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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024.

☐ **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: **001-42195**

OS THERAPIES INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**82-5118368**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
115 Pullman Crossing Road, Suite 103 Grasonville, Maryland	**21638**
(Address of principal executive offices)	(Zip Code)

(410) 297-7793

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	OSTX	NYSE American

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

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

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates, computed by reference to the price at which the common stock was last sold as of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $0.

The number of shares of the registrant's Common Stock outstanding as of March 28, 2025 was 21,663,811 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OS THERAPIES INCORPORATED

TABLE OF CONTENTS

PART I

Cautionary Note Regarding Forward-Looking Statements

This report contains "forward-looking statements" (within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), which may include information concerning our beliefs, plans, objectives, goals, expectations, strategies, anticipations, assumptions, estimates, intentions, future events, future revenues or performance, capital expenditures and other information that is not historical information. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. When used in this report, the words "seek," "estimate," "expect," "anticipate," "project," "plan," "contemplate," "plan," "continue," "intend," "believe" and variations of such words or similar expressions are intended to identify forward-looking statements. All forward-looking statements are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but there can be no assurance that we will realize our expectations or that our beliefs will prove to be correct.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this report. Examples of risks and uncertainties that could cause actual results to differ materially from historical performance and any forward-looking statements include, but are not limited to, the risks described under the section below titled "Risk Factors" of this Form 10-K, as well as any of our subsequent filings with the SEC.

There may be other factors of which we are currently unaware or which we currently deem immaterial that may cause our actual results to differ materially from the forward-looking statements. All forward-looking statements attributable to us or persons acting on our behalf apply only as of the date they are made and are expressly qualified in their entirety by the cautionary statements included in this report. Except as may be required by law, we undertake no obligation to publicly update or revise any forward-looking statement to reflect events or circumstances occurring after the date they were made or to reflect the occurrence of unanticipated events, or otherwise.

We make available through our Internet website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to such reports and other filings made by us with the Securities and Exchange Commission ("SEC"), as soon as practicable after we electronically file such reports and filings with the SEC. Our website address is *www.ostherapies.com*. The information contained on our website is not incorporated by reference into this report.

Note Regarding Intellectual Property

SiLinkers™, CAPs™ and other common law trade names, trademarks or service marks of our company appearing in this report are the property of OS Therapies Incorporated. This report contains additional trade names, trademarks and service marks of other companies that are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this annual report appear without ™ symbol, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owners will not assert their rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship by us of, these other companies.

Item 1. Business.

Overview and Mission

OS Therapies Incorporated ("OS Therapies," the "Company," "we," "our" or "us") is a clinical stage biopharmaceutical company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. Our mission is to address the significant need for new treatments in cancers of the bone in children and young adults. Osteosarcoma is an extremely challenging and often aggressive cancer that has particular treatment challenges due to its location, changing genotypes and high recurrence rates. We are currently seeking to answer the call for new treatments with our lead core product candidate OST-HER2 (also

known as OST31-164). We intend to expand our pipeline beyond Osteosarcoma with this product candidate into other solid tumors with the same recurrence mechanism of action, including breast, esophageal and lung cancers. With the addition of our OST-Tunable Drug Conjugate (OST-tADC) platform, which we consider to be a next generation antibody-drug conjugate (ADC) technology, we will be targeting ovarian, lung and pancreatic cancers. "Tunable" is a term used in drug development that refers to the properties that can be influenced by chemical modifications, and "antibody-drug conjugate" or ADC is a term used to describe a drug made up of a monoclonal antibody attached to a cytotoxic payload, or a highly active and toxic pharmaceutical molecule, through chemical linkers. The ADC links an antibody that can home in on a targeted tumor like and deploy the cytotoxic payload or toxic agent against the tumor. Furthering our founding mission, we also intend to investigate clinical indications for OST-tADC in Osteosarcoma.

We believe that there have not been any new treatments approved by the U.S. Food and Drug Administration (FDA) for Osteosarcoma for more than 40 years. In humans, Osteosarcoma is an extremely rare cancer that primarily affects children, teenagers and young adults generally under 40 years of age. We are not aware of any competing adjuvant therapy for Osteosarcoma to be tested in children that is further along in the development process than OST-HER2. This disease is difficult to diagnose. The standard of care following first line therapies is simply to screen and wait for possible recurrence/metastasis, or the development of secondary malignant growths at a distance from a primary site of cancer. Studies published in the Journal of Clinical Oncology, "Osteosarcoma Relapse After Combined Modality Therapy: An Analysis of Unselected Patients in the Cooperative Osteosarcoma Study Group (COSS)," by Kempf-Bielack B., et al. (January 2005), and "Second and Subsequent Recurrences of Osteosarcoma: Presentation, Treatment, and Outcomes of 249 Consecutive Cooperative Osteosarcoma Study Group Patients," by Bielack S., et al. (February 2009), reported that recurrence/metastasis happens in approximately half of all patients within 12 to 18 months following initial remittance. For those patients that experience recurrence, metastasis is typically to the lungs and brain, with survival rates of approximately 13% over the next year, according to these studies.

Pipeline of Our Product Candidates

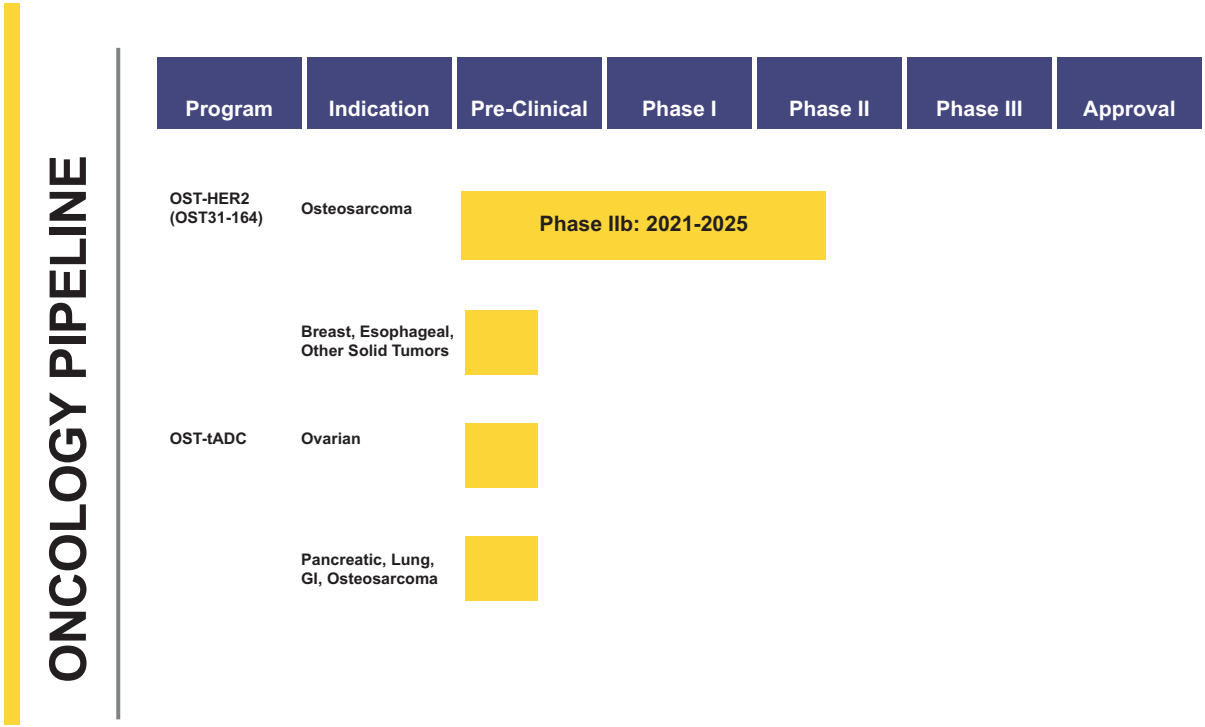
We have built a pipeline of product candidates targeting multiple indications for solid cancers. Our pipeline includes two drug technologies: (i) OST-HER2, an off-the-shelf immunotherapy, which is a type of cancer treatment that helps one's immune system fight cancer, comprised of a genetically weakened and modified strain of *Listeria monocytogenes*, a species of bacteria that causes the infection listeriosis, that expresses HER2 peptides, and (ii) OST-tADC, a next generation tunable ADC with a plug-and-play platform that features tunable pH sensitive silicone linkers (SiLinkers). The payloads may include antibodies, chemotherapeutics, cytotoxins and potentially mRNA treatments directly into and in the vicinity of solid tumors.

OST-HER2 (OST31-164). Our most advanced product candidate, OST-HER2, is a genetically engineered strain of *Listeria monocytogenes*, attenuated for reduced virulence, increased antibiotic susceptibility and the expression of three HER2 protein epitopes fused to immune-enhancing peptides on the membrane of the bacteria. OST-HER2 has received an orphan drug designation in the United States. The FDA may designate a biologic product as an orphan product if it is intended to treat a rare disease or condition, which generally is defined as having a patient population of fewer than 200,000 individuals in the United States. Osteosarcoma has an incidence rate of new cases of approximately 1,000 individuals affected per year in the United States. Orphan product designation, subject to limited exceptions, can provide a period of market exclusivity for a product that is the first to receive marketing approval for the designated indication. Other potential indications may include breast, esophageal, lung and other solid tumors. In August 2021, OST-HER2 was awarded rare pediatric disease designation and previously received fast track designation by the FDA. In May 2024, we submitted a request to the FDA for breakthrough therapy designation for OST-HER2. Such designations by the FDA do not convey any advantages or shorten the duration of the regulatory review or approval process.

OST-tADC. Our tunable drug conjugate (tADC) platform is currently in preclinical development. Each tADC contains four main components: ligand, payload cassette adaptor, linker and payload. In addition, tADCs contain units to optimize physicochemical properties. The ligands are selected to bind to receptors overexpressed on cancer cells. Upon binding, the tADC construct gets internalized into the cancer cell, where the payload is released, to cause cell death. The payload cassette adaptors enable the stoichiometrical attachments of linkers and payloads. The SiLinkers represent a novel and pH-sensitive linker system. The SiLinker release profile can be tuned with proximal functional groups, resulting in payload release in the endosome, lysosome or the slightly acidic tumor microenvironment. The SiLinker system is compatible with a variety of payloads and not limited to the employment of cytotoxic drug delivery.

The first set of internal programs focus on the use of SiLinker and conditionally active payloads (CAPs™) drug products. CAPs are cytotoxic drugs which on their own, due to their functional groups, cannot readily permeate cells at physiological pH; however, at the slightly acidic pH of the tumor-microenvironment, after some linker cleavage, these payloads readily permeate into cancer cells, resulting in an enhanced bystander effect. Our lead program targets folate receptor alpha, a protein expressed on the surface of cells that participates in cell signaling, as well as cellular replication and division, and is overexpressed in multiple cancers such as ovarian and endometrial cancers. The lead compound employs folic acid, a small molecule, as the targeting ligands and contains six exatecan-silanols, which is a type of silanol-based cytotoxic payload, as payloads. This discovery work is being carried out at Syngene International Limited, an integrated contract research organization (CRO) based in Bangalore, India.

From time to time, we may evaluate collaboration opportunities for our product candidates. We expect to work opportunistically with pharmaceutical and biotechnology companies, as we have done with BlinkBio, Inc. by in-licensing the OST-tADC technology, seeking to utilize our technology and know-how for developing additional oncologic drug products. The following table summarizes information regarding our product candidates and development programs.



In addition to our development of OST-HER2 for multiple indications of solid cancers in humans, OST-HER2 is a product candidate for veterinary use in canines. As part of our growth strategies, we intend to consider potentially out-licensing OST-HER2 to animal health companies for such use. See "*OS-Focused Clinical Trials and Studies — Preclinical Animal Study*" for more information.

Our Pending Acquisition of HER2 and *Lm*-Related Assets

On January 28, 2025, we entered into an Asset Purchase Agreement (the "HER2 Purchase Agreement") with Ayala Pharmaceuticals, Inc., a Delaware corporation formerly known as Advaxis, Inc. ("Ayala"), pursuant to which we agreed, subject to the terms and conditions set forth therein, to acquire from Ayala *Lm*-based immuno-oncology programs and related intellectual property assets (collectively, the "HER2 Assets"). The HER2 Assets include two investigational new drug (IND) filings with the FDA: (i) ADXS-503 for non-small cell lung cancer; and (ii) ADXS-504 for prostate cancer. The closing of the transaction, which we expect to in the second quarter of 2025, is subject to assignment of a license between Ayala and the Trustees of the University of Pennsylvania (the "Penn License"), execution and delivery of a patent assignment agreement, a termination of license agreement, a lock-up agreement and a registration rights agreement, the approval of the transaction by Ayala stockholders and other customary closing conditions.

Our OS-Focused Clinical Trials and Studies

We and our licensors have conducted a number of clinical trials and studies in the field of Osteosarcoma and Tunable Drug Conjugates to date.

Phase IIb Clinical Trial. In July 2021, a Phase IIb clinical trial to treat Osteosarcoma in humans was commenced and sponsored by us and conducted by George Clinical, Inc., our clinical research services provider, utilizing our OST-HER2 product candidate. The course of the trial involved a regimen of 16 infusions of OST-HER2 administered over 48 weeks to 41 eligible patients from ages 12 to 39 years. As of September 30, 2024, the treatment phase of the trial has been completed, and patients are now being followed for long-term survival. This Phase IIb trial was conducted at major hospitals across 21 sites in 18 states.

On January 15, 2025, we announced that our Phase IIb clinical trial achieved its primary endpoint with statistical significance. The primary outcome measures were the relative proportion of patients experiencing event-free (recurrence-free) survival at 12 months ("Responders") compared to the best available historical control group from U.S. published literature (the "Published Control") by evaluating the patients for recurrence every 3 months, consistent with the standard of care. Trial results showed that 33% of OST-HER2 treated patients were Responders compared to 20% in the Published Control.

The secondary outcome measures were overall survival of patients for three years compared to the three-year overall survival of the Published Control, which will be evaluated by assessing patients every three months over the course of three years, and the incidence of treatment-emergent adverse events as assessed by Common Terminology Criteria for Adverse Events (CTCAE) Grade 5, the safety of which will be assessed throughout the treatment period of 48 weeks with assessments of potential persistence of the vector every three months and continuing for three years after treatment. CTCAE is a method to categorize adverse events across all clinical trials of five grades, with Grade 5 being death. Trial results showed a higher proportion of OST-HER2 treated patients were alive at the 12-month (91% vs. 80%) and 24-month (61% vs. 40%) post-resection timepoints relative to the Published Control. Notably, 100% of patients who were disease-free at 12 months remained alive at 12, 18, 24, and 30 months at their last follow-up. OST-HER2 was well tolerated with a safety profile supportive of regulatory approval; no treatment-emergent adverse events classified as CTCAE Grade 5 (death) were observed.

We believe the efficacy results, combined with the favorable safety profile and the unmet clinical need, support the potential for regulatory approval. We plan to request a Type B or Type C FDA meeting in the first quarter of 2025 to discuss the data and the path to a BLA. Subject to positive FDA feedback, we plan to submit a BLA with the FDA CBER for approval to market the drug candidate in the second quarter of 2025. The FDA generally takes six to ten months to complete its review of a BLA, subject to any FDA request for additional information. We believe that it remains uncertain whether a Phase III clinical trial will be necessary for the advancement of OST-HER2 through the regulatory approval process. We will not know whether a Phase III trial will be required until we receive a determination from the FDA following the filing of a BLA for marketing approval as to whether the results of our ongoing Phase IIb trial provided sufficiently positive endpoint data.

Phase Ib Clinical Trial. From September 2015 to May 2017, a Phase Ib trial to treat Osteosarcoma in humans was sponsored and conducted by Advaxis utilizing ADXS-HER2 (also known as ADXS31-164), the patents of which we agreed to purchase from Ayala to develop and commercialize our lead core product candidate, OST-HER2. The Phase Ib was a multicenter, open-label, dose-escalation study designed to estimate the maximum tolerated dose (MTD) and determine the recommended Phase II dose of ADXS-HER2. The trial was conducted at hospitals in Colorado, Michigan, North Carolina, Pennsylvania and Texas. The course of the trial involved injecting 12 adult patients with HER2 expressing solid tumors with escalating doses of ADXS-HER2 every three weeks during a 12-week treatment cycle. Following the last dose of study treatment, all 12 patients participated in a three-year *Listeria monocytogenes* surveillance period.

The primary outcome measures were the number of patients with dose-limiting toxicities for each dose level as assessed by the CTCAE Grade 4 (time frame: four months), with Grade 4 being life threatening, and the frequency and severity of adverse effects as assessed by CTCAE Grade 4 (time frame: three years). The secondary outcome measures were (i) proportion of patients who have objective tumor response (complete or partial) evaluated by the Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 and RECIST-based immune criteria (ir-RECIST) and (ii) changes in clinical immunology based upon serum, which were measured and evaluated by collection of peripheral blood for preparation of peripheral blood mononuclear cells and serum at baseline, prior to each treatment and post-treatment in

the first treatment cycle only. The results of this study were primarily intended to describe the safety and tolerability of ADXS-HER2. This study was not intended to contribute to the evaluation of the effectiveness of ADXS-HER2 for the treatment of patients with a history of HER2 expressing tumors. Overall, the data presented from this Phase Ib trial demonstrated that ADXS-HER2 IV infusion at the dose of 1×10^9 CFU appeared to be well tolerated in 12 subjects treated and evaluable with no evidence of dose-limiting toxicities. No objective tumor responses (complete or partial) were observed in this late stage, heavily pre-treated patient cohort. Based on the data presented, the recommended Phase II dose of ADXS-HER2 was determined to be $1x10^9$ CFU as it was well tolerated.

Preclinical Animal Study. From July 2012 to September 2015, a preclinical study to treat Osteosarcoma in 18 companion canines (sometimes referred to as a Phase I animal trial) was sponsored and conducted by a previous licensee of Advaxis utilizing ADXS-HER2, the product candidate of Advaxis, from whom we agreed to purchase patents for ADXS-HER2 constructs that enable us to develop OST-HER2. The results showed, in the setting of minimal residual disease where there is a very small number of cancer cells remaining in the body during or after initial treatment, significant improvements in overall survival and metastatic disease progression when compared to an historical control group with Human Epidermal Growth Factor Receptor 2-positive (HER2) appendicular Osteosarcoma, a well-recognized spontaneous model for pediatric Osteosarcoma, treated with amputation and chemotherapy alone. In September 2016, the study results, published in the journal, Clinical Cancer Research, "Immunotherapy with a HER2-Targeting Listeria Induces HER2-Specific Immunity and Demonstrates Potential Therapeutic Effects in a Phase I Trial in Canine Osteosarcoma," by Mason, N. et al. (*https://pubmed.ncbi.nlm.nih.gov/26994144/*), indicated that ADXS-HER2 significantly increased the duration of survival time and one-, two- and three-year survival rates and significantly reduced the incidence of metastatic disease (the spread of cancer cells from an initial or primary site to a different or secondary site within the host's body) when compared with the historical control group. The overall survival rates at one, two and three years for dogs treated with ADXS-HER2 were 77.8%, 67% and 56%, respectively, compared to 55%, 28% and 22%, respectively, for the historical control group. The median survival time (MST) for the historical control group was 423 days, which was significantly shorter than the 956 days for ADXS-HER2 — treated dogs (p=0.014, HR 0.33; 95% confidence intervals; CI, 0.136 – 0.802). The study also noted the important translational relevance of the findings for children with Osteosarcoma. This study for canine Osteosarcoma indications constituted preclinical work as it relates to our development of OST-HER2 to treat Osteosarcoma in humans.

In analyzing preclinical study results, a p-value is used to determine the probability as to whether the difference between two data sets is due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. The FDA's evidentiary standard of efficacy generally relies on a p-value of less than or equal to 0.05. A p-value greater than 0.05 is considered statistically non-significant. As shown above, the results of this preclinical study were statistically significant compared to the historical control group.

Following the study, an application for the use of ADXS-HER2, our OST-HER2, in the treatment of canine Osteosarcoma was submitted to the USDA. In December 2017, ADXS-HER2 was granted a conditional license by the USDA. Because we are the current licensee of ADXS-HER2 constructs, we held the conditional license previously granted to ADXS-HER2 for OST-HER2. The conditional license allowed for commercialization but limited the use of OST-HER2 to treat dogs, one year of age and older, diagnosed with Osteosarcoma. We allowed such conditional license to lapse as a result of improvements made in our manufacturing process that would improve the performance in canines, and we plan to request from USDA a new conditional license for the product once we have contracted for manufacture with a suitable USDA licensed contract manufacturer. To receive full licensure, the USDA requires the submission of additional data that further describes the effects of OST-HER2 on metabolism and shedding in canines and provides substantial evidence of the safety, purity, potency and effectiveness of OST-HER2. We are currently evaluating the best path to development.

Preclinical Development. Our OST-HER2 product candidate for breast, esophageal, lung and other solid tumor indications is currently in preclinical development. Whether additional preclinical trials will be required will depend on several factors, including the outcome of our ongoing Phase IIb clinical trial, the inclusion or exclusion of breast, esophageal, lung or other solid tumor indications in any follow-on study, or master protocol, to the Phase IIb clinical trial and the FDA's determination of whether the preclinical data is sufficient to support the safety and efficacy of the drug. Although we cannot be certain, we believe that OST-HER2 may not require additional preclinical development before progressing to human clinical trials for breast, esophageal, lung and other solid tumor indications if the results of our ongoing Phase IIb clinical trial have sufficiently positive endpoint data as determined by the FDA.

Our OST-tADC product candidate for all indications is also currently in preclinical development. We will need to conduct further preclinical trials for OST-tADC prior to the submission of an IND in order to pursue clinical trials with these candidates. Such preclinical trials are expected to include pharmacokinetics and pharmacodynamics, two-week dose finding toxicology studies in vivo (on living cell lines or in living animals), as well as good laboratory practice (GLP) trials ensuring stability, potency and purity of the IND product candidate.

Our Technology Platform

We are in the process of building a fully integrated platform technology to accelerate the development of a range of product candidates across multiple therapeutic areas. Our platform technology is intended to leverage our management's in-depth experience in immunotherapy research, development and manufacturing to enable us to pursue multiple therapeutic targets. Our scientists and scientific advisors have accumulated decades of collective experience in the field of immunotherapy, oncology and small-molecule drug production, contributing key insights and significant achievement in our clinical development process.

Our Growth Strategies

Our goal is to enrich and lengthen the lives of patients by being a leading, fully integrated biotechnology company. We are seeking to develop, manufacture and commercialize multiple product candidates targeting orphan and non-orphan oncologic diseases across multiple tissue types and therapeutic areas. To achieve our goal, we are pursuing the following growth strategies:

- Consider potentially out-licensing OST-HER2 to animal health companies for veterinary use to treat dogs diagnosed with Osteosarcoma, one year of age or older.
- Obtain marketing approval for OST-HER2 in Osteosarcoma, then quickly pivot to a master protocol within breast, esophageal, lung and other solid tumors where metastases express HER2 that could be targeted by immune cells.
- Conclude pre-clinical and toxicology trials with the lead drug candidate for OST-tADC (OST-tADC-A, Exatecan-silanol-FRa), and file for an IND to initiate a Phase I trial in ovarian cancer and other folate receptor alpha overexpressing cancers like endometrial cancer and some osteosarcomas. We believe that positive results from preclinical two-week and good laboratory practice (GLP) toxicology studies may also stimulate potential out-licensing activity of SiLinker and CAPs drug products, while not limiting therapeutic development.
- Establish global commercial and medical affairs capabilities for OST-HER2 based therapies.

Expansion Opportunities

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary products or technologies or acquisitions of companies with complementary products or technologies. While we have current collaborative agreements in place, we believe in an opportunistic approach to collaboration and licensing; thus, we expect to operate in a manner that is customary in the pharmaceutical industry, including potential acquisitions and partnerships.

We are also aware of increased acquisition and licensing interest from large pharmaceutical firms in biotechnology companies developing ADC technology as a relatively new kind of cancer therapy. In the article, "Seagen Cancer Therapy Draws Suitors" (March 7, 2023), The Wall Street Journal reported that driving this interest, according to analysts, is the potential for ADCs to capture a chunk of the worldwide cancer market. Technical advances by combining the ADCs with widely used cancer agents like immunotherapies have also opened up exploring various potential cancer applications, according to the article.

Our Scientific Collaborations

Scientific Collaborators. We collaborate with experts and physicians to help advance our programs and, together, we are focused on translational strategies to support the clinical study of our new therapy candidates. These collaborations support our goals to translate deep expertise in structure-based drug design into a novel portfolio of precisely targeted therapies. We strive to address medical needs for patients with cancer harboring resistance mutations

in driver kinases using technology originally developed at the University of Pennsylvania under the guidance of Dr. Robert G. Petit, our Chief Medical and Scientific Officer. Our partnering approach with physician-scientists allows us to understand the limitations of existing therapies, which we believe will lead to product candidates that address the dual needs of treatment resistance and kinase selectivity. OST-HER2's compositions and methods of use are covered by three granted U.S. utility patents and one granted Japanese patent that we in-license through our development license and supply agreement with Advaxis and were developed at the University of Pennsylvania and are owned by the University of Pennsylvania, either jointly with Advaxis or solely by the University. See "*Our Licensing Agreements — Advaxis*" and "*Our Intellectual Property*" below.

We have also established collaborations through service agreements with global CROs to provide scale and expertise in research chemistry, chemical manufacturing, biology, pharmacology and toxicology, and clinical studies.

