continued research activities and development of our product candidates. We also expect to incur increased expenses, including costs of accounting, audit, legal, investor and public relations, directors' and officers' insurance, and regulatory and tax related services associated with maintaining compliance with exchange listings and SEC requirements. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to building

a sales and marketing team to support product sales, and marketing and distribution activities, to the extent that such activities are not supported by one or more third-party collaborators.

Other Income (Expense), Net

Interest Income

Interest income consists of interest earned on our invested cash balances and associated with our marketable securities.

Interest Expense

Interest expense consists of interest expense on borrowings under the K2HV Loan Agreement, as well as amortization of debt discount and debt issuance costs.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred each year or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2024, we had U.S. federal net operating loss carryforwards of $123.9 million which can be carried forward indefinitely. As of December 31, 2024, we had state net operating loss carryforwards of $8.6 million which begin to expire in 2036. As of December 31, 2024, we also had U.S. federal and state research and development tax credit carryforwards of $10.8 million and $1.1 million, respectively, which begin to expire in 2035. We have recorded a full valuation allowance against our net deferred tax assets at each consolidated. balance sheet date.

Restructuring Charges

The restructuring charges totaling $5.1 million in the first quarter of 2023 relate to costs incurred in respect of the reprioritization and realignment of resources, including $1.6 million of one-time termination and contractual termination benefits for severance, healthcare and related benefits.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 28,597	$ 25,434	$ 3,163
General and administrative	16,106	14,904	1,202
Restructuring charges	—	5,107	(5,107)
Total operating expenses	44,703	45,445	(742)
Loss from operations	(44,703)	(45,445)	742
Other income (expense), net			
Interest income (expense)	1,203	(229)	1,432
Loss on extinguishment of debt	(942)	—	(942)
Other income (expense), net	261	(229)	490
Loss before income taxes	(44,442)	(45,674)	1,232
Income tax expense	43	30	13
Net loss	$ (44,485)	$ (45,704)	$ 1,219

Research and Development Expenses

Research and development expenses were $28.6 million for the year ended December 31, 2024, compared to $25.4 million for the year ended December 31, 2023. The increase of $3.2 million was primarily due to a $5.6 million increase in clinical trial expenses for our lead product candidate, EO-3021, $2.5 million in expenses to in-license certain technology for our recently nominated EO-1022 candidate, and $0.7 million increase in personnel expenses, including stock-based compensation. The increase is partially offset by a $4.9 million decrease in costs related to manufacturing clinical supply of seribantumab, and $0.7 million decrease in medical affairs expense.

General and Administrative Expenses

General and administrative expenses were $16.1 million for the year ended December 31, 2024, compared to $14.9 million for the year ended December 31, 2023. The increase of $1.2 million was primarily due to an increase of $1.9 million in professional fees and personnel expenses, including stock-based compensation, which was partially offset by a decrease of $0.7 million in administrative costs, including directors' and officers' insurance.

Restructuring Charges

Restructuring charges were $5.1 million for the year ended December 31, 2023, and consisted primarily of charges related to the pipeline prioritization and realignment of resources to advance our EO-3021 product candidate, including $1.6 million of one-time termination and contractual termination benefits for severance, healthcare and related benefits. No such charges were incurred during the year ended December 31, 2024.

Other Income (Expense), Net

Other income, net, was $0.3 million for the year ended December 31, 2024, compared to $0.2 million of other expense, net, for the year ended December 31, 2023. The components of other income (expense), net, were as follows:

Interest Income

Interest income of $5.2 million and $3.9 million for the years ended December 31, 2024 and 2023, respectively, was associated with the balance of marketable securities.

Interest Expense

Interest expense of $4.0 million and $4.1 million for the years ended December 31, 2024 and 2023, respectively, consisted primarily of cash and non-cash interest related to our debt facility with K2HV.

Loss on Extinguishment of Debt

Loss on extinguishment of debt of $0.9 million during the year ended December 31, 2024 consisted of expenses incurred in conjunction with the amendment to our debt facility with K2HV determined to be an extinguishment.

Comparison of the Years Ended December 31, 2023 and 2022

A discussion of changes in our results of operations during the year ended December 31, 2023 compared to the year ended December 31, 2022 has been omitted from this Annual Report on Form 10-K, but may 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 year ended December 31, 2023, filed with the SEC on March 6, 2024.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales or any other sources and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever.

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $93.2 million. Based on current operating plans, we do not expect that this amount will meet our anticipated capital requirements over the next 12 months.

In July 2022, we entered into a Sales Agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which we were permitted to offer and sell, from time to time, shares of common stock having aggregate gross proceeds of up to $50.0 million (the "2022 ATM Shares") at market prices (the "2022 ATM Facility"). During the year ended December 31, 2024, we sold 11,625,295 shares of common stock pursuant to the 2022 Sales Agreement, for net proceeds of $44.2 million, after deducting issuance costs.

In June 2023, we closed an underwritten public offering of (i) 17,810,000 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 4,440,000 shares of common stock and (ii) accompanying warrants to purchase one share of common stock for each share of common stock or pre-funded warrant sold. The combined offering price to the public of each share of common stock and accompanying warrant was $2.2500. The combined offering price to the public of each pre-funded warrant and accompanying warrant was $2.2499. The accompanying warrants have an exercise price of $2.25 per share, are exercisable immediately, and will expire five years following the date of issuance. We received net proceeds of $46.5 million, after deducting underwriting discounts and commissions and other offering expenses of $3.6 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Year Ended December 31,	
	2024	2023
Statement of cash flows data:		
Cash used in operating activities	$ (36,364)	$ (56,180)
Cash (used in) provided by investing activities	(8,365)	11,543
Cash provided by financing activities	44,938	47,975
Net increase in cash and cash equivalents	$ 209	$ 3,338

Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $36.4 million, which consisted primarily of our net loss of $44.5 million, and $1.5 million of net amortization of premium and interest on marketable securities, partially offset by $3.9 million of cash provided by changes in our operating assets and liabilities, $4.3 million of stock-based compensation expense, $0.9 million of loss on extinguishment of debt related to amending our debt facility, and $0.5 million of non-cash interest expense. Changes in our operating assets and liabilities consisted primarily of a decrease of $3.5 million in prepaid expenses and other current assets, an increase of $0.3 million in accrued expenses, and an increase of $0.1 million in accounts payable.

During the year ended December 31, 2023, net cash used in operating activities was $56.2 million, which consisted primarily of our net loss of $45.7 million, $13.7 million of cash used in changes in our operating assets and liabilities, and $0.9 million of net amortization of premium and interest on marketable securities, partially offset by $3.3 million of stock-based compensation expense, and $0.7 million of non-cash interest expense. Changes in our operating assets and liabilities consisted primarily of a decrease of $5.9 million in accounts payable, a decrease of $5.7 million in accrued expenses, and an increase of $2.1 million in prepaid expenses and other current assets.

Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was $8.4 million, which consisted of $69.6 of purchases of marketable securities, offset by $61.2 million of cash proceeds from sales and maturities of marketable securities.

During the year ended December 31, 2023, net cash provided by investing activities was $11.5 million, which consisted of $54.2 million of cash proceeds from sales and maturities of marketable securities, offset by $42.7 million of purchases of marketable securities.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $44.9 million and consisted primarily of $44.2 million of proceeds from issuance of common stock upon at-the-market offerings, $0.5 million of proceeds from issuance of common stock upon exercise of common warrants, and $0.5 million of proceeds from stock option exercises. This is partially offset by a $0.2 million payment of debt extinguishment costs and $0.1 million of payments for common stock repurchases.

During the year ended December 31, 2023, net cash provided by financing activities was $48.0 million and consisted primarily of $46.5 million of proceeds from our underwritten public offering of common stock, pre-funded warrants and warrants, and $1.5 million of proceeds from stock option exercises.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for EO-3021 and EO-1022 and seek to develop, acquire or in-license additional product candidates. The timing and amount of our operating expenditures will depend largely on:

- 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;
- the cost to develop companion or complementary diagnostics as needed for each 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; and
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder.

Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our product candidates;
- disruptions or delays in enrollment of our clinical trials;
- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;
- the number and development requirements of other future product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of obtaining regulatory approvals for our product candidates and any companion or complementary diagnostics we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing and distribution capabilities;
- the costs associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from any product candidates that receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation;

- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims; and

- to the extent we pursue strategic collaborations, including collaborations to commercialize seribantumab or to develop any future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations, if any.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for EO-3021 or our other product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on favorable terms, or at all. 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. If we are unable to raise capital or debt when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Contractual Obligations and Commitments

We enter 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 do not contain any minimum purchase commitments and provide for termination upon notice.