Scientific Advisory Board. We have established a scientific advisory board comprised of seven members with extensive experience in the field of oncology. Our scientific advisors include researchers who publish widely cited research on topics relevant to the study and treatment of cancer, lead clinical units at experienced precision medicine cancer centers in the United States and are actively involved in our drug development process and programs. Our scientific advisory board meets periodically with our board of directors and management to discuss matters relating to our business activities and to establish commercial business alliances. Members of our scientific advisory board are reimbursed by us for out-of-pocket expenses incurred in connection with serving on our advisory board.

Our scientific advisory board currently includes the following physicians and their professional affiliations:

- Nabil M. Ahmed, MD — Texas Children's Hospital
- Peter M. Anderson, MD — Cleveland Clinic
- Doug S. Hawkins, MD — Seattle Children's Hospital
- Meenakshi Hedge, MD — Texas Children's Hospital
- Alejandro Sweet-Cordero, MD — University of California San Francisco
- Brenda Weigel, MD — Masonic Cancer Center — University of Minnesota
- Felasfa M. Wodajo, MD — Inova Fairfax Hospital, Virginia

Patient Advocacy Advisory Board. We have established a patient advocacy advisory board comprised of four members with experience dealing with the effects of Osteosarcoma. This board is responsible for reviewing and establishing our patient advocacy philosophy and policy. This board also develops procedures for patient care evaluation while adhering to regulatory standards. This board identifies gaps in patient care and represents patient interests at FDA meetings, ensuring that patient voices are heard in regulatory discussions. Members of our patient advocacy advisory board are reimbursed by us for out-of-pocket expenses incurred in connection with serving on such board and sign customary non-disclosure agreements.

Our patient advocacy advisory board currently includes the following individuals and their affiliations:

- Miriam Cohen — Founding Member, Chairperson and President of Osteosarcoma Collaborative
- Olivia Egge — Founding Member, Counsel and Patient Advocate of Osteosarcoma Collaborative; Graduate student at Columbia University School of Professional Studies; Osteosarcoma Survivor
- Mac Tichenor — President of Osteosarcoma Institute
- Tony Trent — President of The Tyler Trent Foundation

ADC Advisory Board. We have established an ADC advisory board comprised of two members with extensive experience with ADC technologies. This board is responsible for reviewing and establishing our strategy and policies related to ADCs and helps to design and implement procedures for evaluating the efficacy and safety of our ADC technologies, ensuring compliance with regulatory standards. This board identifies opportunities to enhance ADC technology and address challenges in development, contributing to the advancement of innovative therapies in the field. Members of our ADC advisory board are reimbursed by us for out-of-pocket expenses incurred in connection with serving on such board and sign customary non-disclosure agreements.

Our ADC advisory board currently includes the following professionals and their affiliations:

- Borys Shor, Ph.D. — President and Chief Executive Officer of Manhattan BioSolutions, Inc.
- Jutta Wanner, Ph.D. — Senior Vice President of Drug Discovery at Alpha-9 Oncology, Inc.

Some of the members of our advisory boards may serve as consultants under consulting agreements for which they will receive compensation. To date, however, none of our advisory board members has served as consultants to us, and we have not entered into any consulting agreements with any of them. To our knowledge, none of our advisory board members has any conflict of interest between their obligations to us and their obligations to others. Hospitals, medical centers and companies with which advisory board members are involved may in the future have commercial relationships with us.

Our Licensing Agreements

Advaxis. In November 2020, we entered into an amended and restated development, license and supply agreement with Advaxis, pursuant to which Advaxis granted a license to us that allows us to utilize Advaxis' ADXS-HER2 construct patents to develop and commercialize ADXS-HER2, our lead product candidate (OST-HER2). On January 28, 2025, we entered into the HER2 Purchase Agreement with Ayala, pursuant to which we agreed, subject to the terms and conditions set forth therein, to acquire from Ayala the HER2 Assets.

The closing of the transaction, which we expect to occur in the second quarter of 2025, is subject to assignment of the Penn License, execution and delivery of a patent assignment agreement, a termination of license agreement, a lock-up agreement and a registration rights agreement, the approval of the transaction by Ayala stockholders and other customary conditions.

BlinkBio. In August 2020, we entered into a licensing agreement with BlinkBio, Inc., pursuant to which BlinkBio granted a license to us that allows us to utilize BlinkBio's proprietary technology to develop, manufacture and commercialize certain of our products. BlinkBio granted us an exclusive license for tADC's that are directed towards, binds to or modifies the folate receptor alpha and a co-exclusive license for tADC's that are directed towards, binds to or modifies any target other than the folate receptor alpha, such as HER2. In connection with the license agreement, we also agreed to issue a convertible note to BlinkBio.

See "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for more information on our licensing agreements and the BlinkBio convertible note.

Our Research Services Agreement

George Clinical. In June 2020, we entered into a services agreement, as amended, with George Clinical, Inc., a clinical contract research organization. Pursuant to this agreement, we engaged George Clinical to use its clinical research services for our study entitled "An Open Label, Phase 2 Study of Maintenance Therapy with OST-HER2 after Resection of Recurrent Osteosarcoma."

See "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for more information on our research services agreement with George Clinical.

Our Intellectual Property

Our commercial success depends in part on our ability and the ability of those third parties from whom we in-license patents to obtain and maintain intellectual property protection in the United States and other countries for our current or future product candidates, including our lead core product candidate OST-HER2, our other core product candidate OST-tADC, our non-core product candidates, our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, in-licensing patents and patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

Although we have agreed to acquire the HER2 Assets pursuant to the HER2 Purchase Agreement, we do not currently own any issued patents. We in-license patents and patent applications related to our lead core product candidate OST-HER2 from Advaxis, Inc. and our other core product candidate OST-tADC from BlinkBio, Inc. The intellectual property licensed from Advaxis, Inc. includes nine granted U.S. utility patents and a number of foreign patents and pending patent applications. The patents and patent applications if granted are expected to expire between 2030 and 2035, not including any patent term extension. The intellectual property licensed from BlinkBio, Inc. includes six granted U.S. utility patents and a number of foreign patents and pending patent applications. The patents cover methods of use of silicon based drug conjugates and silanol based therapeutic payloads. The patents and pending patent applications if granted are expected to expire between 2036 and 2037, not including any patent term extension.

We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position in the field of oncology. Our future plans also include reliance on data exclusivity, market exclusivity and patent term extensions when available.

The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of the patents that we in-license have, or that any of such pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect OST-HER2 and OST-tADC or our other current or future product candidates. In addition, if the breadth or strength of protection provided by such patent applications or any patents we may in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our ability to stop third parties from making, using, selling, offering to sell or importing products identical or similar to ours will depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. The patent rights of biotechnology and pharmaceutical companies like ours are generally uncertain and can involve complex legal, scientific and factual issues. Our and any future licensor's current and future patent applications may not result in the issuance of any patent in any particular jurisdiction, and the claims of any current or future issued patents, even if those claims are valid and enforceable, may not provide sufficient protection from competitors. Any owned or in-licensed patent rights we may obtain may not enable us to prevent others from replicating, manufacturing, using or administering our product candidates for any indication. Moreover, the coverage initially claimed in a patent application may be significantly reduced before a patent is issued, and a patent's scope can be reinterpreted after issuance. In addition, any patent we may own or in-license may be challenged, circumvented or invalidated by third parties. As a result, we cannot ensure that any of our product candidates will be protected by valid and enforceable patents. See "*Risk Factors — Risks Related to Our Intellectual Property*" for a more comprehensive description of risks related to our intellectual property.

Our Commercialization Strategy

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. We believe that such a focused sales and marketing organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Clinical data, the size of the addressable patient population and the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Our Future 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 manufacture of our product candidates for preclinical and 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.

All of our product candidates are biopharmaceuticals and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale-up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Currently, the OST-HER2 active pharmaceutical ingredients (API) (e.g., clinical drug substance) are manufactured in accordance with GMPs. The drug product formulation is being developed with the goal of producing lyophilized therapeutics with consistent and immediate release dissolution profiles that can be reproducibly manufactured using automated equipment. All manufacturing activities for the OST-HER2 drug product are performed in accordance with GMPs. We currently rely on these vendors as single-source contract manufacturing organizations.

We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third party ReciBioPharma, a chemical manufacturer, will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs.

As we advance our product candidates through development, we will explore adding backup suppliers for the OST-tADC and drug product for each of our product candidates to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics that we may develop.

Government Regulation

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries.

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

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

Clinical Trials

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ("GCP") an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites and are designed to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug when considering whether a drug satisfies the statutory standard for commercialized. Clinical trials must be approved in the United States by an Institutional Review Board ("IRB"), an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of the human research subject. In other countries, clinical trials may be subject to review and approval by ethics boards similar to IRBs.

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 the FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions or sanctions.

The FDA's current good manufacturing practices (cGMPs) apply to drug product candidates in Phase II and Phase III clinical trials; thus, the product candidates in those trials must be manufactured in compliance with cGMPs.

Marketing Approval

Before we can commercialize any of our current or future product candidates, we must obtain marketing approval. We have not received approval to market any of our current product candidates. We expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication and line of treatment to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and further requires inspection of manufacturing facilities by, the relevant regulatory authority.

The process required by the FDA before biopharmaceuticals may be marketed in the United States generally involves the following:

- nonclinical laboratory and, at times, animal tests;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and some clinical trial sites; and
- FDA approval of an NDA or a BLA, which must occur before a drug or biologic product can be marketed or sold.

We are not permitted to market our current or future product candidates until we receive approval of a BLA from the FDA CBER in the United States or a marketing authorization application from the European Medicines Agency in the European Economic Area or until we receive approval of comparable agencies in other foreign countries.

Post-Market Requirements

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and Good Clinical Practices ("GCPs") for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of

approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or drug recalls;
- fines, warning or other letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

In order to produce our product candidates for clinical trials and our products, if any, for commercial purposes, either at our own facility or at a third-party's facility, we and our third party vendors will need to comply with the FDA's cGMP regulations and guidelines. As part of our ongoing quality and process improvement efforts, we conducted a gap analysis of our cGMP quality system and it identified certain key areas for necessary remediation, including with regard to documentation requirements. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements.

Animal Health Products

Certain U.S. federal regulatory agencies are charged with oversight and regulatory authority of animal health products in the United States. These agencies, depending on the product and its intended use, may include the FDA, the U.S. Department of Agriculture ("USDA") and the U.S. Environmental Protection Agency ("EPA"). The FDA Center for Veterinary Medicine ("CVM") regulates animal pharmaceuticals under the Food, Drug and Cosmetics Act. The EPA is responsible for regulating pesticides, which include some products used for controlling pests and diseases in animals.

U.S. Department of Agriculture. The regulation of veterinary biologics is overseen by the USDA, specifically the USDA Animal and Plant Health Inspection Service ("APHIS") and the USDA Center for Veterinary Biologics ("CVB"). The APHIS and CVB are responsible for regulating veterinary vaccines and some biologics pursuant to the Virus-Serum-Toxin Act. The APHIS is responsible for protecting animal health by regulating the importation, interstate movement and environmental release of veterinary biologics. This includes overseeing the importation and exportation of veterinary biologics, issuing permits for the movement of these products across state lines, and regulating the release of genetically engineered veterinary biologics into the environment. The CVB is responsible for ensuring the safety, purity, potency and efficacy of veterinary biologics, including vaccines, diagnostics, and other biologics used in animals. The CVB evaluates the safety and efficacy of these products before granting them approval for use in animals. The CVB also oversees the manufacturing, testing, labeling and distribution of veterinary biologics and monitors their ongoing safety and effectiveness.

USDA Center for Veterinary Biologics. The CVB reviews and approves applications for veterinary biologics, including vaccines, immunomodulators, diagnostic kits and other biologic products. The CVB evaluates the safety, efficacy and quality of each product and grants licenses for products that meet the necessary regulatory requirements. The licensure process for veterinary biologics involves several key steps, including:

- Pre-License Evaluation. Before a veterinary biologic can be licensed, the manufacturer must submit an application to the CVB. The CVB reviews the application and evaluates the data on the product's safety, efficacy and quality. This evaluation may include laboratory studies, field studies and other relevant information.
- Licensing Decision. Based on its evaluation, the CVB may grant a license for the product or require additional data or studies before making a final decision. If the CVB determines that the product meets all necessary regulatory requirements, it grants a license for the product.

- Labeling. Once a product is licensed, the manufacturer must submit labeling for the product to the CVB for approval. The labeling must include specific information on the product's indications, dosage, administration, contraindications and warnings.

- Manufacturing Standards. The CVB establishes and enforces manufacturing standards for veterinary biologics, including requirements for facilities, equipment and procedures. The CVB conducts inspections of manufacturing facilities to ensure compliance with these standards and may revoke licenses for manufacturers that fail to comply.

- Post-Licensure Surveillance. The CVB monitors veterinary biologics after they are licensed to detect and respond to any safety or efficacy issues that may arise. The CVB may require manufacturers to conduct post-licensure surveillance studies or to report adverse events associated with their products.

Conditional licenses are used to meet an emergency condition, limited market, local situation or other special circumstance. A product may be granted a conditional license if it has demonstrated a reasonable expectation of efficacy and safety, but additional data is needed to fully evaluate its efficacy and safety. To be eligible for conditional licensure, a veterinary biologic must meet certain regulatory criteria, including:

- the product must be intended for use in a target species for which there is a significant need;

- the product must have demonstrated a reasonable expectation of efficacy and safety based on preclinical and/or field studies;

- the product must have an acceptable safety profile; and

- the manufacturer must submit a plan for follow-up studies to address the data gaps or uncertainties identified during the evaluation process.

A product with conditional licensure can be marketed and sold, but it must be labeled with specific conditions, such as limitations on use, required follow-up studies and other specific instructions for use. The product label must also clearly state that the product has been conditionally licensed and that additional data is required to fully evaluate its efficacy and safety. The manufacturer must continue to collect data on the safety and efficacy of the product and submit it to the CVB for review. The CVB may require additional studies or data to be submitted before granting full licensure. To obtain full licensure for a veterinary biologic product that has been granted conditional licensure by the CVB, the manufacturer must meet the follow-up study requirements specified in the conditional license and submit additional data to the CVB demonstrating the safety and efficacy of the product, which may include results from additional studies, post-marketing surveillance data and other relevant information.

In addition to granting licenses, the CVB is responsible for establishing and enforcing manufacturing standards for veterinary biologics, including requirements for facilities, equipment, and procedures. The CVB conducts inspections of manufacturing facilities to ensure compliance with these standards and may revoke licenses for manufacturers that fail to comply. The CVB also monitors veterinary biologics after they are marketed to detect and respond to any safety or efficacy issues that may arise. The CVB may require manufacturers to conduct post-marketing surveillance studies or to report adverse events associated with their products.

Other Healthcare Laws

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, including physicians, play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, as well as third-party payors and other 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 market, sell and distribute our current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

Anti-Kickback Statute. The 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 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 federal and state healthcare programs such as Medicare, Medicaid and TRICARE.

False Claims Act. The False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act.

Analogous State Laws. Analogous state laws and regulations, such as state 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; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act, or the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

On September 24, 2020, the FDA released a final rule effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada.

The Inflation Reduction Act ("IRA") was passed into law on August 16, 2022. The drug pricing reform section of the IRA represents a sweeping change with respect to how the Medicare program will pay for prescription drugs in the future. The IRA drug pricing provisions will be phased in by 2029. Medicare will negotiate a "maximum fair price" directly with manufacturers for the most expensive drugs covered under Medicare Part B and Medicare Part D. In addition, additional rebates will be imposed on manufacturers related to certain Medicare Part B and D covered drugs to the extent their costs are rising faster than inflation. In addition, the Part D benefit will be restructured and in 2025 the existing coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D will sunset. The program will be replaced by a new Part D rebate program pursuant to which manufacturers of certain drugs will pay a rebate of 10 percent off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the catastrophic phase of the benefit. In the catastrophic phase, manufacturers will provide a 20 percent discount off negotiated price.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to designed to create prescription drug price transparency and in some instances control pharmaceutical and biological product pricing or set maximum reimbursement for certain drug products, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare.

Privacy and Data Protection Laws

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996 ("HIPPA") imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HITECH. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

GDPR. The EU General Data Protection Regulation ("GDPR") also confers 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. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the European Union.

CCPA. California recently enacted and has proposed companion regulations to the California Consumer Privacy Act ("CCPA") which went into effect January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. As of March 28, 2020, the California State Attorney General has proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, other records and information we maintain on our customers may be subject to the CCPA. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

Environmental Regulations

Our operations, properties and products are subject to a variety of U.S. and foreign environmental laws and regulations governing, among other things, use of manufacturing components containing substances below established threshold, air emissions, wastewater discharges, management and disposal of hazardous and non-hazardous materials and waste and remediation of releases of hazardous materials. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes.

The use of hazardous substances is regulated and monitored by various environmental regulatory authorities such as the EPA. As such, we are subject to national, state and local laws, regulations and directives pertaining to hazardous substances, pollution and protection of the environment, health and safety, which govern, among other things, emissions to the air, discharges onto land or waters, the maintenance of safe conditions in the workplace, and the generation, handling, storage, transportation, treatment and disposal of waste materials. These laws include, without limitation, the Comprehensive Environmental Response, Compensation, and Liability Act, the Federal Facilities Compliance Act, the Hazardous Materials Transportation Act, and the Resource Conservation and Recovery Act.

Pricing Regulations and Third-Party Coverage and Reimbursement

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. 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 approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods.

Our ability to commercialize any current or future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these current or future product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining 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 the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. 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. In the United States, the principal decisions about coverage and reimbursement of new medicines under the Medicare program are typically made by the Centers for Medicare & Medicaid Services ("CMS") an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Trade Laws

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have, or may have in the future, direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Our Competition

While we are not aware of any competing adjuvant therapy for Osteosarcoma to be tested in children that is further along in the development process than OST-HER2, there are a large number of companies developing or marketing treatments for rare diseases and cancers, including many major pharmaceutical and biotechnology companies. We may face competition from other product candidates in development for these indications, including product candidates in development from AstraZeneca, Y-mAbs Therapeutics and MD Anderson Cancer Center, among others.

Human Capital and Employees

As of March 28, 2025, we had four full-time employees and one part-time employee. We also utilize the services of a limited number of consultants as needed to perform specialized regulatory and medical-related services. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. All of our employees have entered into agreements with our company requiring them not to disclose our proprietary information and assigning to us all rights to inventions made during their employment.

Facilities

Our corporate address is 115 Pullman Crossing Road, Suite 103, Grasonville, Maryland 21638. This space is the accounting office of our Chief Financial Officer and provided to us rent free. We believe that suitable additional or alternative space would be available in the future on commercially reasonable terms, if necessary. As of the date of this annual report, all our operations are conducted remotely.

Recent Developments

On December 24, 2024, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (collectively, the "PIPE investors"), substantially all of whom were our existing stockholders, pursuant to which we agreed to issue and sell to the PIPE investors immediately separable units (the "Units"), with each Unit being comprised of (i) one share of Series A Senior Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and (ii) a warrant to purchase one share of common stock (each, a "Series A Warrant" and such shares, the "Warrant Shares"), at a price per Unit of $4.00, for aggregate gross proceeds of not less than $6 million and not more than $10 million (the "Private Placement"). At two closings occurring on December 31, 2024 and January 14, 2025, we issued to the PIPE investors an aggregate of (i) 1,775,750 shares of Series A Preferred Stock and (ii) Series A Warrants initially exercisable into 1,775,750 shares of common stock. The gross proceeds from the Private Placement, before deducting transaction fees and other estimated Private Placement expenses, were approximately $7,103,000. The Purchase Agreement requires us to seek stockholder approval for any transactions contemplated by the Purchase Agreement and the related documents for which the rules of the NYSE American require stockholder approval ("Stockholder Approval") and to hold a special meeting of stockholders for the purpose of obtaining Stockholder Approval not later than April 10, 2025. In the event Stockholder Approval is not obtained at the first meeting, we are required to call a meeting every four months seeking Stockholder Approval until Stockholder Approval is obtained.

Brookline Capital Markets, a division of Arcadia Securities, LLC ("Brookline"), acted as exclusive placement agent for the issuance and sale of the securities in the Private Placement. Pursuant to the terms of a letter agreement, dated December 27, 2024, between us and Brookline (the "Placement Agency Agreement"), we agreed to pay Brookline an aggregate cash fee (the "Cash Fee") equal to (i) 7% of the gross proceeds received by us from the sale of the securities in the Private Placement to PIPE investors other than certain PIPE investors identified on a schedule thereto ("Reduced Fee Purchasers"), plus (ii) 3% of the gross proceeds received by us from the sale of the securities in the Private Placement to Reduced Fee Purchasers, plus expenses; provided that Ceros Financial Services, Inc., Brookline's selected dealer for the Private Placement ("Ceros"), is entitled to 33.3% of the Cash Fee.

In addition, we agreed to pay Brookline or its designees a fee in the form of warrants to purchase shares of common stock (the "Agent Warrants"). The Agent Warrants are initially exercisable into a number of shares of common stock equal to (i) 7% of the number of shares of common stock initially issuable pursuant to the shares of Series A Preferred Stock issued to PIPE investors, other than Reduced Fee Purchasers in the Private Placement, plus (ii) 3% of the number of shares of common stock initially issuable pursuant to the shares of Series A Preferred Stock issued to Reduced Fee Purchasers in the Private Placement; provided that Ceros or its designee is entitled to 33.3% of the Agent Warrants. At two closings occurring on December 31, 2024 and January 14, 2025, (i) Brookline received an aggregate cash fee of $159,685 and the right to receive Agent Warrants initially exercisable for an aggregate of 39,918 shares of common stock, and (ii) Ceros received an aggregate cash fee of $79,723 and the right to receive Agent Warrants initially exercisable for an aggregate of 19,930 shares of common stock.

On January 28, 2025, we entered into the HER2 Purchase Agreement with Ayala, pursuant to which we agreed, subject to the terms and conditions set forth therein, to acquire from Ayala the HER2 Assets. The HER2 Assets include two IND filings with the FDA: (i) ADXS-503 for non-small cell lung cancer; and (ii) ADXS-504 for prostate cancer. The closing of the transaction, which we expect to occur in the second quarter of 2025, is subject to assignment of the Penn License, execution and delivery of a patent assignment agreement, a termination of license agreement, a lock-up agreement and a registration rights agreement, the approval of the transaction by Ayala stockholders and other customary closing conditions.

Other Information

We were formed as a Delaware limited liability company on April 12, 2018 under the name OS Therapies, LLC. On June 24, 2019, we converted from a limited liability company to a Delaware corporation and changed our name to OS Therapies Incorporated. We completed our initial public offering in August 2024 and our common stock is currently listed on NYSE American under the symbol "OSTX."

We presently conduct all of our operations remotely. Our registered corporate address is 115 Pullman Crossing Road, Suite #103, Grasonville, Maryland 21638, and our telephone number is (410) 297-7793. Our website address is *www.ostherapies.com*. We make available on this website, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish such information to, the SEC. Reports and other information we file with the SEC may also be viewed at the SEC's website at *www.sec.gov*. The information contained on, or that can be accessed through, our website is not incorporated by reference into this report.

Item 1A. Risk Factors.

In addition to the other information contained in this Form 10-K, the following risk factors should be considered carefully in evaluating our company's business. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition or results of operations.

Risk Factor Summary

Our business is subject to certain risks. The risks described under the heading "Risk Factors" immediately following this summary may have an adverse effect on our business, cash flows, financial condition and results of operations or may cause us to be unable to successfully execute all or part of our strategy. Below are the principal factors that make our business speculative or risky:

Risks Related to Our Financial Position and Need for Additional Capital

- We are a clinical stage biopharmaceutical company and have not generated any revenue to date from drug sales, and may never become profitable.
- We have incurred significant operating losses in recent periods and anticipate that we will incur continued losses for the foreseeable future.
- If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or commercialization efforts.
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to Drug Development and Regulatory Approval

- We depend heavily on the success of our core product candidates OST-HER2 and OST-tADC. We may not be able to obtain regulatory permission to conduct future clinical studies, or may not be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals both for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

- Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their future testing in clinical studies or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.
- Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.
- Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.
- Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.
- Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

Risks Related to Intellectual Property

- If we or those from whom we in-license patents are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.
- If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.
- If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.
- We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.
- We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.
- If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- Any in-license patent covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad, including the USPTO and the EPO.

Risks Related to Management and Our Operations

- In our industry in particular, our future success depends on our ability to retain key scientific employees and to attract, retain and motivate qualified personnel.
- Our internal computer systems, or those of our third-party clinical research organizations, or CROs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.
- We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical stage biopharmaceutical company and have not generated any revenue to date from drug sales, and may never become profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, while we have generated significant interest in various research collaboration revenue, we have not generated any commercial revenue from our current core product candidates, including our lead core product candidate OST-HER2 and our other core product candidate OST-tADC, and we do not know and do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue unless and until we complete the development of, obtain marketing approval for, and begin to sell, OST-HER2, which is being evaluated in a Phase IIb clinical trial, or OST-tADC, which is still being evaluated at the preclinical stage. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, OST-HER2 and OST-tADC;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- our ability to establish an appropriate safety profile with IND-enabling toxicology and other preclinical studies for OST-tADC;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression, as applicable, of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- our ability to forecast and meet supply requirements for clinical trials and commercialized products using third-party manufacturers;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- obtaining any necessary licenses to manufacture and distribute OST-HER2 and/or OST-tADC and/or contractual arrangements with third party logistics providers and/or distributors to distribute our products in the United States;
- obtaining and maintaining third-party coverage and adequate reimbursement, if OST-HER2 and/or OST-tADC is approved;

- acceptance of our core product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, if OST-HER2 and/or OST-tADC are approved;
- our ability and the ability of third parties from which we in-license patents to obtain and maintain patent, trade secret and other intellectual property protection, OST-HER2 and/or OST-tADC and regulatory exclusivity for OST-HER2 and/or OST-tADC if and when approved;
- our receipt of marketing approvals for OST-HER2 and/or OST-tADC from applicable regulatory authorities; and
- the continued acceptable safety profiles of our core product candidates following approval.

We have incurred significant operating losses in recent periods and anticipate that we will incur continued losses for the foreseeable future.

Since inception, we have focused substantially all of our efforts on the development of OST-HER2 and OST-tADC and our other clinical developments. To date, we have financed our operations primarily through the sale of convertible notes and other securities to outside investors. From July 2018 to April 2024, we raised an aggregate of approximately $19.2 million in gross proceeds from sales of our convertible notes. On July 31, 2024, we completed our initial public offering, raising $6.4 million in gross offering proceeds. From December 2024 through January 2025, we raised an aggregate of $7.1 million in gross proceeds from the Private Placement. Due to our significant research and development expenditures, we have experienced negative cash flows from operations, even in periods of operating income. For each of the years ended December 31, 2024 and 2023, we incurred a loss from operations and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. 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 our expenses to significantly increase in connection with our ongoing activities, as we:

- complete preclinical studies, initiate and complete clinical trials for product candidates;
- consult with the FDA at each stage of development;
- seek a favorable outcome of our toxicology studies;
- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our core product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our drug candidates and commercialization of any of our drug candidates for which we obtain marketing approval;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel;
- secure facilities to support continued growth in our research, development and commercialization efforts; and
- incur additional costs associated with operating as a public company.

A significant number of additional shares of our common stock may be issued under the terms of existing securities, which issuances would substantially dilute existing stockholders and may depress the market price of our common stock.

At two closings occurring on December 31, 2024 and January 14, 2025, we issued an aggregate of (i) 1,775,750 shares of Series A Preferred Stock and (ii) Series A Warrants initially exercisable into 1,775,750 shares of common stock pursuant to the Private Placement.

Each share of Series A Preferred Stock is convertible into a number of shares of common stock at a conversion ratio equal to (A) the original issue price of the Series A Preferred Stock divided by (B) the conversion price of the Series A Preferred Stock. The original issue price and the conversion price of the Series A Preferred Stock will initially be $4.00 (resulting in an initial conversion ratio of 1:1) and are subject to adjustment as set forth in the Certificate of Designation, Preferences, Rights and Limitations of Series A Senior Convertible Preferred Stock. Each of the Series A Warrants is exercisable into a number of shares of common stock, at an initial exercise price of $4.40 per share. The Series A Warrants are exercisable by the holder for a period of five years from the later of (a) the Resale Effective Date (as defined in the Purchase Agreement) and (b) the date Stockholder Approval is obtained.

In consideration of our purchase of the HER2 Assets, we agreed to pay to Ayala $7.5 million shares of our common stock, based on the volume-weighted average price of our common stock over the 30 trading days immediately preceding the closing date of the HER2 Purchase Agreement.

The number of shares of common stock into which the Series A Preferred Stock and the Series A Warrants may be converted or exercised is also subject to potential increase pursuant to applicable resets and anti-dilution adjustments. For more detailed information about these adjustments, see *"Description of Capital Stock — Series A Preferred Stock — Resets and Anti-Dilution Adjustments."* The issuance of common stock pursuant to the Series A Preferred Stock, Series A Warrants and the HER2 Purchase Agreement would substantially dilute the proportionate ownership and voting power of existing stockholders, and their issuance, or the possibility of their issuance, may depress the market price of our common stock.

If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing OST-HER2 through clinical development and OST-tADC through preclinical development. The FDA allowed our OST31-164-01 study to be conducted in July 2021, and we initiated a Phase IIb clinical trial in 2022. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, product manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. We expect to incur additional costs associated with operating as a public company. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital on a timely basis or on favorable terms, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions, which could materially affect our business, financial condition and results of operations.

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

We may seek additional capital through a combination of public and private equity offerings, including our Equity Line of Credit as well as other debt financings, strategic collaborations and alliances and licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

We have primarily financed our operations through proceeds from the sale of shares of common stock in our initial public offering and convertible notes, shares of our Series A convertible preferred stock and warrants to accredited investors. We have experienced significant negative cash flows from operations in each year since our inception. We do not expect to experience any significant positive cash flows from our existing collaboration agreements and do not expect to have any product revenue in the near term. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we continue to invest significantly in research and development of our programs. As a result, our independent registered public accounting firm has issued a going concern opinion on our financial statements, expressing substantial doubt that we can continue as an ongoing business for the next 12 months after issuance of their report based on us having suffered recurring losses from operations and having a net capital deficiency.

Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will need to raise additional capital to fund our future operations and remain a going concern. However, we cannot guarantee that we will be able to obtain sufficient additional funding or that such funding, if available, will be obtainable on terms favorable to us. In the event that we are unable to obtain sufficient additional funding, there can be no assurance that we will be able to continue as a going concern.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change tax attributes to offset its post-change income may be limited. We have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2024 and 2023, we had federal and state NOLs of approximately $22,236,580 and $16,269,893, respectively, federal and state research and development tax credits of $268,568 and $268,568, respectively, and general business credit carryforwards of approximately $1,672,876 and $1,408,963, respectively. Our ability to utilize these NOLs and tax credit carryforwards may be limited by an "ownership change." If we undergo future ownership changes, many of which may be outside of our control, our ability to utilize our NOLs and tax credit carryforwards could be further limited by Sections 382 and 383 of the Code. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Additionally, our NOLs and tax credit carryforwards could be limited under state law. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to Drug Development and Regulatory Approval

We depend heavily on the success of our lead product candidates, OST-HER2 and OST-tADC. We may not be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

We currently have no product candidates approved for sale and may never be able to develop marketable product candidates. Our business depends heavily on the successful development, regulatory approval and commercialization of the current or future immunotherapy for Osteosarcoma product candidates, of which our lead product candidate, OST-HER2, is in Phase IIb clinical development. OST-tADC will require additional preclinical development and substantial clinical development, testing and regulatory approval before we are permitted to commence its commercialization. The preclinical studies and clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will

require the expenditure of substantial resources beyond the proceeds we raise in this offering. 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, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Medicines Agency (EMA). Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed and commercialized.

We are not permitted to market our current or future product candidates in the United States until we receive approval of a BLA from the FDA CBER, in the European Economic Area (EEA) until we receive approval of a marketing authorization applications (MAA) from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. Obtaining approval of a BLA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of any of our current or future product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agencies;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agencies for marketing approval;
- the FDA or applicable foreign regulatory agencies may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agencies may require that we conduct additional preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agencies may not approve the formulation, labeling or specifications of any of our current or future product candidates;
- the contract research organizations (CROs) that we retain to conduct our preclinical studies and clinical trials may take actions that materially adversely impact our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agencies may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or applicable foreign regulatory agencies may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agencies may not accept data generated at our preclinical studies and clinical trial sites;
- if our BLA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy (REMS) as a condition of approval or post-approval;
- the FDA or an applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current good manufacturing practices (GMPs); or
- the FDA or applicable foreign regulatory agencies may change their approval requirements or policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are focused on patients with rare Osteosarcoma, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Some of our competitors have ongoing clinical trials for current or future product candidates that treat the same patient populations as our current or future product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates.

Patient enrollment may be affected by other factors that we may not be able to control including:

- the willingness of participants to enroll in our clinical trials and available support in our countries of interest;
- the obtaining of informed consent from parents or guardians of pediatric patients which meet evolving regulatory requirements in the United States and other countries;
- the severity of the disease under investigation;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate screening test;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Rare Osteosarcoma has relatively low prevalence and it may be difficult to identify patients with driver genes of the disease, which may lead to delays in enrollment for our trials.

Osteosarcoma has relatively low prevalence and it may be difficult to identify patients with the eligibility criteria we are targeting. Osteosarcoma has an incident rate of approximately 1,000 individuals affected per year in the United States. Our inability to enroll a sufficient number of patients with the target indication for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our current or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we are unable to include patients with the target indication, this could compromise our ability to seek participation in the FDA's expedited review and approval programs, or otherwise to seek to accelerate clinical development and regulatory timelines for our other product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals both for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before

we can commercialize any of our current or future product candidates, we must obtain marketing approval. We have not received approval to market any of our current product candidates and may not obtain regulatory approvals for our future product candidates, if any, from regulatory authorities in any jurisdiction and it is possible that none of our current or future product candidates or any current or future product candidates we may seek to develop in the future will ever obtain regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication and line of treatment to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the current or future product candidates involved. Changes in marketing approval requirements or policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA or BLA. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our current or future product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or that it is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our current or future product candidates may not be sufficient to support the submission of an NDA, a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval requirements or policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates, and our ability to generate revenues will be materially impaired.

Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. While we have initiated clinical trials for OST-HER2, and although there have been limited side effects with this therapy to date, it is likely that there may be adverse side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or future product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition and prospects.

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity, or exaggerated and adverse pharmacologic effects at the target of interest in the test system. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Clinical trials by their nature utilize a sample of the potential patient population. For example, the 41 patients in our Phase IIb trial of OST-HER2 may include a limited number of patients with side effects. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our current or future product candidates are tested in large numbers of patients or if they receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may place a hold on an ongoing clinical trial or may refuse to allow a future clinical trial to be conducted;
- regulatory authorities may withdraw or limit their approval of current or future product candidates;
- we may or a regulatory authority might require that the product or products be recalled;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such current or future product candidates from the marketplace; and
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected current or future product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

A breakthrough therapy designation by the FDA for our current or future product candidate does not convey any advantage in, or shorten the duration of, the regulatory review or approval process, and it does not increase the likelihood that our current or future product candidates will receive marketing approval.

In May 2024, we submitted a request to the FDA for breakthrough therapy designation for OST-HER2, and we may seek a breakthrough therapy designation for some of our other current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our current or future product candidates 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 product candidate does not convey any advantage in, or shorten the duration of, regulatory review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our current or future product candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification.

A fast track designation by the FDA does not convey any advantage in, or shorten the duration of, the regulatory review regulatory review or approval process.

If a drug 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 drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe that a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even though we have received fast track designation for OST-HER2 and may receive fast track designation again in the future for certain current or future product candidates, this designation does not convey any advantage in, or shorten the duration of, regulatory 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.

We may not be able to obtain or maintain orphan drug designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or EMA from approving other competing products.

OST-HER2 received orphan drug designation for Osteosarcoma in the United States, and we may seek orphan drug designation ("ODD") for other current or future product candidates. We are currently preparing to submit required information to the FDA in order to re-establish ODD for OST-HER2 in the first half of 2025. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Further, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus, for example, approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity in the United States for the same drug and same condition.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017. This act, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its Orphan Drug regulations and policies, our business could be adversely impacted.

Although we have obtained rare pediatric disease designation for OST-HER2 for Osteosarcoma patients, we may not be eligible to receive a priority review voucher in the event that FDA approval does not occur prior to September 30, 2026.

The Rare Pediatric Disease Priority Review Voucher Program ("PRV Program") is intended to incentivize pharmaceutical sponsors to develop drugs for rare diseases. A sponsor who obtains approval of an NDA or BLA for a rare disease may be eligible for a Priority Review Voucher ("PRV") under this program, which may be redeemed by the owner of such PRV to obtain priority review for a marketing application. A PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately ten months. Under the 21st Century Cures Act, a drug that receives rare disease designation before September 30, 2024, will continue to be eligible for a PRV if the drug is approved before September 30, 2026. If we do not obtain approval of a BLA for OST-HER2 in patients with Osteosarcoma, and if the PRV Program is not extended by Congressional action, we may not receive a PRV.

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

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or drug recalls;
- fines, warning or other letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;

- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our earlier preclinical studies and clinical trials of our current or future product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

Positive results from our preclinical studies of our current or future product candidates, and any positive results we may obtain from our early clinical trials of our current or future product candidates, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our current or future product candidates according to our current development timeline, the positive results from our preclinical studies and clinical trials of our current or future product candidates may not be replicated in subsequent preclinical studies or clinical trial results. For example, our later-stage clinical trials could differ in significant ways from our ongoing Phase IIb clinical trial of OST-HER2, which could cause the outcome of these later-stage trials to differ from our earlier-stage clinical trials. For example, these differences may include changes to inclusion and exclusion criteria, final dosage formulation, efficacy endpoints and statistical design.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of our current or future product candidates is complex and highly regulated. We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties based in the United States, Europe and Asia for the manufacture of our current or future product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third-party's proprietary process, and a third-party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates. As our current or future product candidates progress through preclinical studies and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our current or future product candidates and additional bridging studies or trials may be required.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

We are not permitted to market or promote any of our current or future product candidates in foreign markets before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, which may cause obtaining regulatory approvals outside of the United States to take longer and be more costly than obtaining approval in the United States;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- reduced protection of intellectual property rights and the existence of additional potentially relevant third-party intellectual property rights;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

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

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the

applicable doctrines or local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates. Although some of our current product candidates are in preclinical and clinical development, our scientific hypotheses may be incorrect or our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodologies may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused on our core programs, including our lead core product candidate OST-HER2 for the treatment of Osteosarcoma and our other core product candidate OST-tADC for the treatment of Osteosarcoma. As a result, we may forego or delay pursuit of opportunities with other current or 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 drugs or profitable market opportunities. Our spending on current and future research and development programs and current or future product candidates for specific indications may not yield any commercially viable drugs. 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 future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If any of these events occur, we may be forced to abandon our development efforts for a program, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or current or future product candidates that ultimately prove to be unsuccessful.

In light of the larger population of patients with Osteosarcoma who reside in foreign countries, our ability to generate meaningful revenues in those jurisdictions may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the United States. There is additionally a remote possibility that price controls may be enacted in the United States.

The incidence of new cases of Osteosarcoma is approximately 1,000 individuals in the United States annually and approximately 20,000 individuals globally. In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and 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 addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as are product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially, based, in part, on the larger population of patients with Osteosarcoma who reside in foreign countries. In parts of Africa and certain countries in the Middle East, the lack of healthcare infrastructure to help adequately diagnose and treat patients may limit our business potential in those otherwise viable markets. Finally, there is a remote possibility that price controls may be enacted in the United States.

Risks Related to Commercialization

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians and patients, as well as reimbursement and coverage by third party payors including Medicare and Medicaid. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage and reimbursement, including from federal healthcare programs such as Medicare and Medicaid; or
- the ability or willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before agreeing to cover and reimburse our products, third party payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, are not only safe but cost effective compared to alternative therapies. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

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

The development and commercialization of new drugs 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 pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology

companies that currently market and sell drugs or are pursuing the development of therapies for rare diseases and cancers, including Osteosarcoma. Some of these competitive drugs and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for rare diseases and cancers, including many major pharmaceutical and biotechnology companies. If OST-HER2 receives marketing approval for the treatment of Osteosarcoma, it may face competition from other product candidates in development for these indications, including product candidates in development from AstraZeneca, Y-mAbs Therapeutics and MD Anderson Cancer Center, among others.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs and resources to defend the related litigation;
- substantial monetary awards to trial participants or patients; and
- the inability to commercialize any current or future product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we initiate a large global trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Even if we are able to commercialize any current or future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. 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 approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more current or future product candidates, even if our current or future product candidates obtain marketing approval.

Our ability to commercialize any current or future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these current or future product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for (i.e., cover) and establish reimbursement levels. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining 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 the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. 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. In the United States, decisions as to coverage and reimbursement by the Medicare program are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Healthcare reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. It is possible that additional governmental action is taken to address the Covid-19 pandemic. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, patient support or distribution of drugs. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product

candidates effectively, or they may engage in practices that pose legal risks to us under applicable anti-kickback, fraud and abuse and other healthcare laws and regulations. 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 our current or future product candidates.

Our relationships with prescribers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, including physicians, play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, as well as third-party payors and customers, will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations will constrain the business and/or financial arrangements and relationships through which we market, sell and distribute our current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, 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 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 federal and state healthcare programs such as Medicare, Medicaid and TRICARE. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory per claim penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the False Claims Act for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Drug Rebate Program. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act (ACA) require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related transfers of value to certain covered recipients (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, as well as physicians assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives) and their immediate family members, and teaching hospitals. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and

- analogous state laws and regulations, such as state 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; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do 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 were to be 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We may face potential liability if we obtain identifiable patient health information from clinical trials sponsored by us.

Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, in the future, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Further, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights 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.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state/provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive 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. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not 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.

If the market opportunities for OST-HER2 and our other current and future product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer. Moreover, because the target patient populations we are seeking to treat are small, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

We focus our research and product development on treatments for Osteosarcoma. The incidence of new cases of Osteosarcoma is approximately 1,000 individuals in the United States annually and approximately 20,000 individuals globally. Given the smaller number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Further, even if we obtain significant market share for OST-HER2 and any of our other current or future product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our target patient populations are relatively small, and there are currently limited standard of care treatments directed at Osteosarcoma. As a result, the pricing and reimbursement of OST-HER2 and any other product candidates we may develop, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell OST-HER2 and any of our other current or future product candidates will be adversely affected.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our ongoing and planned clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support our clinical trials for OST-HER2 and expect to rely on them when we begin clinical trials for OST-tADC and other current or future product candidates. We rely heavily on these parties for execution of clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our current or future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations. Our failure or the failure of third parties that we contract with to comply with these regulations may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our current or future product candidates, or be involved in the design when other parties sponsor the trials, we anticipate that third parties will conduct all of our clinical trials. As a result, many important aspects of our clinical development, including their conduct, timing and response to the ongoing Covid-19 pandemic, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory

requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredient, or API, drug product and drug substance used in our core product candidates are limited in number, and the loss of any of these suppliers could significantly harm our business.

The API drug product and drug substance used in our core product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of all API, drug product or drug substance in the event any of our current suppliers of such API, drug product and drug substance cease their operations for any reason.

For all of our current or future product candidates, we intend to identify and qualify additional manufacturers to provide such API, drug product and drug substance prior to submission of an NDA or a BLA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures. We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.

We have entered into licensing arrangements with Advaxis, Inc. (now Ayala Pharmaceuticals, Inc.) and BlinkBio, Inc. and a Research Service Agreement with George Clinical, Inc., and may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current product candidates and any future product candidates that we may develop.

Going forward, we are seeking strategic partners for the further development and potential commercialization of our non-core and out-licensed programs, including OST-tADC. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or acquisition or other alternative arrangements for our current or future non-core product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

As a result, we may not be able to realize the benefit of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, license arrangements we may enter, if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, license, collaboration or other business development partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to produce our product candidates for clinical trials and our products, if any, for commercial purposes, either at our own facility or at a third-party's facility, we and our third-party vendors will need to comply with the FDA's cGMP regulations and guidelines. As part of our ongoing quality and process improvement efforts, we conducted a gap analysis of our cGMP quality system and it identified certain key areas for necessary remediation, including with regard to documentation requirements. We may encounter difficulties in achieving compliance with quality control and quality assurance requirements and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements, including any failure to remedy the issues identified in the cGMP gap analysis, or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidate as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

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

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

Risks Related to Intellectual Property

If we and those third parties from whom we in-license patents are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Our commercial success depends in part on our ability and the ability of those third parties from whom we in-license patents to obtain and maintain intellectual property protection in the United States and other countries for our current or future product candidates, including our lead core product candidate OST-HER2, our other core product candidate OST-tADC, our non-core product candidates, our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, in-licensing patents and patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business.

Although we have agreed to acquire the HER2 Assets pursuant to the HER2 Purchase Agreement, we do not currently own any issued patents. We in-license patents and patent applications related to our lead core product candidate OST-HER2 from Advaxis, Inc. and our other core product candidate OST-tADC from BlinkBio, Inc. The intellectual property licensed from Advaxis, Inc. includes nine granted U.S. utility patents and a number of foreign patents and pending patent applications. The patents and patent applications if granted are expected to expire between 2030 and 2035, not including any patent term extension. The intellectual property licensed from BlinkBio, Inc. includes six granted U.S. utility patents and a number of foreign patents and pending patent applications. The patents cover methods of use of silicon based drug conjugates and silanol based therapeutic payloads. The patents and pending patent applications if granted are expected to expire between 2036 and 2037, not including any patent term extension. For additional information about our patents, see "*Business — Our Intellectual Property*."

The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of the patents that we in-license have, or that any of such pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect OST-HER2 and OST-tADC or our other current or future product candidates. In addition, if the breadth or strength of protection provided by such patent applications or any patents we may in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Other parties have developed technologies that may be related or competitive to our own or those covered by our in-licensed patents, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in such patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter. 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 at least 18 months after the earliest priority date of patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether the holder of our in-licensed patents was the first to make the inventions claimed in such patents or pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of these in-licensed patent rights cannot be predicted with any certainty.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our in-licensed patents or patents we may own in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of patent or product exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might

expire before or shortly after such candidates are commercialized. Any impairment of our intellectual property rights, or our failure to protect our intellectual property rights adequately, could give third parties access to our technology and product candidates and could materially and adversely impact our business, financial condition, results of operations, and prospects.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although it is our policy to require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality and assignment of inventions agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and 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 information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe the patent applications or any patents we in-license or may in the future own. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put those patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to the patent applications or any patents we in-license or may in the future own. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where these patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or

proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

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

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

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

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

We may from time to time be party to license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 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. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first inventor to file" system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. Accordingly, 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 the patent applications that we have in-licensed and the enforcement or defense of such issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has and other courts have 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. 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 obtain patent protection for our proprietary technology or 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 would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

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

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may 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 trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; and
- we may not develop or in-license additional proprietary technologies that are patentable.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

Our current operations are located in Maryland; and 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.

Our current operations are located in Maryland. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing

facilities of our third-party contract 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. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics 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 headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract 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. 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 our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If the manufacturing facilities of our third-party contract 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 may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We are highly dependent on the research and development, clinical and business development expertise of Paul A. Romness, MPH, our Chairman, President and Chief Executive Officer, and Robert G. Petit, Ph.D., our Chief Medical Officer and Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements or arrangements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our growth strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of March 28, 2025, we had four full-time employees, one part-time employee and a limited number of regulatory and other consultants. We expect to increase our number of employees and the scope of our operations. To manage our anticipated growth and expansion, 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. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth-oriented activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations

may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected growth and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our growth strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future growth and expansion of our company.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the common stock.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Our management has concluded that our internal control over financial reporting was not effective as of December 31, 2024 due inadequate segregation of duties within account processes due to limited personnel, as well as insufficient written policies and procedures for accounting, IT, and financial reporting and record keeping. Disclosing deficiencies or weaknesses in our internal controls, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the common stock. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

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

Global financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in inflation and unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in financial markets and confidence in economic conditions will not occur. Our general growth strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our employees, principal investigators, CROs and consultants 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 that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or 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, but it is not always possible to identify and deter misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person could

allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, debarment from participation in any FDA-related activities, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, debarment from participation in any FDA-related activities, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Common Stock

The issuance of shares in connection with the Private Placement and the HER2 Purchase Agreement could adversely affect the prevailing market price of our shares.

At two closings occurring on December 31, 2024 and January 14, 2025, we issued to the selling stockholders an aggregate of (i) 1,775,750 shares of Series A Preferred Stock and (ii) Series A Warrants initially exercisable into 1,775,750 shares of common stock pursuant to the Private Placement. The number of shares of common stock into which the Series A Preferred Stock and Series A Warrants may be converted or exercised is also subject to potential increase pursuant to applicable resets and anti-dilution adjustments. For more detailed information about these adjustments, see "*Description of Capital Stock — Series A Preferred Stock — Resets and Anti-Dilution Adjustments*." We have also agreed to issue to Ayala $7.5 million shares of our common stock, based on the 30-day VWAP of our common stock immediately preceding the closing date of our purchase of the HER2 Assets. In the future, we may issue additional shares or other equity or debt securities convertible into shares. These issuances and any future issuance could result in substantial dilution to our existing stockholders and could cause our share price to decline.

It is not possible to predict the actual number of ELOC Shares, if any, we will sell under the ELOC Purchase Agreement to Square Gate, or the actual gross proceeds resulting from those sales.

On October 31, 2024, we entered into an Equity Purchase Agreement (the "ELOC Purchase Agreement") with Square Gate Capital Master Fund, LLC — Series 3 (the "Square Gate"), pursuant to which Square Gate has committed to purchase shares of our common stock in an offering amount up to $15,000,000 (the "ELOC Shares"), subject to certain limitations and conditions set forth in the ELOC Purchase Agreement. The ELOC Shares that may be issued under the ELOC Purchase Agreement may be sold by us to Square Gate at our discretion from time to time until the earliest of (i) the date on which Square Gate has purchased ELOC Shares pursuant to the ELOC Purchase Agreement equal to the maximum amount of the committed equity facility (the "Facility" or "Equity Line of Credit"), (ii) October 31, 2026, (iii) written notice of termination by us to Square Gate (which cannot occur at any time that Square Gate holds any of the ELOC Shares), or (iv) written notice of termination by Square Gate to us upon certain events occurring.