In May 2019, we entered into the Asset Purchase Agreement with Merrimack Pharmaceuticals, Inc. (the "previous sponsor"), pursuant to which we acquired all rights and interest to patents, know-how and inventory for assets related to seribantumab. If we are successful in finding a partner to develop and commercialize seribantumab, we may be obligated to pay the previous sponsor up to $54.5 million in development, regulatory and sales milestone payments pursuant to the terms of the asset purchase agreement. Additionally, in conjunction with the asset purchase agreement with the previous sponsor, we assumed the rights and obligations under certain collaboration and license agreements which may require the payment of milestones and/or royalties on future sales of seribantumab. We are currently unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See Note 11 to the accompanying consolidated financial statements for additional information about these license agreements, including with respect to potential payments thereunder.

In July 2022, we entered into the Loan Agreement with K2HV, as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $50.0 million principal in the Term Loan consisting of a first tranche of $30.0 million funded at closing and a subsequent second tranche of up to $20.0 million upon our request, subject to review by the Lenders of certain information from us and discretionary approval by the Lenders. In March 2024, we amended certain terms of the Loan Agreement with K2HV, including amending the amortization date of the Term Loan from March 1, 2025 to June 1, 2026.

The Term Loan will mature on August 1, 2026, with interest-only payments until June 1, 2026, and bears a variable interest rate equal to the greater of (i) 7.95% and (ii) the sum of (A) the prime rate last quoted in *The Wall Street Journal*

(or a comparable replacement rate, as determined by the Lenders, if *The Wall Street Journal* ceases to quote such rate) and (B) 3.20%. Upon the final payment under the Loan Agreement, the Lenders are entitled to an end of term charge equal to 6.45% of the aggregate original principal amount of the term loans made pursuant to the Loan Agreement. We may prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which the Lenders are entitled and certain notice requirements. See Note 7 to the accompanying consolidated financial statements for additional information about the Loan Agreement and the amendment thereto.

In July 2022, we entered into the CSPC License Agreement with CSPC, pursuant to which CSPC granted to us a worldwide exclusive right and license (outside of Greater China) under certain patents identified in the CSPC License Agreement and know-how to develop and commercialize products containing EO-3021 ("Licensed Products") in the treatment of cancer.

Pursuant to the terms of the CSPC License Agreement, we paid to CSPC a one-time, upfront payment of $27.0 million. CSPC will also be eligible to receive up to $148.0 million in potential development and regulatory milestone payments and up to $1.0 billion in potential commercial milestone payments plus royalties on net sales. During the term of the CSPC License Agreement, we are also required to pay to CSPC (i) royalties ranging from mid-single digits through low double digits on net sales of each Licensed Product and (ii) a percentage of non-royalty sublicense income received by us, up to an aggregate of $50.0 million. See Note 11 to the accompanying consolidated financial statements for additional information about the CSPC License Agreement.

Critical Accounting Policies and Significant Judgments and 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 our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Costs and Accruals

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on our behalf. Research and development costs are expensed as incurred. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly.

We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation Expense

We measure stock-based compensation expense at the accounting measurement date based on the fair value of the award and recognize the expense on a straight-line basis over the requisite service period of the award, which is typically the vesting period. Compensation expense is measured using the fair value of the award at the grant date and is adjusted to reflect actual forfeitures as they occur.

We estimate the fair value of stock options using the Black-Scholes option pricing model that takes into account the fair value of our common stock, the exercise price, the expected term of the option, the expected volatility of our common stock, expected dividends on our common stock, and the risk-free interest rate over the expected life of the option.

Expected term — We use the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin Topic 14.D.2 to calculate the expected term as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees.

Expected volatility — We estimate expected volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price.

Risk-free interest rate — The risk-free rate assumption is based on the U.S. Treasury yield curves whose terms are consistent with the expected term of the stock options.

Expected dividend — We have not issued any dividends and do not expect to issue dividends over the life of the options. As a result, we have estimated the dividend yield to be zero.

We classify stock-based compensation expense in our statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs or service payments are classified.

Recent Accounting Pronouncements

For information on new accounting standards and the impact, if any, on our financial position or results of operations, see "Note 2 - Summary of Significant Accounting Policies" in the Notes to the Consolidated Financial Statements included in Part II, Item 8 of this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

All of our cash and money market funds are held with a single financial institution. Due to its size, we believe this financial institution represents a minimal credit risk. Our money market funds are invested in high grade U.S. Treasuries with maturities of 90 days or less. As a result, we believe our money market fund represents a minimal credit risk.

Item 8. Consolidated Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Elevation Oncology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Elevation Oncology, Inc. and Subsidiary (the "Company") as of December 31, 2024, and 2023, and the related consolidated statements operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and 2023, and the results of its operations and its cash flows for the years the ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty

Basis for Opinion

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

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

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

/s/ CohnReznick LLP

We have served as the Company's auditor since 2020

New York City, New York
March 6, 2025

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 49,464	$ 49,255
Marketable securities, available for sale	43,720	33,852
Prepaid expenses and other current assets	1,542	4,857
Total current assets	94,726	87,964
Property and equipment, net	34	59
Other non-current assets	866	1,068
Total assets	$ 95,626	$ 89,091
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 559	$ 507
Accrued expenses	3,908	3,638
Total current liabilities	4,467	4,145
Non-current liabilities:		
Long-term debt, net of discount	31,134	30,137
Total liabilities	35,601	34,282
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2024 and 2023; no shares issued or outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of December 31, 2024 and 2023; 59,198,230 and 42,470,264 shares issued as of December 31, 2024 and 2023, respectively; 59,131,149 and 42,422,531 shares outstanding as of December 31, 2024 and 2023, respectively	6	4
Additional paid-in capital	300,520	250,825
Accumulated other comprehensive income	61	9
Treasury stock, 67,081 and 47,733 shares as of December 31, 2024 and 2023, respectively, at cost	(107)	(59)
Accumulated deficit	(240,455)	(195,970)
Total stockholders' equity	60,025	54,809
Total liabilities and stockholders' equity	$ 95,626	$ 89,091

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

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 28,597	$ 25,434
General and administrative	16,106	14,904
Restructuring charges	—	5,107
Total operating expenses	44,703	45,445
Loss from operations	(44,703)	(45,445)
Other income (expense):		
Interest income (expense), net	1,203	(229)
Loss on extinguishment of debt	(942)	—
Total other income (expense), net	261	(229)
Loss before income taxes	(44,442)	(45,674)
Income tax expense	43	30
Net loss	$ (44,485)	$ (45,704)
Net loss per share, basic and diluted	$ (0.78)	$ (1.25)
Weighted average common shares outstanding, basic and diluted	57,275,454	36,522,716
Comprehensive loss:		
Net loss	$ (44,485)	$ (45,704)
Other comprehensive income:		
Unrealized gain on marketable securities	52	170
Total other comprehensive income	52	170
Total comprehensive loss	$ (44,433)	$ (45,534)

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

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2022	23,312,529	$ 2	$ 199,492	$ (35)	$ (161)	$ (150,266)	$ 49,032
Vesting of restricted common stock	3,945	—	1	—	—	—	1
Issuance of common stock, purchase warrants and pre-funded warrants for the purchase of common stock, net of underwriting discounts, commissions and offering costs of $3,560	17,810,000	2	46,501	—	—	—	46,503
Issuance of common stock upon stock option exercises	1,264,899	—	1,496	—	—	—	1,496
Vesting of restricted stock units, net of withholding	31,158	—	—	(24)	—	—	(24)
Stock-based compensation	—	—	3,335	—	—	—	3,335
Unrealized gain on marketable securities	—	—	—	—	170	—	170
Net loss	—	—	—	—	—	(45,704)	(45,704)
Balance at December 31, 2023	42,422,531	4	250,825	(59)	9	(195,970)	54,809
Issuance of common stock upon at-the-market offering, net of issuance costs	11,625,295	1	44,206	—	—	—	44,207
Issuance of common stock upon stock option exercises	379,425	—	499	—	—	—	499
Issuance of common stock upon exercise of common warrants	200,000	—	450	—	—	—	450
Issuance of common stock upon exercise of pre-funded warrants	4,439,836	1	(1)	—	—	—	—
Issuance of warrants upon amendment of debt facility	—	—	261	—	—	—	261
Vesting of restricted stock units, net of withholding	64,062	—	—	(48)	—	—	(48)
Stock-based compensation	—	—	4,280	—	—	—	4,280
Unrealized gain on marketable securities	—	—	—	—	52	—	52
Net loss	—	—	—	—	—	(44,485)	(44,485)
Balance at December 31, 2024	59,131,149	$ 6	$ 300,520	$ (107)	$ 61	$ (240,455)	$ 60,025