We generally have the right to control the timing and amount of any sales of the ELOC Shares to Square Gate under the ELOC Purchase Agreement. Sales of the ELOC Shares, if any, to Square Gate under the ELOC Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Square Gate all, some or none of the ELOC Shares that may be available for us to sell to Square Gate pursuant to the ELOC Purchase Agreement.

Because the purchase price per share to be paid by Square Gate for the ELOC Shares that we may elect to sell to Square Gate under the ELOC Purchase Agreement, if any, will fluctuate based on the market prices of our shares at the time we elect to sell the ELOC Shares to Square Gate pursuant to the ELOC Purchase Agreement, if any, it is not possible for us to predict, as of the date of this annual report and prior to any such sales, the number of ELOC Shares that we will sell to Square Gate under the ELOC Purchase Agreement, the purchase price per share that Square Gate will pay for ELOC Shares purchased from us under the ELOC Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Square Gate under the ELOC Purchase Agreement.

The ELOC Purchase Agreement provides that we may, in our discretion, from time to time during the term of the ELOC Purchase Agreement, direct Square Gate to purchase the ELOC Shares from us in one or more purchases under the ELOC Purchase Agreement, for a maximum aggregate gross purchase price of up to $15,000,000 of the ELOC Shares. Because the market prices of the ELOC Shares may fluctuate from time to time after the date of this annual report, the actual purchase prices to be paid by Square Gate for the ELOC Shares that we direct it to purchase under the ELOC Purchase Agreement, if any, also may fluctuate significantly based on the market price of the ELOC Shares.

Any issuance and sale by us under the ELOC Purchase Agreement of a substantial number of ELOC Shares could cause substantial dilution to our stockholders. We registered resale under a registration statement 6,212,761 ELOC Shares, which was declared effective by the SEC on January 13, 2025. The number of ELOC Shares ultimately offered for sale by Square Gate is dependent upon the number of ELOC Shares, if any, we ultimately elect to sell to Square Gate under the ELOC Purchase Agreement. However, even if we elect to sell ELOC Shares to Square Gate pursuant to the ELOC Purchase Agreement, Square Gate may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices.

Investors who buy ELOC Shares from Square Gate at different times will likely pay different prices.

Pursuant to the ELOC Purchase Agreement, we will have discretion to vary the timing, price and number of shares sold to Square Gate. If and when we elect to sell the ELOC Shares to Square Gate pursuant to the ELOC Purchase Agreement, after Square Gate has acquired such ELOC Shares, Square Gate may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices. As a result, investors who purchase shares from Square Gate in this offering at different times will likely pay different prices for those shares and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Square Gate in this offering as a result of future sales made by us to Investor at prices lower than the prices such investors paid for their shares in this offering. In addition, if we sell a substantial number of shares to Square Gate under the ELOC Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Square Gate may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales.

Paul A. Romness, MPH, and our other executive officers, directors and their affiliates exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Paul A. Romness, MPH, our Chairman, President and Chief Executive Officer, beneficially owns approximately 11.4% of the outstanding shares of common stock of our company, and other executive officers and directors beneficially own another approximately 3.6% of our outstanding shares. The existing holdings of Mr. Romness and other executive officers, directors and their affiliates represent beneficial ownership in the aggregate of approximately 15.1% of our outstanding common stock. As a result, these stockholders will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. These stockholders may have interests, with respect to their common stock, that are different from those of other investors and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

We are incurring increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a recently public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently adopted by the SEC and the NYSE American to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act under which the SEC adopted additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our July 2024 initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar 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 of directors, our board committees or as executive officers.

We have not paid, and do not intend to pay, dividends on our shares of common stock and, therefore, unless our common stock appreciates in value, our investors may not benefit from holding our shares.

We have not paid any cash dividends on our shares of common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, investors in our common stock will not be able to benefit from owning these shares unless their market price becomes greater than the price paid by such investors and they are able to sell such shares. We cannot assure you that you will ever be able to resell our common stock at a price in excess of the price paid.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Governance

Our board of directors has the ultimate oversight responsibility for the risk management process and regularly reviews issues that present particular risk to us, including those involving cybersecurity. Our board is responsible for ensuring that management has processes in place designed to identify and assess cybersecurity risks to which we are exposed and implement processes and programs designed to manage cybersecurity risks and mitigate and remediate cybersecurity threats and incidents.

Our management is responsible for identifying, considering and assessing material cybersecurity risks on an ongoing basis, establishing processes to ensure that such potential cybersecurity risk exposures are monitored, putting in place appropriate mitigation measures and maintaining cybersecurity programs. In managing cybersecurity risks, we adhere to a structured framework that outlines the roles and responsibilities of management positions and committees.

Cybersecurity Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and trade secrets, data we may collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information ("Information Systems and Data"). Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the cybersecurity program works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

The cybersecurity program within our company helps identify, assess and manage our cybersecurity threats and risks. Our cybersecurity program identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example manual tools, internal or external audits, automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats and threat actors, conducting vulnerability assessments to identify vulnerabilities, conducting scans of the threat environment, and evaluating threats reported to us. Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity software providers, managed cybersecurity service providers, and penetration testing firms. We also use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. We manage cybersecurity risks associated with our use of these providers by reviewing their security assessments and applicable reports.

We are not aware of any risks from cybersecurity threats, including because of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

We face risks from cybersecurity threats that, if realized are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may materially affect us and how we may do so, see our risk factors under "Item 1A. Risk Factors".

Item 2. Properties.

Our corporate address is 115 Pullman Crossing Road, Suite 103, Grasonville, Maryland 21638. This space is the accounting office of our Chief Financial Officer and provided to us rent free. We believe that suitable additional or alternative space would be available in the future on commercially reasonable terms, if necessary. All our operations are presently conducted remotely.

Item 3. Legal Proceedings.

The information contained in Note 7 to our consolidated financial statements included in this Form 10-K is incorporated herein by reference.

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 is traded on NYSE American under the symbol "OSTX."

Holders

As of March 28 2025, there were 142 holders of record of our common stock. The actual number of holders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

We have never paid a cash dividend on our common stock and do not expect to pay a cash dividend in the near future. We currently intend to retain future earnings, if any, to finance our operations and expand our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information as of December 31, 2024 with respect to our common stock that may be issued under our incentive compensation plans and other option grants.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity Compensation Plans Approved by Security Holders. . .	—	$ —	—
Equity Compensation Plans Not Approved by Security Holders	2,870,000	1.86	1,130,000
Total	2,870,000	$ 1.86	1,130,000

Sales of Unregistered Securities

During the quarter ended December 31, 2024, we issued 25,000 shares of our common stock in exchange for marketing services. Additionally, we issued 6,506 shares of our common stock to a former convertible noteholder to settle an outstanding interest obligation following the conversion of our outstanding convertible notes upon consummation of our initial public offering.

Use of Proceeds

On July 31, 2024, our registration statement on Form S-1 (File No. 333-276350) was declared effective by the SEC for our initial public offering, which was underwritten by Brookline Capital Markets. At the closing of our initial public offering on August 2, 2024, we sold 1,600,000 shares of common stock at an initial public offering price of $4.00 per share and received gross proceeds of $6.4 million, which resulted in net proceeds to us of approximately $6.0 million, after deducting underwriting discounts and commissions of approximately $0.4 million. As of March 28, 2025, we estimate that we have used approximately $6 million of the proceeds from our initial public offering for general corporate purposes, including to advance the development of OST-HER2 and OST-tADC. There has been no material change in the planned use of proceeds from that described in the final prospectus for our initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Issuer Purchases of Equity Securities

During the year ended December 31, 2024, we did not repurchase any equity securities.

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 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.

Overview

We are a clinical stage biopharmaceutical company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. Our mission is to address the significant need for new treatments in cancers of the bone in children and young adults. Osteosarcoma is an extremely challenging and often aggressive cancer that has particular treatment challenges due to its location, changing genotypes and high metastases rates. We are currently seeking to answer the call for new treatments that will prevent metastasis and the recurrence of metastases with our lead core product candidate OST-HER2 (also known as OST31-164), a cancer immunotherapy product candidate that produces a cellular immune response against the cancer antigen HER2. In 2021, we opened a clinical study to produce data for the U.S. Food and Drug Administration (FDA) to evaluate the safety and efficacy of OST-HER2 in patients after resection of recurrent Osteosarcoma, which achieved full enrollment of 41 patients in October 2023. We expect topline results from all 41 patients enrolled by the fourth quarter of 2024 and, if successful, intend to seek regulatory approval for OST-HER2 for the prevention of metastases in Osteosarcoma in 2025. Upon success in gaining regulatory approval from the FDA with OST-HER2 in Osteosarcoma, we intend to evaluate OST-HER2's potential use, both alone and in combination with HER2 targeting antibodies such as Herceptin®, in other solid tumors including breast, esophageal and lung cancers. OST-HER2 has potential uses in both the prevention of metastases in solid tumors, and therapeutically against HER2-expressing solid tumors treated with HER targeting antibodies.

We also own rights to OST-Tunable Drug Conjugate (OST-tADC) platform, a next generation antibody-drug conjugate (ADC) silicone dioxide linker technology. "Tunable" is a term used in drug development that refers to the properties that can be influenced by chemical modifications, and "antibody-drug conjugate" or ADC is a term used to describe a drug made up of a monoclonal antibody attached to a cytotoxic payload, or a highly active and toxic pharmaceutical molecule, through chemical linkers. The ADC links an antibody that can home in on a targeted tumor to deploy the cytotoxic payload or toxic agent against the tumor. Furthering our founding mission, we intend to investigate clinical indications for OST-tADC in Osteosarcoma and other solid tumors.

No new treatments have been approved by the FDA for human Osteosarcoma for more than 40 years. In humans, Osteosarcoma is an extremely rare cancer that primarily affects children, teenagers and young adults generally under 40 years of age. We are not aware of any competing adjuvant therapy for Osteosarcoma to be tested in children that is further along in the development process than OST-HER2. This disease is difficult to diagnose. The standard of care following first line therapies is simply to screen and wait for possible recurrence/metastasis, or the development of secondary malignant growths at a distance from a primary site of cancer. Studies published in the Journal of Clinical Oncology, "Osteosarcoma Relapse After Combined Modality Therapy: An Analysis of Unselected Patients in the Cooperative Osteosarcoma Study Group (COSS)," by Kempf-Bielack B., et al. (January 2005), and "Second and Subsequent Recurrences of Osteosarcoma: Presentation, Treatment, and Outcomes of 249 Consecutive Cooperative Osteosarcoma Study Group Patients," by Bielack S., et al. (February 2009), reported that recurrence/metastasis happens in approximately half of all patients within 12 to 18 months following initial remittance. For those patients that experience recurrence, metastasis is typically to the lungs and brain, with survival rates of approximately 13% over the next year, according to these studies.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies are those that, in management's view, are most important to the portrayal of a company's financial condition and results of operations and most demanding on their calls on judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. While our significant accounting policies are described in more detail in Note 2 to our financial statements appearing elsewhere in 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 financial statements.

Warrant Liability

We do not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. We evaluate all of our financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and FASB ASC Topic 815, "Derivatives and Hedging" ("ASC 815"). The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

The Series A Warrants issued in connection with the Purchase Agreement are recognized as a derivative liability in accordance with ASC 815. We recognize the warrant instruments as a liability at fair value and adjust the instruments to fair value at each reporting period. The liability is subject to re-measurement at each balance sheet date until exercised or reclassified, and any change in fair value is recognized in our consolidated statements of operations. The fair value of the Series A Warrants was measured using a Binomial simulation model. The determination of the fair value of the warrant liability may be subject to change as more current information becomes available, and, accordingly, the actual results could differ significantly. As the fair value of the warrant liability is based on a Binomial simulation model, we determined the fair value of the warrant liability was a critical accounting estimate.

Components of Our Results of Operations

Revenue. We did not recognize revenues for the years ended December 31, 2024 and 2023.

Operating Expenses. Our operating expenses are comprised primarily of research and development expenses, general and administrative expenses and licensing costs.

Research and Development Expenses. Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- personnel-related costs, including salaries, benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with our research programs, including under agreements with third parties, such as consultants and contractors and CROs;
- the cost of developing and scaling our manufacturing process and manufacturing drug substance and drug product for use in our research and preclinical and clinical studies, including under agreements with third parties, such as consultants and contractors and contract development and manufacturing organizations (CDMOs); and
- the cost of laboratory supplies and research materials.

We track our direct external research and development expenses on a program-by-program basis. These consist of costs that include fees, reimbursed materials, and other costs paid to consultants, contractors, CDMOs, and CROs in connection with our preclinical, clinical and manufacturing activities. We do not allocate employee costs, costs associated with our discovery efforts, and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and, as such, are not separately classified.

We expect that our research and development expenses will increase substantially as we advance OST-HER2 and OST-tADC into clinical development and expand our discovery, research and preclinical activities.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, investor and public relations and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Licensing Costs. Costs incurred in obtaining technology licenses and asset purchases are charged to licensing costs if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or regulatory success which has no alternative future use. The licenses purchased by us require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility.

Interest Expense. We evaluated the convertible notes issued by us from July 2018 to April 2024 in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), and determined the convertible notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the convertible notes were recorded at the amortized cost.

Cumulative Series A Preferred Stock Dividend. The Series A preferred stock dividend requirement represents the coupon dividends on our preferred stock that has since been converted and is identified as a separate component of our statement of operations to compute net income (loss) available to common stockholders. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly. The cumulative accrued dividend at December 31, 2024 and 2023 was $375,000 and $343,750, respectively. The Series A preferred stock was converted into common stock on a 1:1 basis in February 2024, and the last coupon dividend was issued in the quarter ended March 31, 2024.

Income Taxes. Since our inception, we have not recorded income tax benefits for the net operating losses incurred or the research and development tax credits generated in each year, due to the uncertainty of realizing a benefit from those items.

As of December 31, 2024, we had U.S. federal net operating loss carry forwards of approximately $22,236,580, which may be available to offset future taxable income. The federal net operating loss carry forward indefinitely but may only be used to offset 80% of annual taxable income. As of December 31, 2024, we also had federal and state general business tax credit carry forwards of $1,672,876 available to offset future tax liabilities and expire at various dates beginning in January 1, 2040. We have R&D credits that we opted to convert and use toward payroll taxes in amounts equal to $268,568 as of December 31, 2024. As of December 31, 2024, we also had federal and state research and development tax credit carry forwards of approximately $1,672,876, which may be available to offset future tax liabilities and expire at various dates beginning January 1, 2043 and January 1, 2042, respectively.

Deferred Offering Costs. Deferred offering costs consisted of legal, accounting, printing and filing fees that we capitalized, which will be offset against the gross proceeds from our initial public offering.

Results of Operations

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

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

(In thousands)	December 31, 2024	December 31, 2023
Expenses:		
Research and development expenses	$ 2,839	$ 3,217
General and administrative	3,975	1,121
Licensing	—	5
Total operating expenses	6,814	4,343
Loss from operations	(6,814)	(4,343)
Other income (expenses):		
Non-operating income	34	
Non-operating expenses	(51)	
Interest (expense)	(2,052)	(3,449)
Total other income (expense)	(2,069)	(3,449)
Net loss	(8,883)	(7,792)
Cumulative Series A preferred stock dividend requirement	(31)	(125)
Deemed dividend or Series A convertible preferred stock	(1,972)	—
Net loss available to common shareholders	$ 10,886	$ (7,917)

Research and Development Expenses. Research and development expenses were approximately $2.8 million for the year ended December 31, 2024 compared to approximately $3.2 million for the year ended December 31, 2023. This decrease was primarily due to a decrease in vendor expenses associated with our OST-tADC product. The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023:

(In thousands)	As of December 31, 2024	As of December 31, 2023
Direct research and development expenses by program:		
OST-HER2	$ 2,206	$ 2,598
OST-tADC	51	214
Unallocated research and development expenses:		
Personnel-related	582	405
Total research and development expenses	$ 2,839	$ 3,217

In 2024, the direct research and development expenses related to OST-HER2 were $2.2 million. In 2023, such expenses were primarily lab fees, vendor expenses and payroll. Additionally, in 2024 and 2023, we incurred expenses for our Phase IIb clinical trial. OST-tADC related direct research and development expenses were approximately $0.05 million and $0.2 million for the years ended December 31, 2024 and 2023, respectively.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2024 were approximately $4.0 million compared to $1.1 million for the year ended December 31, 2023. This increase was primarily attributed to increased payments to consultants, along with staff related payroll and legal fees.

Interest Expense. Interest expense for the year ended December 31, 2024 was approximately $2.1 million compared to $3.5 million for the year ended December 31, 2023.

The Series A preferred stock coupon dividend requirement of $31,250 for the year ended December 31, 2024 represents an expense that terminated during the period ended March 31, 2024 upon the conversion of our old Series A preferred shares into shares of our common stock. The Series A preferred stock coupon dividend requirement of $125,000 for the year ended December 31, 2023 represents a 12-month expense. We issued Series A convertible preferred stock with a deemed dividend of $1.97 million as of December 31, 2024.

Liquidity and Capital Resources

Operating Losses

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidates. For the years ended December 31, 2024 and 2023, we reported a net loss of approximately $8.9 million and $7.8 million, respectively, and had an accumulated deficit of approximately $41 million and $29.5 million, respectively. We expect to incur significant expenses at an increasing rate and increasing operating losses for the foreseeable future.

As of December 31, 2024 and 2023, we had cash of approximately $5.5 million and $0.04 million, respectively. We have funded our operations to date primarily from the sale of our convertible notes and Series A securities in our private placements, as well as the sale of our common stock in our initial public offering, which have provided total gross proceeds of $34.6 million as of March 28, 2025. We believe that the net proceeds from our private placements and initial public offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements for the next nine to 12 months.

Cash Flows

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

	December 31,	
(In thousands)	**2024**	**2023**
Cash used in operating activities	$ (7,282,295)	$ (3,006,967)
Cash provided by investing activities	—	1,145
Cash provided by financing activities	12,776,840	2,873,324
Net increase (decrease) in cash	$ 5,494,545	$ (132,498)

Operating Activities

During the years ended December 31, 2024 and 2023, operating activities used approximately $7.3 million and $3.0 million of cash, respectively, resulting from our net loss of approximately $8.9 million and $7.8 million, respectively, offset by net non-cash charges of approximately $1.7 million and $2.8 million, respectively, partially offset by net cash provided by changes in our operating assets and liabilities of approximately $0 million and $2.0 million, respectively.

Net cash provided by changes in our operating assets and liabilities for the years ended December 31, 2024 and 2023 consisted primarily of an increase (decrease) in accounts payable of approximately $ (1.1) million and $1.3 million, respectively, an increase (decrease) in accrued interest of approximately $0.6 million and $0.8 million, respectively, and a change in accrued payroll of approximately $0 million and $(0.3) million, respectively.

Non-cash charges for the years ended December 31, 2024 and 2023 were primarily the result of the amortization of debt discount on our convertible debt of approximately $1.4 million and $2.6 million, respectively. Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses and other current assets in all periods were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoicing and payments.

Investing Activities

During the years ended December 31, 2024 and 2023, net cash provided by investing activities was approximately $0 and $1,145, respectively.

Financing Activities

For the years ended December 31, 2024 and 2023, net cash provided by financing activities was approximately $12.8 million and $2.9 million, respectively.

Convertible Notes. We completed seven separate private financing transactions from July 2018 to April 2024 in which we issued convertible notes and raised total gross proceeds of $19,426,449 from accredited investors. All of the convertible notes were automatically converted into shares of our common stock at the closing of our initial public offering.

Demand Notes. On March 6, 2024 and June 28, 2024, we issued demand promissory notes to a lender who was an investor in one of our prior convertible notes rounds in a principal amount of $100,000 and $150,000, respectively. The demand notes bear interest at a rate of 8% per annum and the principal plus all accrued interest is payable upon demand by such lender. If such notes are not paid on demand by us, interest will accrue at a rate of the lesser of 16% per annum and the highest rate of interest allowable under Maryland law. As of August 14, 2024, we repaid the demand notes in full.

BlinkBio. On August 19, 2020, we issued a convertible note with a principal amount of $2,400,000 (the "BlinkBio Convertible Note") to BlinkBio, Inc., which was a related party because our former Chairman, Colin Goddard, Ph.D., is the Chairman and Chief Executive Officer of BlinkBio, in exchange for the entry into the license agreement. On March 15, 2021, the principal and unpaid accrued interest of $100,000 of the BlinkBio Convertible Note converted into 1,302,082 shares of our Series A preferred stock and then distributed to BlinkBio stockholders. The BlinkBio Convertible Note had a conversion capitalization ceiling of $19.2 million, which limited the price a noteholder must pay in a convertible note-to-common stock conversion occurrence. On February 9, 2024, the 1,302,082 shares of our Series A preferred stock were converted into 651,041 shares of common stock (on a post-split basis).

TEDCO Grant. In May 2021, we received the first of two tranches from TEDCO's Rural & Underserved Business Recovery from Impact of Covid-19 (RUBRIC) Grant in the amount of $50,000. In October 2021, we received the second tranche of $50,000, which brought the total reimbursable grant amount to $100,000. We are obligated to report on and pay to TEDCO 3% of their quarterly revenues for a five-year period following the reward date. Income from grants and investments are not considered revenues. Royalties due to TEDCO are capped at 150% of the amount of the award, or $150,000. We have the option to eliminate the quarterly royalty obligation by making an advance payment prior to the end of the five-year period, in which case, we will receive a 10% reduction of the royalty cap percentage for each year prior to the expiration of the five-year reimbursement period that the grant is repaid in full. If we cease to meet eligibility requirements at any time, the reimbursement obligation will become due to TEDCO immediately; however, the discount for meeting the obligation will still apply.

Private Placement

On December 24, 2024, we entered into the Purchase Agreement with the selling stockholders, substantially all of whom were existing stockholders of the Company, pursuant to which we agreed to issue and sell to the selling stockholders the Units for aggregate gross proceeds of not less than $6 million and not more than $10 million. At two closings occurring on December 31, 2024 and January 14, 2025, we issued to the selling stockholders an aggregate of (i) 1,775,750 shares of Series A Preferred Stock and (ii) Series A Warrants initially exercisable into 1,775,750 shares of common stock. The gross proceeds from the closing of the Private Placement, before deducting transaction fees and other estimated Private Placement expenses, were approximately $7,103,000. The Purchase Agreement requires us to seek stockholder approval for any transactions contemplated by the Purchase Agreement and the related documents for which the rules of the NYSE American require stockholder approval ("Stockholder Approval") and to hold a special meeting of stockholders for the purpose of obtaining Stockholder Approval not later than April 10, 2025. In the event Stockholder Approval is not obtained at the first meeting, we are required to call a meeting every four months seeking Stockholder Approval until Stockholder Approval is obtained.

Brookline acted as exclusive placement agent for the issuance and sale of the securities in the Private Placement. Pursuant to the terms of the Placement Agency Agreement, we agreed to pay Brookline an aggregate cash fee (the "Cash Fee") equal to (i) 7% of the gross proceeds received by the Company from the sale of the securities in the Private Placement to selling stockholders other than certain selling stockholders identified on a schedule thereto ("Reduced Fee Purchasers") plus (ii) 3% of the gross proceeds received by the Company from the sale of the securities in the Private Placement to Reduced Fee Purchasers, plus expenses; provided that Ceros is entitled to 33.3% of the Cash Fee.

In addition, we agreed to pay Brookline or its designees a fee in the form of the Agent Warrants. The Agent Warrants are initially exercisable into a number of shares of common stock equal to (i) 7% of the number of shares of common stock initially issuable pursuant to the shares of Series A Preferred Stock issued to selling stockholders other

than Reduced Fee Purchasers in the Private Placement plus (ii) 3% of the number of shares of common stock initially issuable pursuant to the shares of Series A Preferred Stock issued Reduced Fee Purchasers in the Private Placement; provided that Ceros is entitled to 33.3% of the Agent Warrants. The terms of the Agent Warrants are substantially similar to the terms of the Series A Warrants, except the Agent Warrants are not exercisable until Stockholder Approval is obtained. At two closings occurring on December 31, 2024 and January 14, 2025, (i) Brookline received an aggregate cash fee of $159,685 and 39,918 Agent Warrants, and (ii) Ceros received an aggregate cash fee of $79,723 and 19,930 Agent Warrants.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with our CDMOs, CROs and other third parties to support preclinical research studies and testing and other development activities. These contracts are generally cancellable by us. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

License Obligations and Research Services

Advaxis. In November 2020, we entered into an amended and restated development, license and supply agreement with Advaxis, Inc. (now Ayala Pharmaceuticals, Inc.) ("Advaxis"), a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* (*Listeria monocytogenes*)-LLO (Listeriolysin O) cancer immunotherapies. Pursuant to this agreement, Advaxis granted a license to us that allows us to utilize Advaxis' ADXS-HER2 construct patents to develop and commercialize ADXS-HER2, our lead product candidate (OST-HER2). The agreement was subsequently amended in April 2021 to modify the payment amounts for Milestones 2 and 3 listed in the table below. Under the terms of the amended agreement, we are required to pay to Advaxis (i) a one-time, non-refundable payment of $1,550,000 (the "License Commencement Payment") and (ii) certain amounts based on the achievement of the milestones described in the payment schedule below. As of December 31, 2024, we paid to Advaxis a total of $2,925,000, consisting of (i) the License Commencement Payment for Milestone 1 and (ii) $1,375,000 for Milestone 2.

Payments towards the License Commencement Payment have been recorded as licensing expenses in our Statement of Operations and Comprehensive Loss for the year ended December 31, 2022. We expect to achieve Milestone 3 in 2025. The payment schedule for milestones and corresponding payment amounts is set forth below.

Milestone	Milestone Payment
1. OST has secured funding of at least $2,337,500, in the aggregate (paid)	License commencement payment: $ 1,550,000
2. The earlier to occur of: (A) OST having secured at least $8,000,000, in the aggregate, or (B) completion of the first Clinical Trial (paid)	$ 1,375,000
3. The earlier to occur of: (A) receipt of Regulatory Approval from the FDA for the First Indication of the first Licensed Product or (B) initiation of the first Registrational Trial of the first Licensed Product in the Field	$ 5,000,000
4. Cumulative Net Sales of all Licensed Products in excess of $20,000,000	$ 1,500,000
5. Cumulative Net Sales of all Licensed Products in excess of $50,000,000 Cumulative Net Sales of all Licensed Products in ex	$ 5,000,000
6. Cumulative Net Sales of all Licensed Products in excess of $100,000,000	$ 10,000,000

All milestone payments are non-creditable and non-refundable and are due and payable upon the achievement of the milestone, regardless of any failure by us to provide notice to Advaxis of such achievement.

In addition to the payments upon achievement of the milestones listed in the above payment schedule, we are required to pay to Advaxis (i) a percentage in the high single digits to low double digits of (a) upfront sublicense fees or (b) clinical or regulatory milestone payment amounts, paid by a sublicensee to us in consideration of a sublicense grant to such sublicensee, and (ii) a quarterly royalty of a percentage in the high single digits to low double digits of net sales of our products containing the ADXS-HER2 constructs.

On January 28, 2025, we entered into the HER2 Purchase Agreement with Ayala, pursuant to which we agreed, subject to the terms and conditions set forth therein, to acquire from Ayala the HER2 Assets. Pursuant to the terms of the HER2 Purchase Agreement, the change in milestone payments and royalty consideration owed as it relates to the OST-HER2 program will be follows:

1. Elimination of $3,500,000 payment owed to Ayala upon the first filing of a BLA approval for OST-HER2 with the FDA.

2. Elimination of a total of $16,500,000 in OST-HER2 related sales milestone payments owed to Ayala made up of the following payments:

   - $1,500,000 owed upon reaching cumulative sales of $20,000,000;
   - $5,000,000 owed upon reaching cumulative sales of $50,000,000; and
   - $10,000,000 owed upon reaching cumulative sales of $100,000,000.

3. The reduction in total royalty consideration owed on OST-HER2 related sales from 10% of net sales owed to Ayala to 1.5% of net sales owed under the Penn License. The royalty consideration of 1.5% of net sales owed to the University of Pennsylvania going forward will apply to sales related to:

   - OST-HER2 related sales;
   - ADXS-503 related sales;
   - ADXS-504 related sales; and
   - Sales related to any new immunotherapy drug candidates created from the *Lm* platform during the term of the Penn License.

BlinkBio. In August 2020, we entered into a licensing agreement with BlinkBio, Inc., a privately held developer of drug conjugate therapies designed to facilitate the treatment of cancer. Pursuant to this agreement, BlinkBio granted a license to us that allows us to utilize BlinkBio's proprietary technology to develop, manufacture and commercialize certain of our products. BlinkBio granted us an exclusive license for tunable drug conjugates that are directed towards, binds to or modifies the folate receptor alpha and a co-exclusive license for tunable drug conjugates that are directed towards, binds to or modifies any target other than the folate receptor alpha, such as HER2.

Under the terms of the agreement, we are required to pay to BlinkBio (i) an upfront, non-refundable, non-creditable license fee of $300,000 (the "Up-Front Fee"), (ii) a royalty of 6% of net sales of our products that were made using BlinkBio's proprietary technology, subject to potential reductions on such royalty, and (iii) certain amounts based on the achievement of the milestones described in the payment schedule below.

As of December 31, 2024, we had paid the Up-Front Fee. The payment schedule for milestones and corresponding payment amounts is set forth below.

Milestone Bearing Event	Milestone Payment
1. License Fee to utilize proprietary technology (paid)	Up-front fee + $2.4 million Convertible Note
2. Commencement of a toxicology study commented pursuant to Good Laboratory Practices (under 21 CFR Part 58), such that any resulting positive data would be admissible to applicable Regulatory Authorities to support an IND (commonly referred to as "GLP-Tox").	$ 375,000
3. Completion of a Phase I Clinical Trial	$ 1,500,000
4. Completion of a Phase IIb Clinical Trial	$ 2,500,000
5. Filing of an NDA, BLA or MAA registration (or the equivalent in any other territory around the world)	$ 6,000,000
6. Regulatory Approval in the first of the United States, within the European Union or within the United Kingdom	$ 12,000,000

We are required to make the above cash payments to BlinkBio within 30 days of the achievement of each milestone with respect to the first product to attain each such milestone, except that the first milestone only applies to our first product candidate. The aggregate amount of payments relating to milestones 2 through 6 payable thereunder cannot exceed $22,375,000.

In connection with the license agreement, we also agreed to issue the BlinkBio Convertible Note. See "— *Convertible Notes*" above for more information on the BlinkBio Convertible Note.

George Clinical. In June 2020, we entered into a services agreement, as amended, with George Clinical, Inc., a clinical contract research organization. Pursuant to this agreement, we engaged George Clinical to use its clinical research services for our study entitled "An Open Label, Phase 2 Study of Maintenance Therapy with OST-HER2 after Resection of Recurrent Osteosarcoma." Under the terms of the agreement, we are required to pay to George Clinical certain fees described in the fee schedule below. The total new budget under the agreement is approximately $2,423,928. For the years ended December 31, 2024 and 2023, we paid $714,943 and $444,421, respectively, to George Clinical. These payments have been recorded as research and development expenses in our Statement of Operations and Comprehensive Loss. The fee schedule for certain fees and corresponding payment amounts is set forth below.

George Clinical Payment Schedule	Payment Amount
1. Service Fee Advance (paid)	$ 49,989
2. Service Fee Advance of $212,335 minus the amount already paid, plus PTC Fee Advance of $31,325 (paid)	$ 193,671
3. Statistics Fees – 35% on Electronic Data Capture (EDC) Go Live Date	$ 47,740
4. Statistics Fees – 35% on Development of SAP tables	$ 47,740
5. Statistics Fees – 30% on Final Analysis	$ 40,920
6. Service Fees – Remainder Due	Split monthly over course of study

George Clinical tracks and invoices us for the number of task units completed and pass-through costs are invoiced each month in arrears based on actual costs without mark-up. The PTC Fee Advance will be used to offset the first few months of invoices payable. As of December 31, 2024, the balance due to George Clinical was $359,617.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to Notes to the Financial Statements appearing elsewhere in this annual report.

The JOBS Act

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of the extended transition period for complying with new or revised financial accounting standards.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years; or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

OS THERAPIES INCORPORATED
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
OS Therapies Incorporated

Opinion on the Financial Statements

We have audited the accompanying balance sheets of OS Therapies Incorporated (the "Company") as of as of December 31, 2024 and 2023, and the related statements of operations, stockholders' deficit, 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 then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises 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 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 the Company's 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 audits 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 Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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/ MaloneBailey, LLP

www.malonebailey.com

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

Houston, Texas
March 31, 2025

OS Therapies Incorporated
Balance Sheets

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash	$ 5,533,527	$ 38,982
Deferred Offering Costs	—	751,050
Total Current Assets	5,533,527	790,032
Long Term Assets		
Fixed Assets (Net)	5,270	8,050
TOTAL ASSETS	$ 5,538,797	$ 798,082
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	$ 1,662,068	$ 2,715,399
Accrued Interest on Convertible Notes	—	2,026,323
Accrued Expenses	521,010	162,500
Accrued Payroll and Payroll Taxes – Related Party	97,257	112,137
Accrued Payroll and Payroll Taxes	—	33,543
Redemption Premium	—	4,580,304
Preferred Dividends Payable	375,000	343,750
Convertible Notes – A (Net Debt Discount)	—	1,051,032
Convertible Notes – A (Related Party Net Debt Discount)	—	100,000
Convertible Notes – B (Net Debt Discount)	—	5,154,000
Convertible Notes – C (Net Debt Discount)	—	3,873,417
Convertible Notes – D (Net Debt Discount)	—	1,950,160
Convertible Notes – E (Net Debt Discount)	—	1,100,000
Convertible Notes – F (Net Debt Discount)	—	1,381,732
Warrant Liability (Net of Discount)	1,971,975	—
Make-whole Stock Liability	—	130,000
Total Current Liabilities	4,627,310	24,714,297
Long Term Liabilities		
TEDCO Grant	100,000	100,000
Total Long Term Liabilities	100,000	100,000
Total Liabilities	4,727,310	24,814,297
Commitments and contingencies (See Note 9)		
MEZZANINE EQUITY:		
Series A Convertible Preferred Stock, par value $0.001, 2,500,000 shares authorized; 1,512,500 and 0 issued and outstanding, respectively	6,050,000	—
Total Mezzanine Equity	6,050,000	—
STOCKHOLDERS' DEFICIT		
Common Stock A, par value $0.001, 50,000,000 shares authorized; 20,869,908 and 5,340,000 issued and outstanding, respectively	20,870	5,340
Preferred Stock, par value $0.001, 5,000,000 shares authorized; 0 and 0 shares outstanding, respectively	—	1,302
Additional paid-in capital	35,144,967	5,495,330
Accumulated deficit	(40,404,350)	(29,518,187)
Total Stockholders' Deficit	(5,238,513)	(24,016,215)
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	$ 5,538,797	$ 798,082

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

OS Therapies Incorporated
Statements of Operations
For the Years Ended December 31, 2024 and 2023

	For the year ended December 31, 2024	For the year ended December 31, 2023
OPERATING EXPENSES		
Research & Development	$ 2,839,060	$ 3,216,933
General & Administrative	3,974,786	1,125,712
Loss from Operations	(6,813,846)	(4,342,645)
OTHER INCOME/EXPENSE		
Interest Income	—	2
Non-Operating Income	33,997	—
Non-Operating Expenses	(51,250)	—
Interest Expense	(2,051,839)	(3,448,939)
TOTAL OTHER INCOME/EXPENSE	(2,069,092)	(3,448,937)
NET LOSS	(8,882,938)	(7,791,582)
Cumulative Series A Preferred Stock Dividend Requirement	(31,250)	(125,000)
Deemed Dividend on Series A Convertible Preferred Stock	(1,971,975)	—
NET LOSS available to common shareholders	$ (10,886,163)	$ (7,916,582)
Weighted Average # of Shares	12,377,299	5,429,248
Basic & Diluted Loss per Common Share Outstanding	$ (0.88)	$ (1.46)

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

OS Therapies Incorporated
Statements of Stockholders' Deficit
For the Years Ended December 31, 2024 and 2023

	Common Stock CS – Shares	CS – Par Amount	Preferred Stock Shares	Par Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances, December 31, 2022	4,990,000	$ 4,990	1,302,082	1,302	$ 4,038,083	$ (21,601,603)	$ (17,557,228)
Make Whole Liability to Common Stock	350,000	350	—	—	699,650	—	700,000
Unwind of Make-whole stock Liability	—	—	—	—	757,597	—	757,597
Preferred Dividends	—	—	—	—	—	(125,000)	(125,000)
Net Loss	—	—	—	—	—	(7,791,582)	(7,791,582)
Balances, December 31, 2023	5,340,000	$ 5,340	1,302,082	$ 1,302	$ 5,495,330	$ (29,518,187)	$ (24,016,215)
Conversion of Preferred Stock to Common Stock	651,041	651	(1,302,082)	(1,302)	651	—	—
Preferred Dividends	—	—	—	—	—	(31,250)	(31,250)
Issuance of Common Stock IPO	1,600,000	1,600	—	—	4,473,626	—	4,475,226
Conversion of Convertible Notes to Common Stock	13,153,396	13,153	—	—	24,743,662	—	24,756,815
Conversion of Warrants to Common Stock	411,290	411	—	—	(411)	—	—
Issuance of Common Stock to Investment Advisor	320,133	320	—	—	(320)	—	—
Conversion of Make-Whole Liability to common stock	32,500	33	—	—	129,968	—	130,000
Surrender of Common Stock Investors	(669,958)	(669)	—	—	670	—	1
Stock-based compensation	—	—	—	—	268,300	—	268,300
Shares issued for Services	25,000	25	—	—	24,975	—	25,000
Shares issued for Interest	6,506	7	—	—	8,516	—	8,523
Deemed Dividend on Series A Convertible Preferred Stock	—	—	—	—	—	(1,971,975)	(1,971,975)
Net Loss	—	—	—	—	—	(8,882,938)	(8,882,938)
Balances, December 31, 2024	20,869,908	$ 20,870	—	$ —	$ 35,144,967	$ (40,404,350)	$ (5,238,513)

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

OS Therapies Incorporated
Statements of Cash Flows
For the Years Ended December 31, 2024 and 2023

	December 31, 2024	December 31, 2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (8,882,938)	$ (7,791,582)
Depreciation expense	2,780	4,220
Amortization of Debt Discounts Issuance and Warrants	1,425,679	2,646,459
Make-whole expense	—	116,688
Shares issued for services	25,000	—
Shares issued for interest expense	8,523	—
Stock-based compensation	268,300	—
Adjustments to reconcile net loss to net cash used in operating activities:		
Accounts Payable	(1,053,331)	1,347,602
Accrued Expenses	358,510	147,500
Accrued Interest on Convertible Notes	613,605	802,479
Accrued Payroll and payroll taxes	(48,423)	(280,333)
Net cash used in operating activities	**(7,282,295)**	**(3,006,967)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Shareholder Loan Repayment	—	1,145
Net cash provided by investing activities	**—**	**1,145**
CASH FLOWS FROM FINANCING ACTIVITIES		
Deferred Offering Costs	—	(284,176)
Short Term Borrowings	250,000	—
Short Term Loan Repayments	(250,000)	—
Initial Public Offering (Net of Fees)	5,225,840	—
Sale of Preferred Stock & Warrants	6,050,000	—
Net Proceeds from Conversion of Debt A, B, C, D, E & F	1,501,000	3,157,500
Net cash provided by financing activities	**12,776,840**	**2,873,324**
Net change in cash	5,494,545	(132,498)
Cash – beginning of period	38,982	171,480
Cash – end of period	$ 5,533,527	$ 38,982
Cash paid for interest	$ —	$ —
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Discount on Notes Payable – redemption premium	$ 750,500	$ 1,541,250
Dividends Payable	31,250	125,000
Deemed Dividend on Series A Convertible Preferred Stock	1,971,975	—
Conversion of Make Whole Liability to common stock	130,000	700,000
Conversion of Preferred Stock to common stock	1,302	—
Amortization of deferred offering costs	751,050	—
Conversion of Convertible Notes into Common Stock	24,757,252	—
Conversion of Warrants into Common Stock	411	—
Issuance of Common Stock to Investor Advisor – Settlement	320	—
Clawback of Common Stock for over issuance	(670)	—
Unwind of 4% anti-dilution to Noble”	—	757,597
Deferred offering costs recorded as accounts payable	—	142,664

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

OS Therapies Incorporated
Notes to the Financial Statements
For the Years Ended December 31, 2024 and 2023

NOTE 1 — ORGANIZATION AND DESCRIPTION OF BUSINESS, LIQUIDITY, AND RISK FACTORS

OS Therapies Incorporated ("we," "us," "our," the "Company") is a Delaware corporation incorporated on June 24, 2019. It is based in Rockville, Maryland. The Company is the successor to an LLC formed in 2018.

The Company intends to focus on the identification, development, and commercialization of treatments for Osteosarcoma and other related diseases. As of December 31, 2024, there is one ongoing clinical trial for Osteosarcoma therapy.

Liquidity

The Company has prepared its financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

As of December 31, 2024, the Company had cash of $5,533,527. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital. The Company is currently seeking to raise additional capital through a public or private financing of equity; although there can be no assurances the Company will be successful in such a campaign.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of U.S. Securities and Exchange Commission ("SEC"). The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America, and the Company's fiscal year end is December 31.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Cash

Cash consists primarily of deposits with commercial banks and financial institutions. The Company maintains cash balances at various financial institutions. Both interest and non-interest-bearing accounts with the same insured depository institution are insured by the Federal Deposit Insurance Corporation (FDIC) for a combined total of $250,000. In the normal course of business, the Company may have deposits that exceed the FDIC insured limit. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of December 31, 2024, and December 31, 2023, Chase Bank Checking account had $5,216,354 and $88, respectively. Chase Savings account had $20,000 and $0 as of December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024 and December 31, 2023, SVB Bank Checking account had $287,173 and $28,893, respectively, and the SVB Money Market account had $10,000 and $10,000, respectively. The accounts in excess of the FDIC limits are the Chase checking account and the SVB Bank Checking account.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Redeemable Preferred Stock and Mezzanine Equity

The Company's Series A Preferred Stock, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480 ("ASC 480"), is accounted for as mezzanine equity due to the redemption feature upon a deemed liquidation event: (i) a merger or consolidation, or (ii) the sale, lease, transfer or other disposition of substantially all the assets of the Company. The initial cash proceeds of $6,050,000 were allocated to the Warrants and the residual proceeds were allocated to the Series A Preferred Stock. Because the Series A Preferred Stock is classified as a mezzanine equity, the Company will record a deemed dividend for the accretion of the Series A Preferred Stock to carrying value in accordance with ASC 480.

Fixed Asset Policy

A capital asset is defined as a unit of property that has an economic useful life that extends beyond 12 months. Any items costing below the threshold or not fitting the definition of a capital asset will be expensed in the financial statements. All capital assets are recorded at historical cost as of the date acquired. Computer assets will be capitalized and Straight-Line depreciated over five years for financial statement purposes.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups 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 estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded for the year ended December 31, 2024 or the year ended December 31, 2023.

Deferred Offering Costs

Deferred offering costs consist of capitalized underwriting, legal, accounting and other expenses incurred through the balance sheet date that are directly related to the Company's initial public offering and that were charged to stockholders' equity upon the completion of such offering. On December 31, 2024, the Company had $0 in capitalized deferred offering costs. On December 31, 2023, the Company had $751,050 in capitalized deferred offering costs. Upon completion of the Company's initial public offering on August 2, 2024, the deferred offering costs were charged to stockholders' deficit.

Debt Discount and Redemption Premium

The Company evaluated the Notes in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes will be recorded at the amortized cost.

The initial fair value of the redemption value relating to the convertible debt instruments are capitalized and amortized over the term of the related debt using the straight-line method, which approximates the interest method. If a loan is paid in full, any unamortized financing costs will be removed from the related accounts and charged

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

to operations. Amortization of debt discount is recorded as a component of interest expense. In accordance with ASU 2015-03, Interest — Imputation of Interest, the unamortized debt discount is presented in the accompanying balance sheet as a direct deduction from the carrying amount of the related debt.

Research and Development Costs

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, and supplies.

Revenue Recognition

As of the date of incorporation, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers*, and all subsequent amendments to the ASU (collectively, "ASC 606"), which (i) creates a single framework for recognizing revenue from contracts with customers that fall within its scope and (ii) revises when it is appropriate to recognize a gain (loss) from the transfer of nonfinancial assets.

Stock-Based Compensation

The Company, in accordance with ASC 718, employs the use of stock-based compensation. The compensation expense related to stock granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

Short-term Leases

For short-term leases, 12 months or less, we record rent expense. Our only lease currently meets this exemption and has been expensed. We have not renewed the current lease due to landlord restrictions; the ownership is renovating the premises. We have temporarily moved our primary office to 115 Pullman Crossing Road, Suite #103, in Grasonville, Maryland 21638. The space is the primary office of our Chief Financial Officer and is being provided rent free. In May 2024, we signed a month-to-month lease with JLabs for $750 per month, primarily to have meetings in New York City and to have an office for our staff when they are in town.

Income taxes

The Company accounts for income taxes using the asset-and-liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of a change in tax rate is recognized in the period that includes the enactment date. A valuation allowance is recorded if it is "more likely than not" that some portion or all of the deferred tax assets will not be realized in future periods.

The Company follows the guidance in ASC Topic 740-10 in assessing uncertain tax positions. The standard applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely-than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to be recognized.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Tax positions that meet the more-likely than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more likely than not to be sustained by the relevant taxing authority.

The Company will recognize interest and penalties related to tax positions in income tax expense. As of December 31, 2024 and December 31, 2023, the Company had no unrecognized uncertain income tax positions.

Basic and Diluted Loss per Share

The Company computes loss per share in accordance with ASC 260, *Earnings per Share* ("ASC 260"). ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the statements of operations. Basic EPS is computed by dividing the net loss available to common shareholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible notes payable using the if-converted method. Diluted EPS excludes all diluted potential shares if their effect is antidilutive.

Below is a table listing all preferred stock and common stock equivalents:

Common Stock Equivalents	**12/31/2024**	**12/31/2023**
Convertible Debt	—	10,405,710
Make-Whole Liability	—	32,500
Warrants	280,448	302,141
Preferred Stock	—	651,041
Preferred Stock Warrants	1,512,500	—
Total	1,792,948	11,391,392

The shares of Series A Convertible Preferred Stock issued on December 31, 2024 are not included in the above table as stockholder approval is required for the issuance of shares of common stock upon any conversion thereof. As of December 31, 2024, the maximum number of shares of common stock to be issued upon conversion of all of the 1,512,500 Series A Convertible Preferred Stock is 6,050,000 shares of common stock.

Fair Value Measurements

The Company applies ASC 820 *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date.

The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash, accounts payable, and accrued expenses are approximate fair value because of the short-term maturity of these financial instruments. The redemption feature of the debt instruments is recorded at fair value (See Note 3).

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Warrant liability is recorded at fair value. Currently, there is not an observable market for this type of derivative. Due to the lack of relevant and market reflective Level 1 and Level 2 inputs, the Company valued the warrant liability using Level 3 inputs, which require significant judgment and estimates on behalf of management in developing model assumptions. As of December 31, 2024, the carrying value of the warrant liability in the aggregate was $1,971,975 (See Note 9).

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Warrant Liability

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all its financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and FASB ASC Topic 815, "Derivatives and Hedging" ("ASC 815"). The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

The warrants issued in connection with a Securities Purchase Agreement, dated as of December 24, 2024 (the "Purchase Agreement"), are recognized as a derivative liability in accordance with ASC 815. The Company recognizes the warrant instruments as a liability at fair value and adjusts the instruments to fair value at each reporting period. The liability is subject to re-measurement at each balance sheet date until exercised or reclassified, and any change in fair value is recognized in the Company's consolidated statements of operations. The fair value of the warrants issued in connection with the Purchase Agreement were measured using a Binomial simulation model. The determination of the fair value of the warrant liability may be subject to change as more current information becomes available and accordingly the actual results could differ significantly. The derivative warrant liability is classified as non-current liabilities as their liquidation is not reasonably expected to require the use of current assets or require the creation of current liabilities.

Recent Accounting Pronouncements

The Company has evaluated all recent accounting pronouncements and believes that none of them will have a material effect on the Company's financial position, results of operations, or cash flows.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Accounting Principles Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, requiring public companies to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public companies with a single report segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements of ASU 2023-07 during the year ended December 31, 2024. The Company operates as one operating segment and the Company's CEO is the chief operating decision maker ("CODM"). The CODM uses the consolidated statement of operations to assess financial performance and allocate resources.

NOTE 3 — RELATED PARTY TRANSACTIONS

Accrued Payroll

On December 31, 2024 and December 31, 2023, the Company had a payroll payable to the CEO of $8,871 and $300,000, respectively, and related payroll taxes payable of $88,386 and $7,830, respectively. During the period ended December 31, 2024 and December 31, 2023, the Company made advances on the payroll payable, and the CEO made repayments.

The following summarizes activity in respect to payroll advances to the CEO:

Balance December 31, 2022	$ —
Advances during 2023	316,198
Repayment	(125,000)
Balance December 31, 2023	$ 191,198
Advances during 2024	222,875
Repayment	(414,073)
Balance December 31, 2024	$ 0

In the second and third quarters of 2024, paychecks were issued to Paul Romness, CEO. The paychecks comprised the remaining balance of backpay, less all 2023 payroll advances. The payroll taxes were paid that were associated with the backpay and regular pay and are fully paid. The balance of accrued payroll for Mr. Romness on December 31, 2024 of $8,870 represents a board approved 2024 bonus that was approved and paid in January 6, 2025. All payroll advances shown as employee advances were repaid by December 31, 2024 from Mr. Romness's pending bonus paycheck.

Related Parties — Convertible Debt

Ted Search and John Ciccio, collectively known as Mill River Partners LLC, are members of the Board and held convertible notes with face amounts of $0 and $150,000 as of December 31, 2024, and December 31, 2023, respectively. The convertible notes were converted into common stock upon consummation of the Company's initial public offering on August 2, 2024.

Related Party Accounting Fees

The Company has a bill in accounts payable of $26,765 for the period ended December 31, 2024 and $32,102 for the period ended December 31, 2023 to Shore Accountants MD Inc., an outside accounting firm that handles payroll and bookkeeping and is 100% owned by Christopher Acevedo, the CFO.

NOTE 4 — CONVERTIBLE DEBT

Convertible Debt

The Company's convertible notes are separated into seven groups — A, B, C, D, E, F and BlinkBio — per the table below:

Group	Rate	Maturity	Collateral	Conversion Rate	December 31, 2024 Carrying Amount	December 31, 2023 Carrying Amount
A	10%	10/31/2024	None	80% – 87.5%	$ —	$ 1,151,032
B	6%	10/31/2024	None	80%	$ —	$ 5,154,000
C	6%	10/31/2024	None	80%	$ —	$ 3,873,417
D	6%	10/31/2024	None	50%	$ —	$ 1,950,160
E	6%	10/31/2024	None	50%	$ —	$ 1,100,000
F	6%	10/31/2024	None	50%	$ —	$ 1,381,732
Blink Bio	10%	3/15/2022	None	100%	$ —	$ —

The above convertible notes were all converted into common stock on August 2, 2024 upon consummation of the Company's initial public offering.