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

ELEVATION ONCOLOGY, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	2023
Operating activities		
Net loss	$ (44,485)	$ (45,704)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	4,280	3,335
Non-cash interest expense	486	702
Amortization of premium and interest on marketable securities	(1,450)	(862)
Depreciation expense	24	39
Loss on extinguishment of debt	942	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	3,517	(2,143)
Accounts payable	52	(5,855)
Accrued expenses	270	(5,692)
Net cash used in operating activities	(36,364)	(56,180)
Investing activities		
Purchase of marketable securities	(69,565)	(42,657)
Proceeds from sales and maturities of marketable securities	61,200	54,200
Net cash (used in) provided by investing activities	(8,365)	11,543
Financing activities		
Proceeds from issuance of common stock upon at-the-market offering, net of issuance costs	44,207	—
Proceeds from issuance of common stock, purchase warrants and pre-funded warrants for the purchase of common stock, net of underwriting discounts, commissions, and offering costs	—	46,503
Proceeds from issuance of common stock upon stock option exercises	499	1,496
Proceeds from issuance of common stock upon exercise of common warrants	450	—
Common stock repurchase	(48)	(24)
Payment of debt extinguishment costs	(170)	—
Net cash provided by financing activities	44,938	47,975
Net increase in cash and cash equivalents	209	3,338
Cash and cash equivalents, beginning of year	49,255	45,917
Cash and cash equivalents, end of year	$ 49,464	$ 49,255
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,533	$ 3,164
Cash paid for taxes	$ 47	$ 26

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

ELEVATION ONCOLOGY, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

Elevation Oncology, Inc. (the "Company"), which was formerly known as 14ner Oncology, Inc., was incorporated under the laws of the State of Delaware on April 29, 2019 ("Inception"). The Company is an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs. The Company is leveraging its antibody-drug conjugate ("ADC") expertise to advance a novel pipeline, initially targeting two validated targets in oncology, Claudin 18.2 and HER3. The Company's lead product candidate, EO-3021, is an ADC comprised of a fully human anti-Claudin 18.2 immunoglobulin G1 monoclonal antibody ("mAb") site-specifically conjugated with a cleavable linker to the cytotoxic monomethyl auristatin E ("MMAE") payload. EO-3021 is currently being evaluated in a Phase 1 clinical trial as a monotherapy and in combinations with dostarlimab, a PD-1 inhibitor, and ramucirumab, a VEGFR2 inhibitor, in patients with advanced, unresectable or metastatic gastric/gastroesophageal junction solid tumors. The Company's second product candidate, EO-1022, is a potentially differentiated HER3 ADC being developed for the treatment of patients with HER3-expressing solid tumors, including breast cancer, non-small cell lung cancer and other solid tumors. EO-1022 is an ADC containing seribantumab, a fully human immunoglobulin G2 ("IgG2") anti-HER3 mAb, and an MMAE payload, with glycan site-specific conjugation.

Risks and Uncertainties

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

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

Liquidity and Going Concern

The Company has historical losses from operations and anticipates that it will continue to incur losses for the foreseeable future as it continues the research and development of its product candidates. The Company incurred net losses of $44.5 million and $45.7 million for the years ended December 31, 2024 and 2023, respectively, and had an accumulated deficit of $240.5 million as of December 31, 2024. Through December 31, 2024, the Company has funded its operations with proceeds from the sale of convertible preferred stock, proceeds from public offerings of common stock and warrants, and borrowings under a debt facility. The Company does not expect that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the consolidated financial statements.

The Company is subject to risks, expenses, and uncertainties frequently encountered by companies in its industry. The Company intends to continue its research and development of its product candidates, which will require significant additional funding. If the Company is unable to obtain additional funding in the future and/or its research, development, and commercialization efforts require higher than anticipated capital, there may be a negative impact on the financial

viability of the Company. The Company plans to fund its operations through public and private placements of equity and/or debt, payments from potential strategic research and development arrangements, licensing and/or collaboration arrangements with pharmaceutical companies or other institutions, or funding from other third parties. Such financing and funding may not be available at all, or on terms that are favorable to the Company. Failure to raise additional capital could have a material adverse effect on the Company's ability to achieve its intended business objectives.

As a result of these factors, together with the anticipated increase in spending that will be necessary to continue to research, develop, and commercialize the Company's product candidates, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. The consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP").

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Elevation Oncology Securities Corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires the use of estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates and assumptions on known trends and events and various other factors that management believes to be 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. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accruals for research and development expenses, the valuation of common stock and the assumptions used in the valuation of share-based compensation awards. Changes in estimates are recorded in the period in which they become known. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and, given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available and regularly reviewed by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the discovery and development of cancer therapies for patient populations with significant unmet medical needs.

The Company's Chief Executive Officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for evaluating financial performance and manages its operations as a single operating segment. Segment losses are measured as the Company's net loss as reported on the Company's consolidated statements of operations and comprehensive loss. The Company monitors its cash and cash equivalents and marketable securities as reported on the consolidated balance sheets to determine the liquidity needs and pipeline investment allocation. As the Company has not generated revenue, the CODM assesses Company performance through the achievement of research goals towards advancing the Company's product candidates through stages of development. As such, the CODM is

regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and pipeline investment allocation.

Significant segment expenses and segment net loss were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development		
EO-3021 clinical program	$ 13,274	$ 6,095
Seribantumab clinical program	3,692	10,326
Discovery, preclinical, and other unallocated research and development expense	3,356	1,445
Personnel expenses (including stock-based compensation)	8,275	7,568
General and administrative	16,106	14,904
Restructuring charges	—	5,107
Other segment items[(a)]	(218)	259
Segment net loss	**(44,485)**	**(45,704)**
Reconciliation of segment net loss		
Adjustments and reconciling items	—	—
Net loss	**$ (44,485)**	**$ (45,704)**

[(a)] Other segment items in segment net loss includes other income (expense), net and income tax expense.

All material long-lived assets are maintained in, and all losses are attributable to, the United States of America.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. As of December 31, 2024 and 2023, cash equivalents consisted of money market funds. The Company places its cash with high-credit-quality financial institutions domiciled in the United States.

Deferred Financing Costs

The incremental cost, including the fair value of warrants, directly associated with obtaining debt financing is capitalized as deferred financing costs upon the issuance of the debt and amortized over the term of the related debt agreement using the effective-interest method with such amortized amounts included as a component of interest expense in the consolidated statements of operations and comprehensive loss. Unamortized deferred financing costs are presented on the consolidated balance sheets as a direct deduction from the carrying amount of the related debt obligation.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The Company's money market funds are invested in highly rated funds. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents and does not believe that it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance and drug products. During the years ended December 31, 2024 and 2023, the Company had two vendors that accounted for approximately 71% and 66% of its research and development

expense, respectively. As of December 31, 2024 and 2023, the Company had three and two vendors that accounted for approximately 54% and 39% of the total accounts payable, respectively.

Property and Equipment

Property and equipment consist of computer software that is recorded at cost and depreciated on a straight-line basis over the estimated useful lives of the assets. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying value of assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded through December 31, 2024.

Cloud Computing Arrangements

The Company defers implementation costs incurred in cloud computing hosting arrangements in accordance with Accounting Standards Update ("ASU") 2018-15 and amortizes these costs over the noncancellable term of the cloud computing arrangement, plus any optional renewal periods (1) that are reasonably certain to be exercised by the Company or (2) for which exercises of the renewal option is controlled by the cloud service provider. Costs incurred during the application development stage are capitalized within either prepaid expenses and other current assets, or in other assets, net on the Company's consolidated balance sheets. Amortization of implementation costs is on a straight-line basis over the related hosting arrangement term and is reflected in research and development expenses in the consolidated statements of operations and comprehensive loss.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Non-observable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying amount of the Company's accounts payable approximates fair value due to its short-term nature. The carrying value of the Company's long-term debt approximates its fair value due to its variable interest rate.

Marketable Securities, Available for Sale

All marketable securities have been classified as "available-for-sale" and are carried at fair value, based upon quoted market prices. The Company considers its available-for-sale portfolio as available for use in current operations. Accordingly, the Company may classify certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date.

Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income and reported as a separate component of stockholders' equity until realized. Interest income, realized gains and losses, and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income, net. The cost of securities sold is based on the specific-identification method. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. In accordance with the Company's investment policy, management invests in money market funds, corporate bonds, commercial paper, asset-backed securities and government securities. The Company has not realized any losses on its marketable securities to date.