Group A

Commencing in July 2018 through November 2021, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"). Interest on the unpaid principal balance accrues at a rate of 10% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended on October 24, 2023, under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 80 – 87.5% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $3,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes) or $5,000,000, depending upon the signed agreement terms.

In the event that the Company raises aggregate additional cash proceeds of at least $3,000,000 or $5,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 12.5% of the equity stock conversion price. The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

The Company evaluated the Notes in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried

NOTE 4 — CONVERTIBLE DEBT (cont.)

at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance on December 31, 2024 and December 31, 2023 is summarized as follows:

Debt A	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 1,154,000
Less: discounts (issuance, redemptions)	—	(185,224)
Amortization of discounts	—	182,256
Carrying value	—	1,151,032
Less Related Party Portion	—	(100,000)
Convertible Notes – A	$ —	$ 1,051,032

Group B

Commencing in May 2020, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued a Subordinated Convertible Promissory Note (individually the "Note" or together the "Notes") to the Holders, principally the investors brought in by an investment bank. Interest on the unpaid principal balance accrues at a rate of 6% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended October 24, 2023, under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 80% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $10,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes).

In the event that the Company raises aggregate additional cash proceeds of at least $10,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 12.5% of the equity stock conversion price.

The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

The Company evaluated the Notes in accordance with ASC 480 and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other

NOTE 4 — CONVERTIBLE DEBT (cont.)

accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance at December 31, 2024 and December 31, 2023 is summarized as follows:

Debt B	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 5,154,000
Less: discounts (issuance, redemptions, warrants)	—	(1,818,939)
Amortization of discounts	—	1,818,939
Carrying value	$ —	$ 5,154,000

Group C

Commencing in July 2021, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued a Subordinated Convertible Promissory Note (individually the "Note" or together the "Notes") to the Holders, principally the investors brought in by an investment bank. Interest on the unpaid principal balance accrues at a rate of 6% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended October 24, 2023, under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 80% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to the Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $10,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes).

In the event that the Company raises aggregate additional cash proceeds of at least $10,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 12.5% of the equity stock conversion price.

The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

The Company evaluated the Notes in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been

NOTE 4 — CONVERTIBLE DEBT (cont.)

determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance on December 31, 2024 and December 31, 2023 is summarized as follows:

Debt C	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 3,945,020
Less: discounts (issuance, redemptions, warrants)	—	(1,063,223)
Amortization of discounts	—	991,620
Carrying value	$ —	$ 3,873,417

Group D

Commencing in November 2022, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued a Subordinated Convertible Promissory Note (individually the "Note" or together the "Notes") to the Holders, principally the Investors brought in by an investment bank. Interest on the unpaid principal balance accrues at a rate of 6% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended October 24, 2023 under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 50% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $10,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes).

In the event that the Company raises aggregate additional cash proceeds of at least $10,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 50% of the equity stock conversion price.

In connection with the Group D Convertible Notes, the Company agreed to issue an additional 125,000 shares of common stock to the Group D Holders, prorated based on such Holder's investment amount, as an inducement for their investment in the Group D Convertible Notes.

The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

The Company evaluated the Notes in accordance with ASC 480 and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in

NOTE 4 — CONVERTIBLE DEBT (cont.)

shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance at December 31, 2024 and December 31, 2023 is summarized as follows:

Debt D	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 2,000,000
Less: discounts (issuance, redemptions, warrants)	—	(1,864,654)
Amortization of discounts	—	1,814,814
Carrying value	$ —	$ 1,950,160

Group E

Commencing in February 2023, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued a Subordinated Convertible Promissory Note (individually the "Note" or together the "Notes") to the Holders, principally the investors brought in by an investment bank. Interest on the unpaid principal balance accrues at a rate of 6% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended October 24, 2023 under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 50% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $10,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes).

In the event that the Company raises aggregate additional cash proceeds of at least $10,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 50% of the equity stock conversion price. In connection with the Group E Notes, the Company agreed to issue an additional 68,750 shares of common stock to the Group E Holders, prorated based on such Holder's investment amount as an inducement for their investment in the Group E Notes.

The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

The Company evaluated the Notes in accordance with ASC 480 and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in

NOTE 4 — CONVERTIBLE DEBT (cont.)

shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance at December 31, 2024 and December 31,2023 is summarized as follows:

Debt E	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 1,100,000
Less: discounts (issuance, redemptions, warrants)	—	(550,000)
Amortization of discounts	—	550,000
Carrying value	—	1,100,000
Less related party portion	—	(50,000)
Convertible Notes – E	$ —	$ 1,050,000

Group F

Commencing in June 2023, the Company entered into an unsecured Subordinated Convertible Promissory Note Agreement (the "Agreements") with certain lenders (together, the "Holders" or individually, the "Holder"), pursuant to which the Company issued a Subordinated Convertible Promissory Note (individually the "Note" or together the "Notes") to the Holders, principally the investors brought in by an investment bank. Interest on the unpaid principal balance accrues at a rate of 6% per annum, computed on the basis of the actual number of days elapsed and a year of 365 days. Unless earlier converted into shares of Equity Securities, the principal and accrued interest will be due and payable by the Company on demand by the Holders at any time after the earlier of (i) the Maturity Date (as defined in each Agreement) and (ii) the closing of the Next Equity Financing (as defined below). The stated Maturity Date was extended October 24, 2023, under the same terms, until October 31, 2024.

The Notes will automatically convert into the type of Equity Securities issued in the Next Equity Financing upon closing. The number of shares of such Equity Securities to be issued will be equal to the quotient obtained by dividing the outstanding principal and unpaid accrued interest due on the Note on the date of conversion of 50% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $10,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes).

In the event that the Company raises aggregate additional cash proceeds of at least $10,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due will automatically, and without any action on part of the holder, be converted into fully paid and non-assessable units of the Company's equity stock sold in such qualified financing at 50% of the equity stock conversion price. In connection with the Group F Notes, the Company agreed to issue an additional 214,594 shares of common stock to the Group F Holders, prorated based on such Holder's investment amount, as an inducement for their investment in the Group F Notes.

The Company, at its option, may pay all accrued, but unpaid, interest and other charges in cash or by the issuance of additional equity stock at a rate of the applicable conversion price.

NOTE 4 — CONVERTIBLE DEBT (cont.)

The Company evaluated the Notes in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and determined the Notes are considered share-settled debt and should be recorded as a liability. This conclusion was determined based on the debt providing the holder with a variable number of shares at settlement with an aggregate fair value equal to the debt instrument's outstanding principal. The general measurement guidance in ASC 480 requires obligations that can be settled in shares with a fixed monetary value at settlement (e.g., share-settled debt) to be carried at fair value unless other accounting guidance specifies another measurement attribute. It has been determined that the appropriate guidance for share-settled debt is ASC 835. As a result, the Notes were recorded at the amortized cost. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock.

The convertible debt balance at December 31, 2024 and December 31,2023 is summarized as follows:

Debt F	As of December 31, 2024	As of December 31, 2023
Principal amount outstanding	$ —	$ 1,932,500
Less: discounts (issuance, redemptions, warrants)	—	(966,250)
Amortization of discounts	—	415,482
Carrying value	$ —	$ 1,381,732

Redemption Liability

The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, is determined based upon a Probability-Weighted of Expected Returns Model ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since the Company has not entered into a priced equity round through December 31, 2024. The fair value of the redemption liability is calculated using the initial value of the convertible note less the debt discount rate of 12.5% in Group A, 20% in Groups B and C, and 50% in Groups D, E and F. The redemption liability is then amortized over the remaining life of the note, utilizing the interest rates of 10% and 6% respectively for the groups. The life of each note in Group A is for a set period of 3 years, and is variable in Groups B, C, D, E and F with a range of 12 months to 3 years. The Company retains the option to negotiate an extended maturity date for Groups B, C, D, E and F. The new embedded redemption values were $0 for the year ended December 31, 2024, and $1,541,250 for the year ended December 31, 2023, respectively. On August 2, 2024, the Company consummated its initial public offering, and the convertible notes, including accrued interest, converted into shares of the Company's common stock. The redemption liability was closed to stockholders' equity on such date.

The redemption liability is re-measured at each period end and is summarized as follows:

	As of December 31, 2024	As of December 31, 2023
New Embedded Redemption Value – Group A	—	144,250
New Embedded Redemption Value – Group B	—	1,130,800
New Embedded Redemption Value – Group C	—	789,004
New Embedded Redemption Value – Group D	—	1,000,000
New Embedded Redemption Value – Group E	—	550,000
New Embedded Redemption Value – Group F	—	966,250
Ending Balance	**—**	**$ 4,580,304**

NOTE 4 — CONVERTIBLE DEBT (cont.)

Fees Associated with Convertible Debt Raise

The fees associated with the convertible debt raise are legal and investment fees associated with the issuance of the convertible notes for Groups A, B, C, and D. There were no related parties who received these fees. The fees are amortized over the life of the convertible note utilizing an interest rate of 10% for Group A and 6% for Groups B, C, and D. The debt issuance liability is re-measured at each period end and is summarized in the table below.

	As of December 31, 2024	As of December 31, 2023
Debt Issuance		
Group A	$ —	$ —
Group B	—	—
Group C	—	9,133
Group D	—	—
Group E	—	—
Group F	—	—
Total Net Debt Issuance	$ —	$ 9,133

Make-whole liability — Shares due Noble Capital

In March 2020, the Company signed a new advisory agreement with Noble Capital, in lieu of cash remuneration and the company agreed to issue 4% of the Company's shares, with an anti-dilution clause. The make-whole liability represents the shares earned for the anti-dilution of their stock position over 2020 and 2021. The 2021 year-end had the Company owning an aggregate of 233,202 shares valued in the amount of $408,413, after issuing 200,000 shares in 2020. In 2021, the Company recorded an associated expense to advisory fees of $152,482 to recognize the share value earned on the anti-dilution compensation in 2021. In 2022, the Company set aside 70,624 shares to satisfy the anti-dilution clause. In 2022, the Company recorded an associated expense to advisory fees of $282,496 to recognize the share value earned on the anti-dilution compensation in the 2022.

For the years ended December 31, 2024 and 2023, the Company recorded an additional 0 and 16,672 shares, respectively, with an associated expense to advisory fees of $0 and $66,688, respectively, on the anti-dilution compensation.

On July 1, 2023, the make-whole liability for Noble Capital was determined to be contractually nullified. The Company unwound the liability, and it is reflected in our Statement of Stockholders' Deficit.

Noble Capital and the Company settled on various investment fees in dispute, as well as the shares of the Company's common stock related to the anti-dilution clause that expired in September 2024. Noble Capital was awarded 320,033 shares of common stock and $50,000 in cash.

Make-whole liability — Shares Officers & Directors

In January 2023, 350,000 shares of Class A common stock were issued to officers, key employees, key advisors and directors, leaving 20,000 shares in the balance to be issued to Joacim Borg, a director with a value of $80,000.

On March 1, 2023, the Company hired Alan Musso, former CFO, and, as part of his compensation contract, he was awarded 12,500 shares of common stock with a value of $4.00 per share, the $50,000 in compensation of which is reflected in the make-whole stock liability.

NOTE 4 — CONVERTIBLE DEBT (cont.)

Alan resigned on June 30, 2023, and Christopher Acevedo, current CFO, took his position. Mr. Acevedo was awarded the balance of Mr. Musso's shares upon the successful initial public offering.

The Company's make-whole share liability is summarized in the table below as of September 30, 2024.

Name	Position	# Shares	Value	Date Earned
Alan Musso	Former CFO	3,125	$ 12,500	March 1, 2023
Christopher Acevedo	Current CFO	9,375	37,500	Upon IPO
Joacim Borg	Director	20,000	80,000	July 1, 2022
		32,500	$ 130,000	

The Company issued all of the make-whole shares due to the director and officers in October 2024, and, therefore, the current balance due is 0 shares.

Warrants for Placement Agent — Noble Capital

In March 2020, the Company signed a new advisory agreement with Noble Capital, in lieu of cash remuneration it was provided a 10% warrant fee, in addition to cash remuneration on debt raises from Noble procured investments. The terms of the warrants are five years at an exercise price that equates to the average price the convertible debt holders paid in each debt raise round.

The number of warrants earned in 2020 was 248,855 valued at $248,855. The number of warrants earned in 2021 was 213,782, valued at $427,564. The total warrants earned as of December 31, 2022 was 162,644, valued at $325,288. No warrants were earned in 2023 or 2024.

Warrants earned in 2022, 2021 and 2020 have been accounted for as a discount to the associated convertible debt with the discounts amortized over the term of the related debt. The Debt Discount Accretion expense in warrants in the year ended December 31, 2024 was $49,840 and in the year ended December 31, 2023 was $83,069. The total unamortized discount of those warrants was $0 and $49,840 as of December 31, 2024 and December 31, 2023, respectively.

Warrant holders from Noble Capital exercised their warrants in cashless exercise for an aggregate of 116,313 shares of common stock out of the aggregate 621,691 shares underlying warrants held by such holders in September 2024. In December 2024, warrant holders from Noble Capital exercised their remaining warrants in a reduced cashless transaction for an aggregate of 294,977 shares of common stock.

Warrants for Underwriter and Placement Agent — Brookline Capital Markets

On August 2, 2024, the Company issued a warrant to Brookline Capital Markets to purchase 112,000 shares of the Company's common stock, pursuant to an underwriting agreement entered into between the Company and Brookline. The warrant is exercisable 180 days after July 31, 2024, terminates on July 31, 2029, and has an exercise price of $4.40 per share.

On December 31, 2024, the Company entered into the Purchase Agreement, and, in connection therewith, Brookline earned warrants exercisable into an aggregate of 39,918 shares at an initial exercise price of $4.40 per share, subject to adjustment as set forth therein. The warrants are exercisable by the holder for a period of five years from the date stockholder approval for the issuances contemplated by the Purchase Agreement is obtained.

NOTE 4 — CONVERTIBLE DEBT (cont.)

Short-Term Loan

An investor lent the Company $100,000 on March 7, 2024. The note is a demand note, carrying interest at 8% and was used for working capital purposes. An investor lent the Company $150,000 on June 28, 2024. The note is a demand note, carrying interest at 8% and was also used for working capital purposes. The Company repaid these loans, including accrued interest thereon, in August 2024.

NOTE 5 — TEDCO GRANT

In May of 2021, the Company received the first of two tranches from TEDCO's *Rural & Underserved Business Recovery from Impact of COVID-19 (RUBRIC) Grant* in the amount of $50,000. A second tranche of $50,000 was received in October 2021 for a total reimbursable grant amount of $100,000. The Company is obligated to report on and pay to TEDCO 3% of their quarterly revenues for a five-year period following the reward date. Income from grants and investments are not considered revenues. Royalties due to TEDCO are capped at 150% of the amount of the award or $150,000 total. The Company has the option to eliminate the quarterly royalty obligation by making an advance payment prior to the end of the five-year period, in which case, the Company will receive a 10% reduction of the royalty cap percentage for each year prior to the expiration of the five-year reimbursement period that the grant is repaid in full. If the Company ceases to meet eligibility requirements the reimbursement obligation will become due to TEDCO immediately; however, the discount for meeting the obligation will still apply.

NOTE 6 — INCOME TAXES

Significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 6,559,791	$ 4,799,618
General Business Credit Carryover	1,672,876	1,408,963
R&D Credit (available for payroll tax offset)	268,568	268,568
Subtotal	8,501,235	6,477,149
Valuation allowance	(8,501,235)	(6,477,149)
Total deferred tax assets	$ —	$ —

The federal income tax rate used for the years ended December 31, 2024 and 2023 was 21%. The Maryland rate was 8.25%.

For years ended December 31, 2024 and December 31, 2023, the Company had federal net operating loss ("NOL") of $22,236,580 and $16,269,893, respectively. The 2019 NOL carryforward of $292,144 will expire in tax years up through 2037. The NOLs generated in tax years 2020 and beyond will carry forward indefinitely, but the deductibility of such federal NOLs is limited. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

The Company's issuances of common stock have resulted in ownership changes as defined by Section 382 of the Code; however, the Company has not conducted a Section 382 study to date. It is likely that a future analysis may result in the conclusion that a substantial portion, or perhaps substantially all, of the Company's NOL carryforwards and R&D tax credit carryforwards will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of the carryforwards may be limited, and a portion of the carryforwards may expire unused. The Company is subject to U.S. federal tax examinations by tax authorities for the year 2021 due to the fact that NOL carryforwards exist going back to 2019 that may be utilized on a current or future year tax return.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

Employee Commitments

There are no employee commitments as the Company operates on an At-Will employment basis.

Rental Agreement

The Company had a rental agreement with BXP Shady Grove Lot 7 LLC, beginning in April 2023 and ending in December 2023. The payment term of the license agreement was $1,000 per month. Rent expense for the year ended December 31, 2023 was $12,000. The Company has not renewed its lease and has a mailing address at 115 Pullman Crossing Road, Suite 103, Grasonville, Maryland 21638. The Company has rented, on a month-to-month basis, a virtual office at JLabs in New York, New York. The current rent for JLabs is $787.50 per month, with rent expense in 2024 of $3,250 and $0 in 2023.

License Obligation and Manufacturing Agreements Advaxis

The Company entered into an exclusive license agreement with Advaxis, Inc in September 2018, as amended, pursuant to which it acquired the right to develop and commercialize Advaxis HER2 Construct, the Company's product candidate and the use of Advaxis HER2 Construct patents.

Per the agreement, all milestone payments are non-creditable and non-refundable and will be due and payable upon the occurrence of the corresponding milestone event. For clarity, each milestone payment is payable only once. As of December 31, 2020, the Funding Milestone had been achieved and payment in full was made in January 2021. As of May 2021, the second milestone had been completed and paid. For the year ended December 31, 2024, no payments were made.

The milestone events and financial terms are as follows:

Milestone	Amount
1. OST has secured funding of at least Two Million Three Hundred Thirty-Seven Thousand Five Hundred US Dollars ($2,337,500), in the aggregate (The Funding Milestone) (paid). . .	License Commencement Payment $1,550,000
2. The earlier to occur of: (A) OST having secured at least Eight Million US Dollars, in the aggregate or (B) Completion of the first Clinical Trial (with "Completion" meaning that the final patient has enrolled in first Clinical Trial) (paid).	$ 1,375,000
3. The earlier to occur of: (A) receipt of Regulatory Approval from the FDA for the First Indication of the first Licensed Product or (B) Initiation of the first Registrational Trial of the first Licensed Product in the Field	$ 5,000,000
4. Cumulative Net Sales of all Licensed Products in excess of Twenty Million US Dollars ($20,000,000)	$ 1,500,000
5. Cumulative Net Sales of all Licensed Products in excess of Fifty Million US Dollars ($50,000,000) Cumulative Net Sales of all Licensed Products in ex	$ 5,000,000
6. Cumulative Net Sales of all Licensed Products in excess of One Hundred Million US Dollars ($100,000,000).	$ 10,000,000

All milestone payments are non-creditable and non-refundable and will be due and payable upon the occurrence of the corresponding date or milestone, regardless of any failure by the Company to provide the notice required by Section 6.4a of the licensing agreement. For clarity, each milestone payment is payable only once. As of December 31, 2020, the first milestone had been achieved. As of January 7, 2021, the license commencement payment was paid in full. As of May 21, 2021, the second milestone had been completed and paid in full.

NOTE 7 — COMMITMENTS AND CONTINGENCIES (cont.)

Additionally, on an aggregate basis across all licensed products during the royalty term, the Company will pay quarterly to Advaxis royalties on net sales of licensed products, royalty rates range from a percentage in the high single digits to low double digits. No royalties were payable in the year ended December 31, 2024.

BlinkBio

In July 2020, the Company entered into a Licensing Agreement with BlinkBio, Inc., to utilize their proprietary technology. As of August 2020, the $300,000 License fee was fully paid and recorded in license expense. These payments have been recorded in the Licensing expenses of the accompanying statement of operations. No payments were due or made in 2024. A payment schedule for future milestones is summarized below.

Milestone Bearing Event	Milestone Payment
1. License Fee to utilize proprietary technology (paid)	$300,000 + $2.4 million Convertible Note
2. Commencement of a toxicology study commented pursuant to Good Laboratory Practices (per 21 CFR Part 58) such that any resulting positive data would be admissible to applicable Regulatory Authorities to support an IND (commonly referred to as "GLP-Tox")	$ 375,000
3. Completion of a Phase I Clinical Trial	$ 1,500,000
4. Completion of a Phase II Clinical Trial	$ 2,500,000
5. Filing of an NDA, BLA or MAA registration (or the equivalent in any other territory around the world)	$ 6,000,000
6. Regulatory Approval in the first of the United States, within the EU or within the UK	$ 12,000,000

The Company will make the cash payments set forth in the table above by wire transfer of immediately available funds, to BlinkBio within 30 days of the occurrence of each milestone set forth with respect to the first Product to attain each such milestone, except that the first Milestone above will apply with respect to The Company's first product candidate. During the Royalty Term, the Company will pay BlinkBio a royalty of 6% on Net Sales on a Product-by-Product and country-by-country basis during the Royalty Term, in a country in which no Valid Claim Covers the manufacture, use, or sale of a Product, the royalty on Net Sales of such Product in such country will be reduced to 3%. No royalties were due in the year ended December 31, 2024; no payments were made in the year 2023.

For the avoidance of doubt, each milestone payment will be payable only once, and the aggregate amount of Milestone payments payable hereunder will not exceed $22,375,000. A Milestone may be achieved by the Company or a Commercial Sublicensee.

George Clinical Inc.

In June 2020, the Company entered into a Research Service Agreement, as amended, with George Clinical Inc., to use their clinical research services for the Company's study: "*An Open Label, Phase 2 Study of Maintenance Therapy with OST-HER2 after Resection of Recurrent Osteosarcoma*". Under the terms of the agreement, the Company is required to pay to George Clinical certain fees described in the fee schedule below. The total budget under the agreement is approximately $2,436,928. For the year ended December 31, 2024 and year ended

NOTE 7 — COMMITMENTS AND CONTINGENCIES (cont.)

December 30, 2023, the total research and development expenses recorded in the statement of operations was $714,943 and $444,421, respectively. The fee schedule for certain fees and corresponding payment amounts is set forth below.

George Clinical Payment Schedule	Payment Amount
1. Service Fee Advance (paid)	$ 49,989
2. Service Fee Advance of $212,335 minus the amount already paid, plus PTC Fee Advance of $31,325 (paid)	$ 193,671
3. Statistics Fees – 35% on Electronic Data Capture (EDC) Go Live Date	$ 47,740
4. Statistics Fees – 35% on Development of SAP tables	$ 47,740
5. Statistics Fees – 30% on Final Analysis	$ 40,920
6. Service Fees – Remainder Due	Split monthly over course of study

George Clinical will track and invoice the Company for the number of task units completed and pass through costs will be invoiced each month in arrears based on actual costs without mark-up. The PTC Advance Fee will be used to offset final pass through fees payable. As of December 31, 2024, the balance due to George Clinical was $359,617.

Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while management generally believes that there will be adequate insurance to cover different liabilities at such time the Company becomes a public company and commences clinical trials, the Company's future insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, could have a material adverse effect on the Company's results of operations or financial position. The Company is currently in arbitration for a claim brought by its former investment advisor. The claim is for underwriter compensation for the Company's initial public offering in August 2024. The Company believes the claim is meritless as it awaits a formal meeting.

NOTE 8 — EQUITY

Common Stock

In 2021, the Company split common stock into two classes with fifty million shares of Class A common stock, $0.001 par value per share ("Class A Common Stock") designated and twenty million shares of Class B common stock, $0.001 par value per share ("Class B Common Stock"). On February 9, 2024, the Company changed the name of the Class A Common Stock and Class B Common Stock to combine into the name common stock, with 50,000,000 shares authorized. As of December 31, 2024 and December 31, 2023, the Company had 20,869,908 and 5,340,000 shares of common stock outstanding, respectively. Common stock has voting rights.

On August 2, 2024, the Company consummated its initial public offering and sold 1.6 million shares of common stock at a price of $4.00 per share. Concurrent with this consummation, all outstanding convertible notes, including accrued interest thereon, automatically converted into approximately 13.2 million shares of common stock, at conversion prices ranging from $0.39 per share to $2.59 per share, after applying share discounts ranging from 50% to 87.5% and valuation ceilings ranging from $5 million to $50 million, as applicable.

NOTE 8 — EQUITY (cont.)

During the fourth quarter of 2024, the Company issued 25,000 shares of common stock in exchange for $25,000 of marketing services. Additionally, the Company issued 6,506 shares of common stock to a former convertible noteholder to settle an outstanding interest obligation of $8,523 following the conversion of the Company's outstanding convertible notes upon consummation of the Company's initial public offering.

Preferred Stock

In 2021, 5,000,000 shares of Preferred Stock were authorized, 1,400,000 were designated as Series A Preferred Stock, with 1,302,082 shares issued of Series A Preferred Stock. Series A Preferred Stock has 5% cumulative coupon and liquidation priority above all shares of the Company's common stock. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly.

On February 9, 2024, the Series A Preferred Stock outstanding was converted to common stock on a one common share for every two preferred shares basis upon the filing of the Company's third amended and restate certificate of incorporation. Effective February 9, 2024, the company had five million shares of authorized Preferred Stock, none of which were outstanding.

The dividend due for the year ended December 31, 2024 and for the year ended December 31, 2023 was $31,250 and $125,000, respectively, for a total accrued dividend payable at December 31, 2024 of $375,000

The Preferred Stock has the following rights and privileges:

Voting — Votes together with the common stock on all matters on an as-converted basis. Approval of a majority of the New Preferred Stock voting as a separate class will be required to, among other things: (i) adversely change rights of the New Preferred Stock, (ii) change the authorized number of shares of New Preferred Stock.

Conversion — Each share of New Preferred Stock is convertible into one share of common stock (subject to proportional adjustments for stock splits, stock dividends and the like) at any time at the option of the holder. Conversion ratio will be subject to adjustment on a broad-based, weighted average basis in the event of subsequent issuances at a price less than the original issue price (as adjusted) subject to customary exceptions. The conversion into common stock occurred on February 9, 2024.

Liquidation — One times the original issue price of the New Preferred Stock plus declared but unpaid dividends on each share of New Preferred Stock (or, if greater, the amount that the New Preferred Stock would receive on an as-converted basis) will be paid first on each share of New Preferred Stock, and the balance of proceeds to be paid to common stock. A merger, reorganization, or similar transaction (including a sale, exclusive license or other disposition of all or substantially all of the assets of the Company or its subsidiaries) will be treated as a liquidation, thereby triggering payment of the liquidation preference described above. For the avoidance of doubt, the liquidation preference is intended to provide the Investor (and its permitted assigns) with an aggregate liquidation payment of $2,500,000.

	Total as of December 31, 2024	Total as of December 31, 2023
Shares issued to investors	—	1,302,082
Total shares issued	—	1,302,082

NOTE 8 — EQUITY (cont.)

Stock Options

The following is the common stock options issued to employees and consultants for services during the year ended December 31, 2024:

	Common Stock Options			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Years	Intrinsic Value
Outstanding at January 1, 2024	—	—	—	—
Granted	2,866,750	$ 1.86	5	—
Forfeited	—	—	—	—
Exercised	—	—	—	—
Outstanding at December 31, 2024	2,866,750	$ 1.86	4.92	—
Exercisable at December 31, 2024	—	—	—	—

The Company valued the options using the closing stock price of the Company's common Stock on the date of grant and the following assumptions:

	2024	2023
Volatility (based on peer companies)	106%	—
Risk Free Interest Rate	4.09%	—
Dividends	None	—
Estimated Life in years	2.95	—

During the years ended December 31, 2024 and 2023, the Company recognized share-based compensation expense of $268,300 and $0, respectively, related to common stock options. The Company expects to recognize additional compensation expense of $3,244,126 in 2025 related to these common stock options assuming all awards will vest.

NOTE 9 — REDEEMABLE PREFERRED STOCK, MEZZAININE EQUITY AND WARRANT LIABILITY

Securities Purchase Agreement

On December 24, 2024, the Company entered into the Purchase Agreement with various institutional and accredited investors. The Company completed the initial closing on December 31, 2024 and sold an aggregate of 1,512,500 immediately separable units (the "Units"), each Unit consisting of (i) one share of the Company's Series A Senior Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and (ii) a warrant to purchase one share of common stock (each, a "Warrant" and, collectively, the "Warrants"), at a price per Unit of $4.00. The Warrant has an exercise price of $4.40 per share, subject to adjustment therein, and a term of five years from the date stockholder approval of the common stock issuances contemplated by the Purchase Agreement is obtained. The gross proceeds from the initial closing to the Company, before deducting transaction fees and other estimated expenses, was 6,050,000.

Based on the terms of the Series A Preferred Stock and the Company's Certificate of Designation, and in accordance with ASC 480, the Series A Preferred Stock is accounted for as mezzanine equity due to the redemption feature upon a deemed liquidation event: (i) a merger or consolidation, or (ii) the sale, lease, transfer or other disposition of substantially all the assets of the Company. The initial cash proceeds of $6,050,000 were allocated to the Warrants and the residual proceeds were allocated to the Series A Preferred Stock.

NOTE 9 — PREFERRED STOCK AND WARRANT LIABILITY (cont.)

Based on the terms of the Warrants and in accordance with ASC 815, the Warrants are accounted for as a liability due to the variable exercise price subject to adjustment. Currently, there is not an observable market for this type of derivative. Due to the lack of relevant and market reflective Level 1 and Level 2 inputs, the Company valued the Warrant liability using Level 3 inputs, which require significant judgment and estimates on behalf of management in developing model assumptions. The Company determined to value of the Warrant liability using a Binomial Simulation, which takes into consideration the fair market value of the Company's stock, the variable nature of the exercise price, the estimated exercise period, the volatility of its common stock, and the risk-free interest rate. The following assumptions were made in the model: (1) a variable exercise price with a floor of $4.40 per share, (2) current common stock price of $4.28 per share, (3) discount rate of 4.38%, and (4) expected stock price volatility of 24.90%. As of December 31, 2024, the carrying value of the Warrant liability in aggregate was $1,971,975.

The Series A Preferred Stock and Warrants were issued in a basket transaction. When two or more instruments are issued in a basket transaction and some instruments will be remeasured at fair value, the proceeds are first allocated to the instruments recorded at their fair value. Next, the residual method is used to allocate the proceeds to the instrument(s) that are not remeasured at fair value. In this case, the Warrant is subsequently measured at fair value, and the Series A Preferred Stock instrument is measured at initial carrying value. The Company will first allocate the proceeds to the Warrant liability, with the residual allocated to the Series A Preferred Stock liability. Because the Series A Preferred Stock is classified as a mezzanine equity, the Company will record a deemed dividend for the accretion of the Series A Preferred Stock to carrying value in accordance with ASC 480. The following table reflects the allocation of the cash proceeds, which results in a deemed dividend recorded in the consolidated statement of operations in the amount of $1,971,975 for the year ended December 31, 2024.

	As of December 31, 2024
Cash proceeds	$ 6,050,000
Fair value of Warrant liability	(1,971,975)
Residual value allocated to Series A Preferred Stock	(4,078,025)
Unallocated cash proceeds	$ —

	For the year ended December 31, 2024
Residual value allocated to the Series A Preferred Stock	$ 4,078,025
Deemed dividend	1,971,975
Carrying value of Series A Preferred Stock	$ 6,050,000

NOTE 10 — SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates as one operating segment. The Company's chief operating decision maker ("CODM") is its Chief Executive Officer, who reviews financial information presented on a consolidated basis. The CODM uses consolidated operating margin and net income to assess financial performance and allocate resources. These financial metrics are used by the CODM to make key operating decisions, such as the determination of the rate at which the Company seeks to grow global operating margin and the allocation of budget between cost of revenues, sales and marketing, technology and development, and general and administrative expenses.

NOTE 10 — SEGMENT AND GEOGRAPHIC INFORMATION (cont.)

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2024 and 2023:

	For the year ended December 31, 2024	For the year ended December 31, 2023
OPERATING EXPENSES		
Research & Development	$ 2,839,060	$ 3,216,933
General & Administrative	3,974,786	1,125,712
Loss from Operations	(6,813,846)	(4,342,645)
OTHER INCOME/EXPENSE		
Interest Income	—	2
Non-Operating Income	33,997	—
Non-Operating Expenses	(51,250)	—
Interest Expense	(2,051,839)	(3,448,939)
TOTAL OTHER INCOME/EXPENSE	(2,069,092)	(3,448,937)
NET LOSS	(8,882,938)	(7,791,582)

NOTE 11 — SUBSEQUENT EVENTS

Equity Line of Credit — On October 31, 2024, the Company entered into an Equity Purchase Agreement (the "Equity Purchase Agreement") with Square Gate Capital Master Fund, LLC-Series 3 ("Square Gate"), pursuant to which the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to $15,000,000 (the "Maximum Commitment Amount") worth of shares of Common Stock, at the Company's sole discretion, over the 24 months following entry into such agreement, subject to certain conditions precedent and other limitations set forth in the Equity Purchase Agreement. Concurrently with the execution of the Equity Purchase Agreement, the Company also agreed to issue to Square Gate, as part of the consideration, shares of the Company's common stock worth a total of 3% of the Maximum Commitment Amount (the "Initial Commitment Shares"). The Company filed a registration statement on Form S-1 covering the resale of the shares to be issued pursuant to the Equity Purchase Agreement, which was declared effective by the SEC on January 13, 2025.

Advaxis/Ayala Royalty Agreement — On January 28, 2025, the Company entered into an Asset Purchase Agreement (the "HER2 Purchase Agreement") with Ayala Pharmaceuticals, Inc., a Delaware corporation formerly known as Advaxis, Inc. ("Ayala"), pursuant to which the Company agreed, subject to the terms and conditions set forth therein, to acquire from Ayala all HER2 and *Lm*-related programs and assume certain of Ayala's liabilities associated with the acquired assets (the "HER2 Purchase"). Pursuant to the HER2 Agreement, the agreed upon change in milestone payments and royalty consideration owed as it relates to the OST-HER2 program are as follows:

(i) Elimination of $3,500,000 payment owed to Ayala upon the first filing of a Biologics Licensing Authorization approval for OST-HER2 with the FDA;

(ii) Elimination of a total of $16,500,000 in OST-HER2 related sales milestone payments owed to Ayala.

(iii) The reduction in total royalty consideration owed on OST-HER2 related sales from 10% of net sales owed to Ayala to 1.5% of net sales owed under the Penn License.

NOTE 11 — SUBSEQUENT EVENTS (cont.)

In consideration, the Company has agreed to pay an aggregate purchase price of $8,000,000, consisting of $500,000 in cash consideration and a number of shares of the Company's common stock valued at $7,500,000 and to be calculated based on the volume-weighted average price of the Company's common stock over the 30 trading days immediately preceding the closing date of the HER2 Purchase. The closing of the HER2 Purchase, which the Company expects to occur in the second quarter of 2025, is subject to assignment of a license between Ayala and the Trustees of the University of Pennsylvania, execution and delivery of a patent assignment agreement, a termination of license agreement, a lock-up agreement and a registration rights agreement, the approval of the transaction by Ayala stockholders and other customary closing conditions

Second PIPE Closing — On January 14, 2025, the Company consummated a second closing under the Purchase Agreement, pursuant to which it sold to investors an aggregate of 263,250 Units, comprised of an aggregate of (i) 263,250 shares of Series A Preferred Stock and (ii) Warrants to purchase 263,250 shares of common stock. The gross proceeds to the Company from the closing, before deducting transaction fees and other estimated expenses, was approximately $1,053,000. The issuance of the shares of common stock issuable upon the conversion of the securities issued pursuant to the Purchase Agreement is awaiting shareholder approval at the Company's special meeting, and, once such approval is obtained, these liabilities will convert into stockholders' equity.

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

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of December 31, 2024, we carried out an evaluation, with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13(a)-15(f) and 15(d)-15(f) under the Exchange Act. Management assessed our internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on such assessment, management has concluded that our internal control over financial reporting was not effective as of the year ended December 31, 2024 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the audit committee of our board of directors. We determined that we have inadequate segregation of duties within account processes due to limited personnel. Also, we have insufficient written policies and procedures for accounting, IT and financial reporting and record keeping (no control procedures in place).

Our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended December 31, 2024 that have materially affected, or are 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.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About Our Executive Officers, Key Employees and Directors

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of March 28, 2025.

Name	Age	Position
Executive Officers and Key Employees:		
Paul A. Romness, MPH	59	Founder, Chairman, President and Chief Executive Officer
Robert G. Petit, Ph.D.	65	Chief Medical Officer and Chief Scientific Officer
Christopher P. Acevedo	62	Chief Financial Officer
Gerald Commissiong	42	Chief Business Officer
Non-Executive Directors:		
John Ciccio	44	Director
Avril McKean Dieser	63	Director
Karim Galzahr	51	Director
Olivier R. Jarry	51	Director
Theodore F. Search, Pharm.D.	43	Director

Executive Officers

Paul A. Romness, MPH has served as our President, Chief Executive Officer and a member of our board of directors since he founded our company in April 2018. He has served as Chairman of our board of directors since October 2024. Through his research, Mr. Romness has grown OS Therapies into a clinical research and development biotechnology company with two platform technologies, including the initial OST-HER2 *Listeria monocytogenes*, as well as OST-tADC, a next generation tunable drug conjugate delivery system. Prior to founding our company, Mr. Romness served as a Principal for PR Strategies from 2014 to March 2018. Prior to PR Strategies, Mr. Romness served as the Vice President of Government Affairs and Public Policy at Boehringer Ingelheim from 2008 to 2014, and the Director of State Government Affairs at Amgen Inc. from March 2005 to March 2008. Earlier in his career, Mr. Romness served in several roles at Johnson & Johnson from March 1990 to March 2003. Mr. Romness holds a Masters of Public Health from the Milken Institute School of Public Health of George Washington University and a B.S. degree in Finance from American University. As our founder, President, Chief Executive Officer, a director and largest stockholder, Mr. Romness leads our company. His more than 25 years of experience in the biopharmaceutical industry, day-to-day operational leadership of our company and in-depth knowledge of our product candidates and platform technologies make him well qualified as a member of our Board.

Robert G. Petit, Ph.D. has served as our Chief Medical Officer and Chief Scientific Officer since September 2019. Dr. Petit has also served as Principal for RGP Biotech, LLC, where he advises clients on non-clinical and clinical development programs, since June 2019, and Senior Vice President, Head of Early Clinical Development for Orionis Biosciences Inc., an early stage drug discovery and development biotech company, since March 2022. Dr. Petit currently serves as the Chairman of the Scientific Advisory Board of Advaxis, Inc. (now Ayala Pharmaceuticals, Inc.), where he previously served as the Chief Scientific Officer and Executive Vice President from March 2013 to June 2019. He is also a member of the scientific advisory boards of Systems Oncology, LLC, a cancer therapy discovery and development company, and Saros Therapeutics, an early-stage biotech company committed to re-engineering innate immune activation to improve cancer immunotherapy. From June 2019 to December 2019, Dr. Petit served as the Chief Scientific Officer of Carisma Therapeutics, Inc., a biotechnology company that develops novel chimeric antigen receptor macrophage technology to treat solid tumors. Prior to joining Advaxis as Chief Scientific Officer, Dr. Petit served in various roles for Bristol-Myers Squibb, including U.S. Medical Strategy Lead, Director of Medical Strategy for New Oncology Products and Director of Global Clinical Research, from 2005 to 2010. Prior to joining Bristol-Myers Squibb, Dr. Petit served as Vice President of Clinical Development at MGI Pharma Inc. and Aesgen Inc. Dr. Petit is an accomplished biopharmaceutical executive and medical scientist who has been instrumental in securing FDA approvals for six new drug applications and biologic license applications for oncology and immunotherapy product candidates and is named in more than 100 patents. His scientific focus has been to develop immunologic based

therapies with a particular emphasis on immunologic oncology treatment. Dr. Petit has provided expert guidance and counsel to a multitude of emerging biotech companies in the fields of immunology and oncology as a member of their respective scientific advisory boards. He earned his Ph.D. from the Ohio State University College of Medicine and B.S. degree from Indiana State University.

Christopher P. Acevedo has served as our Chief Financial Officer on a part-time basis since July 2023. Pursuant to his employment letter with us, he has agreed to spend 12 hours a month, on average, performing services in such position. Mr. Acevedo also owns and operates a certified public accounting firm with offices in Delaware and Maryland, serving a wide range of small to medium businesses, mainly in the service sector, since 2010. He holds CPA certificates in the states of Delaware, Maryland and Pennsylvania. Mr. Acevedo graduated from the University of Delaware with an M.B.A. in Business Administration and a B.S. degree in Accounting, minoring in Finance. Mr. Acevedo demonstrates extensive knowledge of complex financial, accounting and operational issues highly relevant to our growing biotechnology business.

Key Employees

Gerald Commissiong has served as our Chief Business Officer since April 2024. He also currently acts as a Managing Partner at Fortitude Advisors LLC, an executive advisory firm, since July 2018 and currently serves as the President and CEO of Tollo Health. For more than 15 years, Mr. Commissiong has been a senior executive officer of publicly held, emerging growth healthcare companies. He served as the Chief Executive Officer and director of Todos Medical Ltd., an in vitro diagnostics company focused on the development of novel blood tests for the early detection of cancer and neurodegenerative disorders, from January 2020 to July 2023. Prior to that position, Mr. Commissiong was the co-founder and served as Chief Executive Officer, President and a member of the Board of Directors of Amarantus BioScience Holdings, Inc., a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology, regenerative medicine and orphan diseases, from 2008 to December 2021. Mr. Commissiong has helped secured $90 million in investment capital throughout his career. Mr. Commissiong graduated from Stanford University receiving a B.S. degree in Management Science and Engineering with a focus on financial decisions. Mr. Commissiong played professional football in the Canadian Football League for the Calgary Stampeders.

Non-Executive Directors

John Ciccio has served as a member of our Board since December 2020. Mr. Ciccio has served as the Chief Operating Officer — Technology & Data Solutions of Syneos Health, Inc. (Nasdaq: SYNH), a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success, since July 2022. Prior to joining Syneos Health, Mr. Ciccio served as the President and Chief Executive Officer of Adheris Health from 2019 to July 2022 and the President and a member of the board of managers of Skipta LLC from 2014 to 2018, where he played a critical role in Skipta's sale to Informa PLLC. Mr. Ciccio has also served as a member of the board of directors of Full Code Medical Simulation since March 2022. In 2018, Mr. Ciccio was awarded the PharmaVOICE 100 — Commanders & Chiefs and the PM360 ELITE 100 as a Transformational Leader. Mr. Ciccio holds a B.A. degree in Government from Harvard University. Mr. Ciccio is well qualified to serve as a director of our company due to his substantial knowledge and years of working experience in the biotechnology and pharmaceutical industry and with growth-stage companies.

Avril McKean Dieser joined our board of directors on October 28, 2024. She is currently the Vice President, Head of Legal Patient Evidence of UCB, Inc., a subsidiary of UCB, S.A., a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or the central nervous system, since August 2016, and previously from April 2008 to April 2013. At UCB, she leads a team of attorneys supporting UCB's global assets, global payer functions, and regulatory, medical and patient communities, including clinical development. Ms. McKean Dieser was formerly a member of the AbbVie Inc. legal team providing global product support for the immunology and oncology franchises and was the government pricing lawyer for all pharmaceutical and combination products from May 2013 to July 2016. Prior to joining the pharmaceutical industry, Ms. McKean Dieser practiced corporate law in Atlanta, Georgia at two nationally recognized law firms. She earned her J.D. degree from The Catholic University Columbus School of Law and is admitted to practice law in the states of Georgia and Illinois. Prior to receiving her law degree, Ms. McKean Dieser received an M.A. in Public Administration from the University of Maryland, European Division and a B.A. degree in English Literature from Duquesne University. Ms. McKean Dieser lost her son, Edward, to

Osteosarcoma in January 2024 at the age of 21. Ms. McKean Dieser is well qualified to serve as a director of our company due to her substantial knowledge of the pharmaceutical regulatory and commercialization environment and more than 21 years of working experience in corporate controls and governance.

Karim Galzahr joined our board of directors on January 28, 2025 in accordance with the terms of the Purchase Agreement. He is currently a managing partner at OKG Capital, an early stage medtech and life science investor, which he founded in 2022, and the Chief Executive Officer of OKG Services SA, a life science and medtech management company. Mr. Galzahr has served on the board of directors of various privately held companies in the medical diagnostics, medtech, life science, and healthcare technology sectors since 2022. Notably, he has served as a director of NeoTX Holdings, Inc., a privately held clinical stage immune oncology drug discovery company developing innovative therapies for the treatment of solid cold tumors, since November 2024, 52 North Health Ltd., a privately held company focused on remote monitoring and home diagnostics solutions for acute oncology and other serious diseases including neutropenic sepsis, since October 2024, iQure Pharma Inc., a privately held global biotech company focused on the development of new therapeutics for neurodegenerative diseases, since March 2023, and Deeplook Medical, Inc., a privately held breast cancer detection and diagnostic imaging software provider, since January 2023. Mr. Galzahr also serves as an Investment Manager of Edo Investments Limited, a privately held public and private investment management company, and Investment Advisor of MJ Assets Limited, a private wealth investor focusing on disruptive technologies that have significant positive social impact, positions he has held since 2021. Mr. Galzahr received a B.A. degree in Philosophy, Politics and Economics from the University of Oxford. Mr. Galzahr brings over 30 years of experience in all aspects of finance including M&A, asset management, corporate development and strategic advisory work across the technology sector and medical technology sectors, making him highly qualified to be a director of our company.

Olivier R. Jarry joined our board of directors on October 28, 2024. He is currently the Co-founder and Chief Executive Officer of Libera Bio S.L., a private Spanish biopharmaceutical company devoted to the development of a new class of precision therapeutics to address intracellular cancer targets, since April 2018. He also serves as the Chief Operating Officer of Advantage Therapeutics Inc., an investigational-stage company focused on the diseases of aging, since May 2023 and as Chief Financial Officer of Rational Vaccines, Inc., an investigational-stage infectious disease company focused on combating herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) infections, since August 2021. Mr. Jarry served as an advisor to DarioHealth Corp. (Nasdaq: DRIO) from November 2016 to September 2017, and then as its President and Chief Commercial Officer until January 2020. Between 2015 and 2016, he served as Senior Vice President of the Consumer Sector and Officer at Intrexon Corp. (NYSE: XON), a biotechnology company focused on engineering biological systems to enable DNA-based control over the function and output of living cells. Prior to Intrexon, from 2011 to 2012, Mr. Jarry served as the Head of Strategy, Operations and Market Access, focusing on Emerging Markets, for Bristol-Myers Squibb (NYSE: BMY), where he oversaw the product launch and growth of innovative medicines relating to oncology, virology, rheumatology, cardiovascular and diabetes. Prior to that, between 2009 and 2010, Mr. Jarry served as the Global Business Unit Head of Bayer Diabetes Care, a division of Bayer HealthCare Pharmaceuticals LLC. Prior to his time at Bayer HealthCare, from 2001 to 2009, Mr. Jarry served in several leadership roles at Novartis International AG (NYSE: NVS), including working as Global Division Head of Strategy, Business Development & Licensing at Novartis Headquarters in Switzerland, Senior Vice President and Region Head for Latin America and for Asia-Pacific for Novartis' Consumer Health Division, Head of India Rural Business and Head of Western/Eastern Europe, Russia, CIS — Vaccines division. Mr. Jarry holds a M.Sc. degree from Ecole Centrale de Paris, a MEng. degree from Délégation Générale pour l'Armement, and a Trium Executive MBA degree jointly awarded by NYU Stern School of Business, London School of Economics and Political Science and Hautes Études Commerciales Paris. Mr. Jarry's more than 40 years of building fast-growing companies in neuroimmunology, oncology, cell & gene therapy, synthetic biology and digital therapeutics makes him well qualified as a member of the Board.

Theodore F. Search, Pharm.D. has served as a member of our Board since December 2020. Dr. Search is the Founder of Skipta, an Informa Pharma Intelligence Company, and served as the Chief Executive Officer and Chairman of Skipta from 2009 to 2017, when Skipta was sold to Informa Health. Since the completion of the sale in 2017, Dr. Search has served as the Chief Executive Officer — RWD Intelligence of Norstella, a provider of pharmaceutical consultancy services and solutions. Dr. Search has been invited to speak at various conferences around the globe and was named among the Top 100 Most Inspiring People in the Life Sciences Industry in 2015 and among the Top 100 Elite Entrepreneurs in the pharmaceutical and healthcare industry in 2016. Dr. Search holds a Doctor of Pharmacy

degree from the University of Pittsburgh and is a board licensed Pharmacist in the Commonwealth of Pennsylvania. Dr. Search provides decades of experience in leading and managing technology and product development operations in the pharmaceutical industry and with early-stage companies, making him well qualified to be a member of our Board.

Audit Committee

John Ciccio (chair), Avril McKean Dieser and Theodore F. Search, Pharm.D. serve on our Audit Committee. Our board has determined that each member of the Audit Committee is "independent" for Audit Committee purposes as that term is defined by the rules of the SEC and NYSE American, and that each has sufficient knowledge in financial and auditing matters to serve on the Audit Committee. Our board of directors has designated Mr. Ciccio as an "Audit Committee financial expert," as defined under the applicable rules of the SEC. Under Rule 10A-3 under the Exchange Act, we are permitted to phase in our compliance with the independent Audit Committee requirements set forth in NYSE American Rule 5605(c) and Rule 10A-3 under the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our board of directors intends to cause our Audit Committee to comply with the transition rules within the applicable time periods.

The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the Audit Committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements will be included in our annual report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the Audit Committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions. A current copy of this code is posted on the Governance section of our website, which is located at *www.ostherapies.com*. The information on our website is deemed not to be incorporated in this annual report or to be a part of this annual report. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who own more than 10% of a registered class of our equity securities to file with the SEC statements on Form 3, Form 4 and Form 5 of ownership and changes in ownership. Officers, directors and greater than 10% stockholders are required by regulation to furnish us with copies of all Section 16(a) reports that they file.

Based solely upon a review of Forms 3, 4 and 5 and any amendments to those forms that have been furnished to us, we believe that all parties subject to the reporting requirements of Section 16(a) filed all such required reports during and with respect to the fiscal year ended December 31, 2024, except that Shalom Auerbach, a 10% owner of our securities, filed late a Form 3 with respect to reporting his initial beneficial ownership and a Form 4 with respect to reporting transactions that occurred on August 2, 2024.