When the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made. The credit-related impairment amount is recognized in the consolidated statements of operations and comprehensive loss. Credit losses are recognized through the use of an allowance for credit losses account in the consolidated balance sheets and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations and comprehensive loss. There were no credit losses recorded during the years ended December 31, 2024 and 2023.

Comprehensive Income

The Company's only element of other comprehensive income is unrealized gains and losses on available-for-sale marketable securities.

Patent Costs

The legal and professional costs incurred by the Company to maintain its patent rights have been expensed as part of general and administrative expenses. As of December 31, 2024 and 2023, the Company has determined that these expenses have not met the criteria to be capitalized.

Research and Development Costs

Research and development costs consist of salaries and benefits, including associated stock-based compensation, and fees paid to other entities that conduct certain research and development activities on the Company's behalf. Research and development costs are expensed as incurred. The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf based on actual time and expenses incurred by them. Further, the Company accrues expenses related to clinical trials based on the level of patient activity according to the related agreement. The Company monitors patient enrollment levels and related activity to the extent reasonably possible and adjusts estimates accordingly.

The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received rather than when the payment is made.

Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of accrued research and development expenses.

Stock-Based Compensation

The Company measures stock-based compensation cost at the accounting measurement date based on the fair value of the award and recognizes the expense on a straight-line basis over the requisite service period of the award, which is typically the vesting period. Compensation expense is measured using the fair value of the award at the grant date and is adjusted to reflect actual forfeitures as they occur.

The Company estimates the fair value of stock options using the Black-Scholes option pricing model that takes into account the exercise price, the fair value of the Company's common stock, the expected term of the option, the expected volatility of the Company's common stock, expected dividends on the Company's common stock, and the risk-free interest rate over the expected life of the option.

Fair value of common stock—Upon IPO, the fair value of the Company's common stock is determined based on the quoted market price of its common stock.

Expected term—The Company uses the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin Topic 14.D.2 to calculate the expected term as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees.

Expected volatility—The Company estimates expected volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its traded stock price.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury yield curves whose terms are consistent with the expected term of the stock options.

Expected dividend—The Company has not issued any dividends and does not expect to issue dividends over the life of the options. As a result, the Company has estimated the dividend yield to be zero.

The Company measures compensation expense for restricted stock units based on the fair value on the date of grant using the market value of the Company's common stock. The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs or service payments are classified.

Net Loss per Common Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and the effect of dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The Company's participating securities contractually entitle the holders of such shares to participate in

dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The Company accounts for uncertainty in income taxes recognized. If the tax position is deemed more likely than not to be sustained, it would then be assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. To date the Company has no uncertain tax positions and there have been no interest and penalties.

Recently Implemented Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in Accounting Standards Codification ("ASC") 280 on an interim and annual basis. The Company adopted this standard effective January 1, 2024, on a retrospective basis, and the application of ASU 2023-07 did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands the disclosures required for income taxes. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The Company does not expect the adoption of this guidance to have a material impact on the Company's financial statements.

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*, which requires additional disclosures about the nature of expenses included in the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently assessing the impact of the adoption of this guidance.

In December 2024, the FASB issued ASU 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments,* which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU 2024-04 is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently assessing the impact of the adoption of this guidance.

3. FAIR VALUE MEASUREMENTS OF FINANCIAL ASSETS

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used for such measurements were as follows (in thousands):

	As of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	$ 38,066	$ —	$ —	$ 38,066
Total	$ 38,066	$ —	$ —	$ 38,066
Marketable Securities				
Corporate debt securities	$ —	$ 24,426	$ —	$ 24,426
Commercial paper	—	3,354	—	3,354
U.S. Government debt securities	—	15,940	—	15,940
Total	$ —	$ 43,720	$ —	$ 43,720

	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	$ 45,287	$ —	$ —	$ 45,287
Total	$ 45,287	$ —	$ —	$ 45,287
Marketable Securities				
Corporate debt securities	$ —	$ 4,571	$ —	$ 4,571
Commercial paper	—	12,442	—	12,442
U.S. Government debt securities	—	16,839	—	16,839
Total	$ —	$ 33,852	$ —	$ 33,852

Corporate debt securities, commercial paper, and U.S. Government debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. During the years ended December 31, 2024 and 2023, the Company had no transfers into or out of Level 3.

4. MARKETABLE SECURITIES

The following tables summarize the fair value of the Company's marketable securities by type (in thousands):

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 24,394	$ 32	$ —	$ 24,426
Commercial paper	3,352	2	—	3,354
U.S. Government debt securities	15,913	27	—	15,940
Total	$ 43,659	$ 61	$ —	$ 43,720

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 4,569	$ 3	$ (1)	$ 4,571
Commercial paper	12,444	—	(2)	12,442
U.S. Government debt securities	16,830	9	—	16,839
Total	$ 33,843	$ 12	$ (3)	$ 33,852

5. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,	
	2024	2023
Accrued compensation	$ 2,274	$ 2,393
Accrued preclinical and clinical trial costs	1,124	756
Accrued interest	280	302
Accrued consulting	107	68
Accrued restructuring charges	—	3
Accrued other	123	116
Total accrued expenses	$ 3,908	$ 3,638

6. RESTRUCTURING CHARGES

On January 6, 2023, the Company announced a pipeline prioritization and realignment of resources to advance its EO-3021 product candidate. The Company paused further investment in the clinical development of its seribantumab product candidate and realigned its resources to focus on advancing EO-3021 and other pipeline programs. The Company intends to pursue further development of seribantumab only in collaboration with a partner. Concurrently with this announcement, the Board of Directors of the Company (the "Board") approved a reduction of the Company's workforce across all areas of the Company. The workforce reduction was substantially completed in January 2023 and was fully completed in April 2023. These actions reflect the Company's determination to refocus its strategic priorities around EO-3021 and other pipeline programs.

Additionally, on January 5, 2023, the Company and the former President and Chief Executive Officer (the "former CEO") of the Company, entered into a Separation Agreement (the "Separation Agreement") following the mutual agreement between the Board and the former CEO regarding his departure from his positions with the Company.

Pursuant to the Separation Agreement, the former CEO ceased his role as the Company's President and CEO and resigned as a director of the Board, effective January 5, 2023.

The reprioritization and realignment of resources included total restructuring charges of approximately $5.1 million, which included $1.6 million of one-time termination and contractual termination benefits for severance, healthcare and related benefits. The one-time termination benefits were recorded in January 2023 under the provisions of ASC 420, *Exit or Disposal Cost Obligation*, as this is the period the termination plan was both approved and communicated to the impacted employees. The contractual termination benefits were recorded in January 2023 under the provisions of ASC 712, *Compensation-Nonretirement Postemployment Benefits*, which is the period in which the contractual postemployment benefits became probable of recognition. In addition, the Company recorded a one-time stock-based compensation charge of $0.5 million in 2023.

All restructuring charges were paid as of January 2024.

7. DEBT

K2 HealthVentures Loan and Security Agreement

In July 2022, the Company entered into a loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC (together with its affiliates, "K2HV", and together with any other lender from time to time party thereto, the "Lenders"), as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides up to $50.0 million principal in term loans (the "Term Loan") consisting of a first tranche of $30.0 million funded at closing and a subsequent second tranche of up to $20.0 million upon the Company's request before March 1, 2025, subject to review by the Lenders of certain information from the Company and discretionary approval by the Lenders.

In connection with entering into the Loan Agreement, the Company also issued to K2HV a warrant to purchase shares of common stock (see Note 8), which was an incremental cost to the Loan Agreement; thus, the allocated fair value of the warrant was recorded as part of the issuance cost.

In March 2024, the Company entered into an amendment to the Loan Agreement with K2HV (the "Loan Agreement Amendment"), pursuant to which: (i) the amortization date of the Term Loan provided under the Loan Agreement was amended from March 1, 2025 to June 1, 2026; (ii) the Company issued to K2HV an additional warrant to purchase shares of common stock (the "Amendment Warrant") (see Note 8); (iii) upon the Lenders' Conversion Election (as defined below), designated holders will also receive the Conversion Warrant (as defined below); and (iv) the Company paid an amendment fee of $0.2 million.

The Term Loan will mature on August 1, 2026, with interest only payments until June 1, 2026, and thereafter interest and principal payments for the remaining three months. It bears a variable interest rate equal to the greater of (i) 7.95% and (ii) the sum of (A) the prime rate last quoted in *The Wall Street Journal* (or a comparable replacement rate, as determined by the Lenders, if *The Wall Street Journal* ceases to quote such rate) and (B) 3.20%. Upon the final payment under the Loan Agreement, the Lenders are entitled to an end of term charge equal to 6.45% of the aggregate original principal amount of the term loans made pursuant to the Loan Agreement. The final payment fee is being accreted and amortized into interest expense using the effective interest rate method over the term of the loan. This could change given it is a variable interest rate facility.

The Company may prepay, at its option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium as follows: 3% of the loan amounts prepaid if such prepayment occurs in the first year after funding; 2% if such prepayment occurs in the second year after funding; 1% if such prepayment occurs in the third year after funding; and 0% thereafter.

The Lenders may elect at any time following the closing and prior to the full repayment of the term loans to convert any portion of the principal amount of the term loans then outstanding, up to an aggregate of $3.25 million in principal

amount, into shares of the Company's common stock, $0.0001 par value per share, at a conversion price of $2.25 (the effective price per share of common stock sold in the Company's June 2023 offering (see Note 9)), subject to customary 19.99% Nasdaq beneficial ownership limitations. The Company also granted registration rights to the Lenders with respect to shares received upon such conversion.

Further, the Lenders may elect to invest up to $5.0 million in future equity financings of the Company, provided such investment is limited to no more than 10% of the total amount raised in such equity financing.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict the Company's ability to, among other things, dispose of assets, make changes to the Company's business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. The Loan Agreement also contains covenants requiring that the Company maintain cash, cash equivalents and marketable securities balance of at least $25.0 million so long as the Company's total market capitalization is less than $250.0 million.

As security for its obligations under the Loan Agreement, the Company granted the Lenders a first priority security interest on substantially all of the Company's assets (other than intellectual property), subject to certain exceptions.

The Company analyzed the Loan Agreement Amendment under ASC 470-50 to determine if extinguishment accounting was applicable. Under ASC 470-50-40-10, debt instruments are considered to be substantially different if a modification or an exchange affects the terms of a conversion option, from which the change in the fair value of the conversion option is at least 10% of the carrying amount of the original debt instrument immediately before the modification or exchange. Since the change of the fair value of the conversion option exceeded 10% upon the execution of the Loan Agreement Amendment, the Company determined the modification to be substantive, and extinguishment accounting was applicable. In accordance with the extinguishment accounting guidance, the Company recorded $0.9 million as loss on extinguishment of debt, which represents unamortized debt issuance costs of the original loan as of the amendment date (including the unamortized allocated fair value of the warrant issued to K2HV in connection with entering into the Loan Agreement), new lender fees, and the fair value of the Amendment Warrant upon issuance.

As of December 31, 2024, the effective interest rate is 11.83% for the first tranche.

The book value of debt approximates its fair value given the variable interest rate. Long-term debt and the unamortized discount balances are as follows (in thousands):

	December 31,	
	2024	2023
Outstanding principal amount	$ 30,000	$ 30,000
Add: accreted liability of final payment fee	1,134	686
Less: unamortized debt discount, long-term	—	(549)
Long-term debt, net of discount	$ 31,134	$ 30,137

The Company's total interest expense was $4.0 million and $4.2 million for the years ended December 31, 2024 and 2023, respectively. The following summarizes the components of total interest expense (in thousands):

	Year Ended December 31,	
	2024	2023
Interest paid or accrued	$ 3,511	$ 3,466
Non-cash amortization of debt discount (including warrants)	38	214
Non-cash accrued back-end fee	448	488
	$ 3,997	$ 4,168

Scheduled future principal payments on total outstanding debt as of December 31, 2024 are as follows (in thousands):

2025	$ —
2026	30,000
	$ 30,000

8. K2 WARRANT AND AMENDMENT WARRANT

In connection with the Term Loan and Loan Agreement (see Note 7), the Company issued warrants to purchase 339,725 shares of the Company's common stock with an exercise price of $1.3246 (the "K2 Warrant"). In connection with the Loan Agreement Amendment executed March 2024 (see Note 7), the Company issued an additional warrant to purchase 55,249 shares of the Company's common stock, with an exercise price per warrant of $2.7150 (the "Amendment Warrant"). Additionally, pursuant to the Conversion Election, the Lenders may receive the Conversion Warrant (see Note 7). K2HV may at any time and from time to time exercise this K2 Warrant, Amendment Warrant, or Conversion Warrant (after the Conversion Election), in whole or in part, by delivering to the Company the original copy of the respective warrant, together with a duly executed notice of exercise.

The Company also granted registration rights to the Lenders with respect to shares issuable upon exercise of the K2 Warrant, Amendment Warrant, and Conversion Warrant (after the Conversion Election).

All 394,974 shares subject to the K2 Warrant and Amendment Warrant are outstanding as of December 31, 2024.

	Shares	Initial Recognition Date	Exercise Price	Expiration Date
K2 Warrant	339,725	July 27, 2022	$ 1.3246	July 27, 2032
Amendment Warrant	55,249	March 1, 2024	2.7150	March 1, 2034
Total warrants outstanding	394,974			

The allocated fair value upon issuance of the K2 Warrant and Amendment Warrant was estimated to be approximately $0.4 million and $0.3 million, respectively, and was recorded as additional paid-in capital on the Company's consolidated balance sheets. The fair value of the K2 Warrant and Amendment Warrant was estimated using a Black-Scholes option-pricing model with the following assumptions:

	K2 Warrant	Amendment Warrant
Stock price	$1.41	$5.01
Strike price	$1.32	$2.72
Volatility (annual)	75.30%	105.00%
Risk-free rate	2.74%	4.10%
Estimated time to expiration (years)	10	10
Dividend yield	—%	—%

9. EQUITY

Preferred Stock

The Company has authorized preferred stock amounting to 10,000,000 shares as of December 31, 2024 and 2023.

Common Stock

The Company has authorized common stock amounting to 500,000,000 shares of $0.0001 par value as of December 31, 2024 and 2023.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any. No dividends have been declared or paid by the Company since its inception.

At-the-Market Offering

In July 2022, the Company entered into a Sales Agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company was permitted to offer and sell, from time to time, shares of common stock having aggregate gross proceeds of up to $50.0 million (the "2022 ATM Shares") at market prices (the "2022 ATM Facility"). The Company agreed to pay Cowen a commission of up to 3% of the gross proceeds of any sales of the 2022 ATM Shares pursuant to the 2022 Sales Agreement.

During the year ended December 31, 2024, the Company sold 11,625,295 of the 2022 ATM Shares pursuant to the 2022 Sales Agreement, with net proceeds of approximately $44.2 million after deducting $1.4 million of issuance costs.

In May 2024, the Company entered into a new sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC ("TD Cowen"), under which the Company may offer and sell, from time to time, shares of common stock having aggregate gross proceeds of up to $75.0 million (the "2024 ATM Shares") at market prices (the "2024 ATM Facility"). The Company will pay TD Cowen a commission of up to 3% of the gross proceeds of any sales of the 2024 ATM Shares pursuant to the 2024 Sales Agreement. As of December 31, 2024, the Company has not sold any 2024 ATM Shares pursuant to the 2024 Sales Agreement.

June 2023 Public Offering

On June 8, 2023, Elevation entered into an Underwriting Agreement (the "Purchase Agreement") with SVB Securities LLC and Cowen, as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell an aggregate of 17,810,000 shares of its common stock, par value $0.0001 per share (each a "Share" and collectively the "Shares"), pre-funded warrants to purchase 4,440,000 shares of its common stock (the "Pre-Funded Warrants") and common stock warrants (the "Common Warrants" and collectively with the Pre-Funded Warrants, the "Warrants") to purchase 22,250,000 shares of its common stock to the Underwriters. Each full Share was sold together with one Common Warrant at the public offering price of $2.25 per share, less underwriting discounts and commissions. Each full Pre-Funded Warrant was sold together with one Common Warrant at a public offering price of $2.2499 per Pre-Funded Warrant, which represents the per Share and Common Warrant public offering price less a $0.0001 per share exercise price for each such Pre-Funded Warrant.

The Common Warrants are exercisable at any time after the date of issuance and have an exercise price of $2.25 per share, subject to adjustment. The Common Warrants expire five years from the date of issuance. The Pre-Funded Warrants are exercisable at any time after the date of issuance and had no expiration date. The aggregate exercise price of the Pre-Funded Warrants, except for a nominal exercise price of $0.0001 per share of common stock, was pre-funded to the Company and, consequently, no additional consideration (other than the nominal exercise price of $0.0001 per share of common stock) is required for the exercise of the Pre-Funded Warrants.

The offering closed on June 13, 2023, and the Company received gross proceeds of $50.1 million before deducting underwriting discounts, commissions and offering expenses. As of the close of the offering, the Company issued 17,810,000 shares of common stock and Common Warrants to purchase 17,810,000 shares of common stock for a total consideration of $40.1 million and 4,440,000 shares of common stock and Pre-Funded Warrants to purchase 4,440,000 shares of common stock for a total consideration of $10.0 million. The terms and conditions of the Warrants are as noted and governed by the agreements entered into with the holders on June 13, 2023. Underwriting discount and commissions and other offering expenses of approximately $3.6 million incurred directly related to the offering were reflected as a reduction in additional paid-in capital.

As of December 31, 2024, Common Warrants for 200,000 shares have been exercised and all of the Pre-Funded Warrants have been exercised. The Pre-Funded Warrants were exercised by means of cashless exercise, resulting in the issuance of 4,439,836 shares.

The following is a summary of warrants outstanding pursuant to the purchase agreement as of December 31, 2024:

	Shares	Initial Recognition Date	Exercise Price	Expiration Date
Common Warrants	22,050,000	June 13, 2023	$ 2.2500	June 13, 2028

The fair value of the Warrants issued to the Investors in the offering was approximately $35.6 million. The fair value of the Common Warrants was measured using a Monte Carlo simulation model with the following assumptions:

Stock price	$1.65
Strike price	$2.25
Volatility (annual)	110.00%
Risk-free rate	3.93%
Estimated time to expiration (years)	5
Dividend yield	—%

Total proceeds were allocated between the Shares and Warrants on a relative fair value basis given both securities are equity classified.

10. STOCK-BASED COMPENSATION

Stock-based compensation expense as reflected in the Company's consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 1,207	$ 610
General and administrative	3,073	2,725
Stock-based compensation expense included in operating expenses	$ 4,280	$ 3,335

2021 Equity Incentive Plan

The Company has two equity incentive plans: the 2019 Equity Incentive Plan ("2019 Plan") and the 2021 Equity Incentive Plan ("2021 Plan"). New awards can only be granted under the 2021 Plan, under which the Company is able to issue equity awards to employees, Board members, consultants, and advisors. The 2021 Plan became effective on June 24, 2021, the date the prospectus related to the Company's IPO was deemed effective by the SEC. The 2021 Plan authorizes the award of stock options, restricted stock awards ("RSAs"), stock appreciation rights ("SARs"), restricted stock units ("RSUs"), cash awards, performance awards and stock bonus awards. The Company initially reserved 1,483,445 shares of its common stock, plus any reserved shares not issued or subject to outstanding grants under the 2019 Plan on the effective date of the 2021 Plan, for issuance pursuant to awards granted under the 2021 Plan. As of December 31, 2024, 505,627 shares remained available for future issuance under the 2021 Plan. The number of shares reserved for issuance under the 2021 Plan will increase automatically on January 1, 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number as may be determined by the Board in any particular year. As such, 2,956,557 shares were added to the Plan in January 2025.

2021 Employee Stock Purchase Plan

The Company has adopted the Employee Stock Purchase Plan ("ESPP") which became effective June 24, 2021, the date the prospectus related to the Company's IPO was deemed effective by the SEC, to enable eligible employees to purchase shares of its common stock with accumulated payroll deductions at a discount beginning on a date to be determined by the Board or compensation committee. The ESPP is intended to qualify under Section 423 of the Internal Revenue Code. The Company initially reserved 228,222 shares of its common stock for sale under the ESPP. As of December 31, 2024, no offering periods have commenced, and 1,117,631 shares remained available for future issuance under the ESPP. The

aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1, 2022 through 2031 by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by the Board in any particular year. As such, 591,311 shares were added to the Plan in January 2025.

The aggregate number of shares issued over the term of the ESPP, subject to stock splits, recapitalizations or similar events, may not exceed 4,564,440 shares of the Company's common stock.

Stock Options

The following is a summary of the Company's stock option activity for the year ended December 31, 2024:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	4,178,194	$ 2.98	8.22	$ 11
Granted	2,807,650	2.85		
Exercised	(379,425)	1.31		
Cancelled	(289,356)	4.20		
Outstanding at December 31, 2024	6,317,063	$ 2.97	8.22	$ 4
Vested at December 31, 2024	2,834,077	$ 3.50	6.88	$ —
Vested and expected to vest at December 31, 2024	6,317,063	$ 2.97	8.22	$ 4

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2024 and 2023 was less than $0.1 million and $1.6 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2024 and 2023 was $1.94 and $0.59 per share, respectively. The fair value of each stock option was estimated using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.46 - 4.65 %	3.67 - 4.54 %
Volatility	72 - 76 %	72 - 77 %
Dividend yield	— %	— %
Expected term (years)	6 - 7	2 - 7

The fair value of options that vested during the years ended December 31, 2024 and 2023 was $2.1 million and $5.1 million, respectively. The Company recorded stock-based compensation expense associated with stock option awards of $3.1 million and $2.5 million during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, there was $5.4 million of total unrecognized compensation cost related to unvested stock options, which the Company expects to recognize over a remaining weighted average period of 2.5 years.

Restricted Common Stock

The terms of the 2019 Plan permitted certain option holders to exercise options before their options were vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement and are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the lesser of the price paid by the purchaser or the fair value of the shares at the time of repurchase. Such shares are not deemed to be issued for accounting purposes until they vest and are therefore excluded from shares outstanding until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified as common stock and additional paid-in capital as the shares vest and the repurchase right lapses. As of December 31, 2023, there were no

unvested shares of restricted common stock. The Company has no such liabilities from the early exercise in the accompanying consolidated balance sheets as of December 31, 2024, and 2023. The Company recorded no stock-based compensation expense associated with restricted common stock during each of the years ended December 31, 2024 and 2023.

Restricted Stock Units

The Company issues restricted stock units ("RSUs") to employees that generally vest over a four-year period with 25% of awards vesting after one year and then quarterly thereafter. Any unvested shares will be forfeited upon termination of services. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is amortized straight-line over the vesting period.

The following table summarizes activity related to RSUs for the year ended December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	155,797	$ 8.25
Granted	437,025	2.77
Vested	(83,410)	10.03
Cancelled	(39,431)	2.31
Unvested at December 31, 2024	469,981	$ 3.34

The aggregate fair value of RSUs that vested during the years ended December 31, 2024 and 2023 was $0.8 million and $0.1 million, respectively. The Company recorded stock-based compensation expense associated with RSU awards of $1.2 million and $0.8 million for each of the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the total unrecognized expense related to all RSUs was $1.3 million, which the Company expects to recognize over a weighted average period of 2.3 years.

In connection with the vesting of RSUs, the Company adopted a net settlement method whereby shares of common stock are withheld to satisfy tax withholding and remittance obligations. As of December 31, 2024, the Company withheld 67,081 shares, which are held in Treasury Stock, for $0.1 million.

11. ASSET PURCHASE AND LICENSE AGREEMENTS

CSPC License Agreement

In July 2022, the Company entered into a license agreement (the "CSPC License Agreement") with CSPC Megalith Biopharmaceutical Co., Ltd., a subsidiary of CSPC Pharmaceutical Group Limited (the "Licensor"), with an effective date of July 27, 2022 (the "Effective Date"), pursuant to which the Licensor granted to the Company a worldwide exclusive right and license (outside of the People's Republic of China, Hong Kong, Taiwan and Macau) under certain patents identified in the CSPC License Agreement (the "Licensed Patents") and know-how (collectively, the "Licensed IP") to develop and commercialize products ("Licensed Products") containing EO-3021 (SYSA1801) (the "Licensed Compound") in the treatment of cancer (the "Field").

Subject to certain conditions set forth in the CSPC License Agreement, the Company may grant sublicenses (including the right to grant further sublicenses) to its rights under the CSPC License Agreement to any of its affiliates or any third party. Either party to the CSPC License Agreement may assign its rights under the CSPC License Agreement (i) in connection with the sale or transfer of all or substantially all of its assets to a third party, (ii) in the event of a merger or consolidation with a third party, or (iii) to an affiliate; in each case contingent upon the assignee assuming in writing all of the obligations of its assignor under the CSPC License Agreement.

Under the terms of CSPC License Agreement, the Company paid to the Licensor a one-time upfront license fee of $27.0 million, and is required to pay to the Licensor milestone payments of up to $148.0 million following the achievement of

certain development and regulatory milestones and additional milestone payments of up to approximately $1.0 billion following the achievement of certain commercial milestones.

During the Term (as defined below), the Company is also required to pay to the Licensor (i) royalties ranging from mid-single digits through low double digits on net sales of each Licensed Product and (ii) a percentage of non-royalty sublicense income received by the Company of up to an aggregate of $50.0 million.

Under the terms of the CSPC License Agreement, the development of the Licensed Compound and the first Licensed Product will be governed by a clinical development plan, including anticipated timeline goals in connection with the clinical trials for the first Licensed Product (the "Development Plan"). The Development Plan may be amended by a joint steering committee established by the Company and the Licensor.

The Company will purchase Licensed Products for any clinical or commercial supply from the Licensor under the terms of a supply agreement. Until the Company has completed the first Phase 2 clinical trial for the first Licensed Product in the United States, the Licensor shall supply the Licensed Compound to the Company for clinical purposes as the Company requests, but only to the extent necessary for the Company to conduct such clinical trial, at no cost to the Company.

The CSPC License Agreement will expire automatically upon the expiration of the last royalty term of the last Licensed Product (the "Term"), with each royalty term expiring on a country-by-country basis upon the later of: (i) the expiration or abandonment of the last-to-expire Licensed Patent covering a Licensed Product; (ii) 10 years after the date of first commercial sale in the applicable country; and (iii) expiration of regulatory exclusivity for the Licensed Product in the applicable country. Following the expiration of the Term, the License will become non-exclusive and fully-paid.

The CSPC License Agreement may be terminated by the Company for any reason upon 180 days prior written notice to the Licensor. The Licensor may terminate the CSPC License Agreement if the Company or any sublicensee commences an action challenging the Licensed Patents or following the occurrence of certain change of control transactions. Either party may terminate the CSPC License Agreement (i) for an uncured material breach of the CSPC License Agreement by the other party or (ii) if, at any time, the other party undergoes certain bankruptcy, insolvency or dissolution proceedings.

Merrimack Asset Purchase Agreement

In May 2019, the Company entered into an asset purchase agreement with Merrimack Pharmaceuticals, Inc. (the "previous sponsor"), pursuant to which it acquired all rights and interest to patents, know-how and inventory for assets related to seribantumab, a fully human immunoglobulin G2 monoclonal antibody against HER3.

Pursuant to the asset purchase agreement, the Company made an upfront, non-refundable payment of $3.5 million at closing. If the Company succeeds in finding a partner to develop and commercialize seribantumab, the Company may be obligated to pay the previous sponsor up to $54.5 million in development, regulatory and sales milestone payments.

Under the terms of the asset purchase agreement, the Company assumed the rights and obligations of the following collaboration and license agreements previously held by the previous sponsor:

- *Dyax*—The Company assumed all rights and obligations provided for under the amended and restated collaboration agreement executed between Dyax Corp. ("Dyax") and the previous sponsor (the "Dyax Agreement"). Pursuant to the Dyax Agreement, Dyax utilized its proprietary phage technology to identify antibodies that would bind to targets of interest to the previous sponsor. Additionally, Dyax granted to the previous sponsor a world-wide, non-exclusive, royalty free right to use and make any and all of the antibodies identified by Dyax for certain research purposes. Seribantumab was identified as a result of the research activities performed under the Dyax Agreement.

  Pursuant to the terms of the Dyax Agreement, the Company may be obligated to pay Dyax milestone payments of up to approximately $9.3 million if certain development and regulatory milestones are achieved. In addition,

Dyax is entitled to mid-single digit royalties based on net sales of seribantumab. The Company's obligation to pay royalties to Dyax continues on a product-by-product and country-by-country basis until the later of a specified number of years after the first commercial sale in such country and the expiration of the patent rights covering seribantumab in such country.

The Dyax Agreement will remain in effect, unless earlier terminated, for so long as the Company continues to develop or commercialize seribantumab. Either party may terminate the agreement in the event of an uncured material breach by the other party. The Company also has the right to terminate the agreement in its entirety or on a product-by-product basis at any time upon 90 days' prior written notice.

- *Ligand Pharmaceuticals*—The Company assumed all rights and obligations provided for under the amended commercial license agreement executed between Selexis SA ("Selexis") and the previous sponsor (the "Selexis Agreement"). Pursuant to the Selexis Agreement, the Company received non-exclusive rights to technology for use in the manufacture of seribantumab and may be required to make milestone payments of up to approximately €0.9 million, per licensed product, if certain development and regulatory milestones are achieved. Additionally, Selexis may have the right to obtain a royalty of the greater of €0.2 million annually and less than one percent on net sales of seribantumab. The obligation to pay royalties with respect to each product sold in a country continues until the expiration of the patent rights covering the product in such country. Either party may terminate the agreement in the event of an uncured material breach by the other party. The Company also has the right to terminate the agreement at any time upon 60 days' prior written notice. In November 2021, the Selexis Agreement was assigned to Ligand Pharmaceuticals Incorporated.

- *National Institute of Health*—The Company assumed all rights and obligations provided for under the amended commercial license agreement executed between the U.S. Public Health Service, a division of the U.S. Department of Health and Human Services (the "NIH") and the previous sponsor (the "NIH Agreement"). Pursuant to the NIH Agreement, the Company received non-exclusive rights in the United States to patents related to certain antibodies associated with seribantumab. If certain development and regulatory milestones are achieved, the Company may be obligated to pay NIH additional milestone payments of up to approximately $0.4 million per licensed product.

The Company evaluated the asset purchase agreement with the previous sponsor under ASC Topic 805*, Business Combinations,* and concluded that the transaction did not meet the requirements to be accounted for as a business combination and therefore was accounted for as an asset acquisition. Accordingly, the upfront payment of $3.5 million was expensed as research and development expenses in the statement of operations for the year ended December 31, 2019. Additionally, the Company concluded that all consideration to be paid under the asset purchase agreement is contingent in nature and will be recognized when the respective contingency is resolved. The Company assessed the contingent events which would result in the payment of a milestone as of December 31, 2024 and 2023, and concluded no such payments were required.

Synaffix License Agreement

In September 2024, the Company entered into a license agreement with Synaffix B.V. ("Synaffix") for certain technology for worldwide use in its HER3 ADC program. If this technology is part of a development candidate that is successfully developed and commercialized in the future, the Company would potentially be obligated to pay up to $365.5 million in development, regulatory and commercial milestones and tiered royalties in the low to mid-single digit percentages on net sales of the respective product. The agreement will remain in effect, unless earlier terminated, on a country-by-country basis, until the last expiry of any royalty term for each product in such country.

For the year ended December 31, 2024, the Company incurred $2.5 million under this agreement, which was recorded as research and development expenses in the consolidated statement of operations and comprehensive loss.

12. COMMITMENTS AND CONTINGENCIES

The Company, from time to time, may be involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. The Company was not a defendant in any lawsuits as of December 31, 2024.

13. INCOME TAXES

The Company recorded a current provision for income taxes of less than $0.1 million for each of the years ended December 31, 2024 and 2023. The Company has incurred net pre-tax losses in the United States only for all periods presented. The Company has not reflected any benefit of such net operating loss ("NOL") carryforwards in the accompanying consolidated financial statements. The provision for income taxes differs from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year Ended December 31,	
	2024	2023
Profit before tax at federal statutory rate	21.0 %	21.0 %
State tax benefit, net of federal benefit	0.6 %	0.6 %
Research and development credit carryovers	10.2 %	2.7 %
Stock-based compensation	(1.5)%	(1.5)%
Permanent differences	(0.0)%	(0.0)%
Return to provision true ups	2.0 %	0.6 %
Change in valuation allowance	(32.4)%	(23.5)%
Effective income tax rate	(0.1)%	(0.1)%

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the NOL carryforwards. The Company has recorded a valuation allowance against its deferred tax assets on December 31, 2024 and 2023 because the Company's management believes that it is more likely than not that these assets will not be fully realized in the near future. The increase in the valuation allowance of approximately $14.4 million in the year ended December 31, 2024 primarily relates to the generation of NOLs and research and development credits, and the capitalization of research and development costs that will be amortized in the future.

The Tax Cuts and Jobs Act (TCJA) requires taxpayers to capitalize and amortize research and development costs under Section 174 effective for tax years beginning on or after January 1, 2022. As a result, the Company capitalized $25.2 million and $24.1 million of research and development costs for the years ended December 31, 2024 and 2023, respectively, that will be amortized for tax purposes over five years if performed in the U.S. and over 15 years if performed outside of the U.S.

As of December 31, 2024, the Company had federal NOL carryforwards of approximately $123.9 million, all of which can be carried forward indefinitely, and state NOL carryforwards of $8.6 million, which begin to expire in 2036. The Company also has federal tax credits of $10.8 million and state tax credits of $1.1 million which may be used to offset future tax liabilities and will begin to expire in 2035. NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities.

Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted a study to assess whether a change of ownership has occurred or whether there have been multiple changes of ownership since Inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of ownership, as defined by Section 382 and 383 of the Internal Revenue Code, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to the annual limitations under Section 382 and 383 of the Internal Revenue Code.

Net deferred tax asset (liability) in the accompanying consolidated balance sheets consists of the following (in thousands):

	December 31,	
	2024	2023
Deferred tax assets and (liabilities)		
Net operating losses	$ 26,500	$ 20,243
Research and development expenses	15,494	13,431
Research and development credit	11,636	5,869
Accrued expenses	612	564
Stock-based compensation	348	168
Other	155	148
Intangible assets	5,589	5,511
Gross deferred tax asset	60,334	45,934
Valuation allowance	(60,330)	(45,931)
Net deferred tax asset	4	3
Fixed assets	(4)	(3)
Deferred tax liabilities	(4)	(3)
Net deferred tax asset (liability)	$ —	$ —

The Company will recognize both accrued interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. As of December 31, 2024, all tax returns remain open.

14. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except share and per share data):

	Year Ended December 31,	
	2024	2023
Net loss	$ (44,485)	$ (45,704)
Weighted average common stock outstanding, basic and diluted	57,275,454	36,522,716
Net loss per share, basic and diluted	$ (0.78)	$ (1.25)

As discussed in Note 9, as part of its June 2023 underwritten public offering, the Company issued and sold pre-funded warrants to purchase 4.4 million shares of its common stock, which were exercisable immediately and each of which was exercisable for one share of the Company's common stock. The exercise price of each pre-funded warrant was $0.0001 per share of common stock. As the $0.0001 price per share represents nominal consideration and the pre-funded warrants were immediately exercisable with no further vesting conditions or contingencies associated with them, the weighted average common stock outstanding, basic and diluted, and net loss per share, basic and diluted, for the year ended December 31, 2023, as previously disclosed have been adjusted to reflect the impact of the pre-funded warrants. As of December 31, 2024, all of the pre-funded warrants have been exercised.

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted

net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2024	2023
Outstanding stock options	6,317,063	4,178,194
Unvested RSUs	469,981	155,797
K2 Warrant and Amendment Warrant	394,974	339,725
Common Warrants	22,050,000	22,250,000
Conversion Warrant	1,444,444	—
Convertible Debt (as-converted to common stock)	1,444,444	1,444,444
	32,120,906	28,368,160

15. DEFINED CONTRIBUTION PLAN

The Company has a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. As currently established, the Company is not required to make contributions to the 401(k) Plan. The Company made matching contributions of $0.2 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment,

management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control – Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2024, our internal control over financial reporting is effective based on those criteria.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. For as long as we remain a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act and report less than $100 million of annual revenues in our most recent fiscal year, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2024 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except to the extent provided below, the information required by this Item 10 will be included in the sections captioned "Corporate Governance," "Election of Directors," "Executive Officers" and "Delinquent Section 16(a) Reports," as applicable, in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates (the "Proxy Statement"), which information is incorporated herein by reference.

We post our code of business conduct and ethics, which applies to all employees, including all executive officers, senior financial officers and directors, in the "Governance" sub-section of the "Investor Relations" section (https://investors.elevationoncology.com) of our corporate website at www.elevationoncology.com. Our code of business conduct and ethics complies with Item 406 of SEC Regulation S-K and the rules of Nasdaq. We intend to disclose any changes to the code that affect the provisions required by Item 406 of Regulation S-K, and any waivers of the code of ethics for our executive officers, senior financial officers or directors, on our corporate website.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the section captioned "Executive Compensation" in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 12 will be included in the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 13 will be included in the sections captioned "Certain Relationships and Related Party Transactions" and "Corporate Governance" in our Proxy Statement, which information is incorporated herein by reference.

Item 14. Principal Accountant's Fees and Services

The information required by this Item 14 will be included in the section captioned "Ratification of Appointment of Independent Registered Public Accounting Firm" in our Proxy Statement, which information is incorporated herein by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(1) Consolidated Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

		Incorporated by Reference				
Exhibit No.	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed herewith**
3.1	Restated Certificate of Incorporation, as amended.	10-K	001-40523	3.1	March 6, 2024	
3.2	Amended and Restated Bylaws.	8-K	001-40523	3.1	March 3, 2023	
4.1	Form of Common Stock Certificate.	S-1/A	333-256787	4.1	June 21, 2021	
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	001-40523	4.2	March 3, 2022	
4.3	Amended and Restated Investors' Rights Agreement, dated November 10, 2020, by and among the Registrant and certain of its stockholders.	S-1	333-256787	4.2	June 4, 2021	
4.4†	Warrant to Purchase Common Stock, issued July 27, 2022, to K2 HealthVentures Equity Trust LLC.	10-Q	001-40523	4.1	November 3, 2022	

4.5†	Warrant to Purchase Common Stock, issued March 1, 2024, to K2 HealthVentures Equity Trust LLC.	10-Q	001-40523	4.1	May 2, 2024
4.6	Form of Common Stock Purchase Warrant.	8-K	001-40523	4.1	June 9, 2023
10.1#	Form of Indemnity Agreement.	S-1/A	333-256787	10.1	June 21, 2021
10.2#	2019 Equity Incentive Plan, as amended, and forms of award agreements.	S-1	333-256787	10.2	June 4, 2021
10.3#	2021 Equity Incentive Plan, and forms of award agreements.	S-1/A	333-256787	10.3	June 21, 2021
10.4#	2021 Employee Stock Purchase Plan, and forms of award agreements.	S-1/A	333-256787	10.4	June 21, 2021
10.5†	Asset Purchase Agreement dated May 28, 2019, by and between the Registrant and Merrimack Pharmaceuticals, Inc., as amended.	S-1	333-256787	10.5	June 4, 2021
10.6†	Amended and Restated Collaboration Agreement dated January 24, 2007, between Dyax Corp. and Merrimack Pharmaceuticals, Inc., as amended.	S-1	333-256787	10.6	June 4, 2021
10.7†	Commercial License Agreement dated June 4, 2008, between Selexis SA and Merrimack Pharmaceuticals, Inc.	S-1	333-256787	10.7	June 4, 2021
10.8#	Employment Agreement dated July 12, 2023, by and between the Registrant and Joseph J. Ferra, Jr.	10-Q	001-40523	10.1	November 2, 2023
10.9#	Offer Letter dated March 16, 2022, by and between the Registrant and David Dornan.	10-K	001-40523	10.10	March 9, 2023
10.10#	Employment Agreement dated July 12, 2023, by and between the Registrant and Tammy Furlong.	10-Q	001-40523	10.2	November 2, 2023
10.11#	Employment Agreement dated February 5, 2021, by and between the Registrant and Valerie Malyvanh Jansen, as amended.	10-K	001-40523	10.11	March 3, 2022
10.12#	Form of Change in Control and Severance Agreement.	10-Q	001-40523	10.1	August 6, 2024

10.13†	Loan and Security Agreement, dated July 27, 2022, by and among the Registrant, the lenders, K2 HealthVentures LLC, as administrative agent, and Ankura Trust Company, LLC, as collateral agent.	10-Q	001-40523	10.1	November 3, 2022	
10.14†	First Amendment to Loan and Security Agreement, dated March 1, 2024, by and among the Registrant, the lenders and K2 HealthVentures LLC, as administrative agent.	10-Q	001-40523	10.1	May 2, 2024	
10.15†	License Agreement, dated July 27, 2022, by and between the Registrant and CSPC Megalith Biopharmaceutical Co., Ltd.	10-Q	001-40523	10.2	November 3, 2022	
19	Insider Trading Policy					X
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of CohnReznick LLP, Independent Registered Public Accounting Firm.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32*	Certification of Principal Executive Officer and 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	Policy Relating to Recovery of Erroneously Awarded Compensation.	10-K	001-40523	97	March 6, 2024	
101.INS	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	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).	X

*	This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
†	The Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K and/or has omitted certain portions of this exhibit as permitted under Item 601(b)(10) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.
#	Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELEVATION ONCOLOGY, INC.

Date: March 6, 2025

By: /s/ Joseph J. Ferra, Jr.
Joseph J. Ferra, Jr.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 6, 2025 by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title
/s/ Joseph J. Ferra, Jr. Joseph J. Ferra, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Tammy Furlong Tammy Furlong	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Steven A. Elms Steven A. Elms	Chairman of the Board
/s/ R. Michael Carruthers R. Michael Carruthers	Director
/s/ Julie M. Cherrington, Ph.D. Julie M. Cherrington, Ph.D.	Director
/s/ Timothy P. Clackson, Ph.D. Timothy P. Clackson, Ph.D.	Director
/s/ Darcy Mootz, Ph.D. Darcy Mootz, Ph.D.	Director
/s/ Alan B. Sandler, M.D. Alan B. Sandler, M.D.	Director