Item 11. Executive Compensation.

As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The compensation provided to our named executive officers for the years ended December 31, 2024 and 2023 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers for the year ended December 31, 2024 were:

- Paul A. Romness, MPH, our President and Chief Executive Officer;
- Robert G. Petit, Ph.D., our Chief Medical Officer and Chief Scientific Officer; and
- Christopher Acevedo, our Chief Financial Officer.

Through December 31, 2024, the compensation of our named executive officers only consisted of annual base salaries. Our named executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As part of our transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require. We have issued ISO options to our executive officers as of December 2024 with a three-year vesting period. The options have not vested and have a fair value of $0 as of the filing of this annual report.

Summary Compensation Table

The following table shows the total compensation earned by, or paid to, our named executive officers for services rendered to us in all capacities during the years ended December 31, 2024 and 2023.

Name and principal position	Year	Salary ($)	Bonus ($)	Option awards ($)	Non-Equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Paul A. Romness, MPH	2024	480,000	200,000[1]	2,754,316	—	—	3,354,316
President and Chief Executive Officer	2023	360,000	—	—	—	—	360,000
Robert G. Petit, Ph.D.	2024	420,000	—	245,046	—	—	665,046
Chief Medical and Scientific Officer	2023	300,000	—	—	—	—	300,000
Christopher Acevedo	2024	36,000	—	122,523	—	—	158,523
Chief Financial Officer	2023	36,000	—	—	—	—	36,000

(1) This represents an incentive bonus approved by our board of directors and awarded to Mr. Romness for the successful completion of our Equity Line of Credit and Private Placement.

Narrative Disclosure to Summary Compensation Table

Annual Base Salaries. Our named executive officers each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

For the year ended December 31, 2024, the annual base salary for each of Mr. Romness, Dr. Petit, and Mr. Acevedo was $480,000, $420,000 and $36,000, respectively. For the year ended December 31, 2023, the annual base salary for each of Mr. Romness, Dr. Petit, and Mr. Acevedo was $360,000, $300,000 and $36,000, respectively.

Employment Agreements and Arrangements

Paul A. Romness Employment Agreement

On February 21, 2023, Paul A. Romness, MPH entered into an employment agreement with us. The employment agreement with Mr. Romness extends for a term expiring on February 21, 2026. Pursuant to the employment agreement, Mr. Romness has agreed to devote substantially all of his time, attention and ability to our business as our Chief Executive Officer. The employment agreement provides that Mr. Romness will receive a base salary during the first year of his employment at an annual rate of $360,000 for services rendered in such position. During the second year of his employment under the employment agreement, Mr. Romness' annual base salary will be determined by our board of directors but will not be less than $360,000. In addition, Mr. Romness may be entitled to receive, as determined by our board of directors, a cash bonus in respect of each fiscal year. Mr. Romness is entitled to participate in our regular employee fringe benefit programs, including our medical and hospitalization insurance and life insurance, as well as the 2023 Plan.

The employment agreement provides for termination by us upon (i) the death or disability of Mr. Romness (defined as a period of more than 60 consecutive days or more than a total of 90 days in the aggregate during any period of 12 consecutive months), (ii) his willful and material malfeasance, dishonesty or substance abuse, (iii) his material and continuing breach, non-performance or non-observance of any of the terms of his employment agreement (or confidentiality agreement and non-competition agreement referenced below), but only after notice to him and his failure to timely cure any such default, or (iv) his conviction of a crime involving moral turpitude. In the event the employment agreement is terminated by us for any other reason, Mr. Romness will be entitled to compensation for the balance of the term. The employment agreement with Mr. Romness does not have any change of control provisions.

Together with his employment agreement, Mr. Romness entered into our standard form of confidentiality and non-competition agreement. This agreement contains covenants restricting Mr. Romness from engaging in any activities competitive with our business during the term of his employment agreement and one year thereafter and prohibiting him from disclosure of confidential information regarding our company at any time.

Robert G. Petit Employment Letter

On June 23, 2020, Robert G. Petit, Ph.D. entered into an employment letter with us. Pursuant to the employment letter, Dr. Petit has agreed to devote his business time, best efforts, skill, knowledge, attention and energies to the advancement of our business and interests and to the performance of his duties and responsibilities, on a full-time, "at-will" basis, as our Chief Medical and Scientific Officer. The employment letter provides that Dr. Petit will receive a base salary at a rate of $20,000 per monthly pay period for services rendered in such position. In addition, Dr. Petit will be eligible to receive a performance bonus of up to 50% of the base salary paid to him based on his personal performance and our company's performance during the calendar year, as determined by our board of directors in its sole discretion. Dr. Petit is entitled to participate in all of our bonus and benefit programs that we establish and make available to our employees, including the 2023 Plan.

The employment letter provides that if we terminate Dr. Petit's employment without "Cause" or he terminates his employment for "Good Reason," we will provide him with severance pay in the form of continuation of his base salary for a total of 12 months and a prorated bonus payment equivalent to 35% of his annualized base salary. For these

purposes, "Cause" means, among others, (a) his engagement in any conduct that materially and adversely affects the business interests or reputation of our company, (b) any breach by him of his employment letter or of the restrictive covenants contained in his invention and non-disclosure agreement and non-competition and non-solicitation agreement with us, (c) his failure to perform, or negligence in his performance of, any material duties required of or assigned to him, (d) his fraud or embezzlement or (e) his conviction of any crime involving dishonesty or moral turpitude, or any felony, in the cases of (a), (b) and (c), following written notice and an opportunity for Dr. Petit to timely cure any such conduct, breach or deficiency; and "Good Reason" means, among others, (i) a material reduction in Dr. Petit's authority, duties or responsibilities, (ii) a material reduction of his base salary or (iii) a material breach by our company of our obligations under his employment letter, in all cases, following written notice and an opportunity for our company to timely cure the circumstances. The employment letter with Dr. Petit does not have any change of control provisions.

Together with his employment letter, Dr. Petit entered into an invention and non-disclosure agreement and a non-competition and non-solicitation agreement, which contained covenants (a) restricting him from engaging in any activities competitive with our business during the term of his employment letter and for a period of one year thereafter, (b) prohibiting him from disclosing confidential information regarding our company at any time, (c) confirming that all intellectual property developed by him and relating to our business constitutes our sole and exclusive property, and (d) preventing him from recruiting, soliciting or hiring away employees of our company for a period of one year after his employment with us.

Christopher P. Acevedo Employment Letter

On January 1, 2023, Christopher P. Acevedo entered into an employment letter with us. Pursuant to the employment letter, Mr. Acevedo has agreed to devote his business time, best efforts, skill, knowledge, attention and energies to the advancement of our business and interests and to the performance of his duties and responsibilities, on an "at-will" basis, as our Chief Financial Officer. Mr. Acevedo will serve in such position on a part-time basis consisting of 12 hours per month, on average. The employment letter provides that Mr. Acevedo will receive a base salary at a rate of $3,000 per monthly pay period for services rendered in such position. Mr. Acevedo also received 200,000 shares of our common stock pursuant to his employment letter for his past service to our company. In addition, following the end of calendar year 2023 and subject to the approval of our board of directors, Mr. Acevedo will be eligible to receive a performance bonus of up to 50% of the base salary paid to him based on his personal performance and our company's performance during the calendar year, as determined by our board of directors in its sole discretion. Mr. Acevedo is entitled to participate in all of our bonus and benefit programs that we establish and make available to our employees, including our 2023 Incentive Compensation Plan. We agreed to grant as an incentive to Mr. Acevedo, effective on March 31, 2023, stock options to purchase 100,000 shares of our common stock at an exercise price of $0.001 per share.

The employment letter provides that if we terminate Mr. Acevedo's employment without "Cause" or he terminates his employment for "Good Reason," we will provide him with severance pay in the form of continuation of his base salary for a total of 12 months and a prorated bonus payment equivalent to 35% of his annualized base salary. For these purposes, "Cause" means (a) his engagement in any conduct that materially and adversely affects the business interests or reputation of our company, (b) any breach by him of his employment letter or of the restrictive covenants contained in his invention and non-disclosure agreement or non-competition and non-solicitation agreement with us, (c) his failure to perform, or negligence in his performance of, any material duties required of or assigned to him, (d) his fraud or embezzlement or (e) his conviction of any crime involving dishonesty or moral turpitude, or any felony, in the cases of (a), (b) and (c), following written notice and an opportunity for Mr. Acevedo to timely cure any such conduct, breach or deficiency; and "Good Reason" means (i) a material reduction in Mr. Acevedo's authority, duties or responsibilities, (ii) a material reduction of his base salary or (iii) a material breach by our company of our obligations under his employment letter, in all cases, following written notice and an opportunity for our company to timely cure the circumstances. The employment letter with Mr. Acevedo does not have any change of control provisions.

Together with his employment letter, Mr. Acevedo entered into an invention and non-disclosure agreement and a non-competition and non-solicitation agreement, which contained covenants (a) restricting him from engaging in any activities competitive with our business during the term of his employment letter and for a period of one year thereafter, (b) prohibiting him from disclosing confidential information regarding our company at any time, (c) confirming that all intellectual property developed by him and relating to our business constitutes our sole and exclusive property, and (d) preventing him from recruiting, soliciting or hiring away employees of our company for a period of one year after his employment with us.

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2024, we had outstanding the following stock option awards for our named executive officers.

	Option awards					Stock awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (#)	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($)
Paul A. Romness, MPH	—	800,000	—	1.86	—	—	—	—	—
Robert G. Petit, Ph.D.	—	400,000	—	1.86	—	—	—	—	—
Christopher P. Acevedo	—	200,000	—	1.86	—	—	—	—	—

2023 Incentive Compensation Plan

Our board of directors and stockholders adopted the OS Therapies Incorporated 2023 Incentive Compensation Plan and reserved 4,000,000 shares of our common stock for issuance under the plan. The purpose of the 2023 Incentive Compensation Plan is to assist us in attracting, motivating, retaining and rewarding high-quality executives and other employees, officers, directors, consultants and other persons who provide services to us by enabling such persons to acquire or increase a proprietary interest in our company in order to strengthen the mutuality of interests between such persons and our stockholders, and providing such persons with performance incentives to expend their maximum efforts in the creation of stockholder value.

Director Compensation

The following table presents the total compensation for each person who served as a non-executive member of our board of directors during the year ended December 31, 2024. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-executive members of our board of directors in 2024.

Name	Fees earned or paid in cash ($)	Fair value of options granted ($)	All other compensation ($)	Total ($)
Colin Goddard, Ph.D. (Chairman)[1]	12,500	32,162	—	44,662
Joacim Borg[1]	—	24,505	20	24,525
John Ciccio	—	24,505	—	24,505
Avril McKean Dieser[2]	—	24,505	—	24,505
Olivier R. Jarry[2]	—	24,505	—	24,505
Theordore F. Search, Pharm.D.	—	24,505	—	24,505

(1) Dr. Goddard and Mr. Borg resigned from our board of directors on October 28, 2024.

(2) Ms. McKean Dieser and Mr. Jarry were elected to our board of directors effective October 28, 2024.

Non-Executive Director Compensation Policy

Our board of directors has adopted a non-executive director compensation policy that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-executive directors. Under the policy, each director who is not an employee will be paid cash compensation, as set forth below:

	Annual retainer
Board of Directors:	
Members	$ —
Annual retainer for Chairman	$ 5,000
Additional retainer for Audit Committee chair	$ —
Additional retainer for Compensation Committee chair	$ —
Additional retainer for Nominating and Corporate Governance Committee chair	$ —

We will reimburse all reasonable out-of-pocket expenses incurred by non-executive directors in attending meetings of the board of directors and committees thereof.

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

The following table sets forth information known to us regarding the beneficial ownership of shares of our common stock as of March 28, 2025 by (i) each person known by us to be the beneficial owner of more than 5% of our common stock, (ii) each of our named executive officers and directors and (iii) all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the applicable rules and regulations of the SEC and includes voting or investment power with respect to our capital stock. Unless otherwise indicated, we believe that all persons named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o OS Therapies Incorporated, 115 Pullman Crossing Road Suite #103, Grasonville MD 21638.

As of March 28, 2025, we had outstanding 21,663,811 shares of common stock, unvested common stock options of 2,720,000 and 1,775,750 shares of Series A Preferred Stock.

Unless otherwise indicated, the address of each beneficial owner is c/o OS Therapies Incorporated, 115 Pullman Crossing Road Suite #103, Grasonville MD 21638.

Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
5% Stockholders		
Shalom Auerbach	2,829,582[1]	13.1%
Executive Officers and Directors		
Paul A. Romness, MPH	2,473,000[2]	11.4%
Robert G. Petit, Ph.D.	200,000[3]	*
Christopher P. Acevedo	109,375[4]	*
John Ciccio	237,917[5]	1.1%
Avril McKean Dieser	2,500	*
Karim Galzahr	—	—
Olivier R. Jarry	—	—
Theodore F. Search, Pharm.D.	237,918[6]	1.1%
All directors and executive officers as a group (8 persons)	3,260,710	15.1%

* Represents less than 1% of outstanding shares.

(1) Based on information contained in the Amendment No. 2 to Schedule 13D filed with the SEC on March 12, 2025, Shalom Auerbach beneficially owns an aggregate of 2,829,582 shares of our common stock with sole voting and dispositive power over such shares. Mr. Auerbach's registered address is 15 Atlantic Avenue, Suite M2, Lynbrook, New York 11563.

(2) Excludes 800,000 shares of common stock issuable pursuant to outstanding options subject to a three-year vesting period commencing on December 5, 2025.
(3) Excludes 400,000 shares of common stock issuable pursuant to outstanding options subject to a three-year vesting period commencing on December 5, 2025.
(4) Excludes 100,000 shares of common stock issuable pursuant to outstanding options subject to a three-year vesting period commencing on December 5, 2025.
(5) Includes 217,917 shares of common stock held of record by Mill River Partners LLC, with respect to which Mr. Ciccio shares investment and dispositive power with Dr. Search. Excludes 40,000 shares of common stock issuable pursuant to outstanding options subject to a three-year vesting period commencing on December 5, 2025.
(6) Includes 217,918 shares of common stock owned of record by Mill River Partners LLC, with respect to which Dr. Search shares investment and dispositive power with Mr. Ciccio. Excludes 40,000 shares of common stock issuable pursuant to outstanding options subject to a three-year vesting period commencing on December 5, 2025.

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

Certain Relationships and Related Transactions

Our Policy Regarding Related Party Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interest and/or improper valuation (or the perception thereof). Our board of directors has adopted a written policy on transactions with related persons that is in conformity with the requirements for issuers having publicly held common stock that is listed on the NYSE American. Under our policy:

- any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by the Audit Committee; and
- any employment relationship or transaction involving an executive officer and any related compensation must be approved by the compensation committee of the board of directors or recommended by the compensation committee to the board of directors for its approval.

In connection with the review and approval or ratification of a related person transaction:

- management must disclose to the committee or disinterested directors, as applicable, the name of the related person and the basis on which the person is a related person, the material terms of the related person transaction, including the approximate dollar value of the amount involved in the transaction, and all the material facts as to the related person's direct or indirect interest in, or relationship to, the related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction complies with the terms of our agreements governing our material outstanding indebtedness that limit or restrict our ability to enter into a related person transaction;
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction will be required to be disclosed in our applicable filings under the Securities Act or the Exchange Act, and related rules, and, to the extent required to be disclosed, management must ensure that the related person transaction is disclosed in accordance with the Securities Act and the Exchange Act and related rules; and
- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction constitutes a "personal loan" for purposes of Section 402 of SOX.

In addition, the related person transaction policy provides that the committee or disinterested directors, as applicable, in connection with any approval or ratification of a related person transaction involving a non-employee director, should consider whether such transaction would compromise the director's status as an "independent," "outside," or "non-employee" director, as applicable, under the rules and regulations of the SEC and the NYSE American.

Related Party Transactions

The following is a description of transactions or series of transactions since January 1, 2024, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, the lesser of $120,000 or one percent of the average of the Company's total assets for the last two completed fiscal years; and
- in which any of our executive officers, directors or holder of 5% or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this annual report under "Executive Compensation."

Group A and Group D Convertible Notes. In each of July 2019 and February 2020, we issued a Group A Convertible Note in the principal amount of $25,000 and $75,000, respectively, to Mill River Partners LLC. Interest on the unpaid principal balance accrues at a rate of 10% per annum, and the Group A Convertible Notes are set to mature on October 31, 2024. In February 2023, we issued a Group E Convertible Note in the principal amount of $50,000 to Mill River Partners LLC. The Group E Convertible Notes bear interest at a rate of 6% per annum and mature on October 31, 2024. The Group A Convertible Notes and Group E Convertible Notes automatically converted into common stock upon the consummation of our initial public offering in July 2024.

John Ciccio and Theodore F. Search, Pharm.D., members of our board of directors, are members of the board of managers of Mill River Partners LLC. Mill River Partners LLC holds 435,835 shares of our common stock as of March 28, 2025.

Payroll Advance. On December 31, 2024 and December 31, 2023, we had a payroll payable to Mr. Paul Romness, our Chief Executive Officer, of $8,871 and $300,000, respectively, and related payroll taxes payable of $88,386 and $7,830, respectively. During the period ended December 31, 2024 and December 31, 2023, we made advances on the payroll payable, and Mr. Romness made repayments.

The following summarizes activity in respect to payroll advances to Mr. Romness:

Balance December 31, 2022	$ —
Advances during 2023	316,198
Repayment	(125,000)
Balance December 31, 2023	$ 191,198
Advances during 2024	222,875
Repayment	(414,073)
Balance December 31, 2024	$ 0

In the second and third quarters of 2024, paychecks were issued to Mr. Romness. The paychecks comprised the remaining balance of backpay, less all 2023 payroll advances. The payroll taxes were paid that were associated with the backpay and regular pay and are fully paid. The balance of accrued payroll for Mr. Romness on December 31, 2024 of $8,870 represents a board approved 2024 bonus that was approved and paid in January 6, 2025. All payroll advances shown as employee advances were repaid by December 31, 2024 from his pending bonus paycheck.

Accounting Fees. We had a bill in accounts payable of $26,765 for the period ended December 31, 2024 and $32,102 for the period ended December 31, 2023 to Shore Accountants MD Inc., an outside accounting firm that handles payroll and bookkeeping and is 100% owned by Mr. Christopher Acevedo, our Chief Financial Officer.

Director Independence

Our board of directors has determined that all members of the board of directors, except Paul A. Romness, are independent directors, including for purposes of the rules of the NYSE American and the SEC. In making such independence determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-executive director. In considering

the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our outstanding common stock. We believe that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the NYSE American exchange and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. Mr. Romness is not an independent director under these rules because he is the current President and Chief Executive Officer of our company and largest stockholder.

Item 14. Principal Accounting Fees and Services.

Principal Accountant Fees and Services

The following table represents aggregate fees billed to us for services related to the year ended December 31, 2024 and 2023 by MaloneBailey, LLP, our independent registered public accounting firm.

	2024	2023
Audit Fees[(1)]	$ 255,000	$ 130,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 255,000	$ 130,000

(1) Audit fees consist of fees for professional services provided primarily in connection with the annual audit of our financial statements, quarterly reviews and services associated with SEC registration statements and other documents issued in connection with our initial public offering, including comfort letters and consents.

All of the services described above were pre-approved by our Audit Committee. The Audit Committee concluded that the provision of these services by MaloneBailey would not affect their independence.

Audit Committee's Pre-Approval Policies and Procedures

The Audit Committee pre-approves all services, including both audit and non-audit services, provided by our independent registered public accounting firm. For audit services, each year the independent registered public accounting firm provides the Audit Committee with an engagement letter outlining the scope of the audit services proposed to be performed during the year, which must be formally accepted by the Audit Committee before the audit commences. The independent registered public accounting firm also submits an audit services fee proposal, which also must be approved by the Audit Committee before the audit commences. None of the fees for services described above under the captions "Tax Fees" or "All Other Fees" approved by the Audit Committee were approved pursuant to the exception provided by paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

PART IV.

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as a part of this annual report:

(1) **Financial Statements**.

Information in response to this Item is included in Part II, Item 8 of this annual report.

(2) **Financial Statement Schedule**.

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

(3) **Exhibits**.

The following is a list of exhibits filed or furnished as part of this annual report:

Exhibit number	Description
3.1	Third Amended and Restated Certificate of Incorporation of OS Therapies Incorporated.[1]
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of OS Therapies Incorporated.[2]
3.3	Amended and Restated Bylaws of OS Therapies Incorporated.[1]
3.4	Certificate of Designation of Rights, Preferences and Limitations of Series A Senior Convertible Preferred Stock of OS Therapies Incorporated.[6]
4.1	Specimen Common Stock Certificate.[1]
4.2	Form of Representative's Warrant.[3]
4.3	Form of Placement Agent Warrant (Group B Convertible Notes placement).[1]
4.4	Form of Placement Agent Warrant (Group C Convertible Notes placement).[1]
4.5	Form of Placement Agent Warrant (Group D Convertible Notes placement).[1]
4.6	Form of Common Stock Purchase Warrant.[6]
4.7	Form of Agent Warrant.[6]
4.8	Form of Warrant.[8]
4.9*	Description of Registered Securities.
10.1†	Form of Group A Convertible Note.[1]
10.2†+	Form of Group B Convertible Note.[1]
10.3†+	Form of Group C Convertible Note.[1]
10.4†+	Form of Groups D, E and F Convertible Note.[1]
10.5+¥	Amended and Restated Development, License and Supply Agreement, dated as of November 13, 2020, by and between OS Therapies Incorporated and Advaxis, Inc. (now Ayala Pharmaceuticals, Inc.).[1]
10.5.1	First Amendment to Amended and Restated Development, License and Supply Agreement, dated as of April 23, 2021, between OS Therapies Incorporated and Advaxis, Inc. (now Ayala Pharmaceuticals, Inc.).[1]
10.6+	License Agreement, dated as of August 19, 2020, by and between OS Therapies Incorporated and BlinkBio, Inc.[1]
10.7#	Employment Agreement, dated as of February 21, 2023, between OS Therapies Incorporated and Paul A. Romness, MPH.[1]
10.8#	Employment Letter, dated June 23, 2020, between OS Therapies Incorporated and Robert G. Petit, Ph.D.[1]
10.9#	Form of Indemnification Agreement between OS Therapies Incorporated and each of its directors.[1]
10.10#	OS Therapies Incorporated 2023 Incentive Compensation Plan.[1]
10.10.1#	Form of First Amendment to the OS Therapies Incorporated 2023 Incentive Compensation Plan.[1]
10.11#	Employment Letter, dated January 1, 2023, between OS Therapies Incorporated and Christopher P. Acevedo.[1]
10.12	Equity Purchase Agreement between the registrant and Square Gate Capital Master Fund, LCC — Series 3, dated as of October 31, 2024.[4]

Exhibit number	Description
10.13	Registration Rights Agreement between the registrant and Square Gate Capital Master Fund, LCC — Series 3, dated as of October 31, 2024 (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 1, 2024).[4]
10.14+	Securities Purchase Agreement, dated December 24, 2024, by and among OS Therapies Incorporated and the purchasers party thereto.[6]
10.15	Form of Registration Rights Agreement by and among OS Therapies Incorporated and the purchasers party thereto.[6]
10.16	Form of Voting Agreement by and among OS Therapies Incorporated, the stockholders party thereto and the purchasers party thereto.[6]
10.17	Letter Agreement, dated December 27, 2024, by and between OS Therapies Incorporated and Brookline Capital Markets, a division of Arcadia Securities, LLC.[6]
10.18	Amendment No. 1 to Securities Purchase Agreement and Amendment to Registration Rights Agreement.[7]
10.19+	Asset Purchase Agreement, dated as of January 28, 2025, between OS Therapies Incorporated and Ayala Pharmaceuticals, Inc.[8]
10.20	Form of Registration Rights Agreement between OS Therapies Incorporated and Ayala Pharmaceuticals, Inc.[8]
23.1*	Consent of MaloneBailey, LLP, independent registered public accounting firm.
24.1*	Power of Attorney (set forth on signature page of this annual report).
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. § 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. § 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	OS Therapies Incorporated Clawback Policy.
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

(1) Incorporated herein by reference to the Registrant's Registration Statement on Form S-1 filed May 30, 2024 (File No. 333-279839).

(2) Incorporated herein by reference to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed June 7, 2024 (File No. 333-279839).

(3) Incorporated herein by reference to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed June 13, 2024 (File No. 333-279839).

(4) Incorporated by reference to Exhibit 3.3 of the Registrant's Registration Statement on Form S-1 filed May 30, 2024 (File No. 333-279839).

(5) Incorporated herein by reference to the Registrant's Current Report on Form 8-K filed on November 1, 2024.

(6) Incorporated herein by reference to the Registrant's Current Report on Form 8-K filed on December 30, 2024.

(7) Incorporated herein by reference to the Registrant's Current Report on Form 8-K filed on January 14, 2025.

(8) Incorporated herein by reference to the Registrant's Current Report on Form 8-K filed on January 29, 2025.

* Filed herewith.

** Furnished herewith.

† Pursuant to Instruction 2 to Item 601 of Regulation S-K, the convertible notes are identical for all noteholders in the particular group except for face or principal amount, issuance date and the name of the payee.

\+ Pursuant to Item 601(a)(5) of Regulation S-K, certain schedules and exhibits have been omitted. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon its request.

¥ Pursuant to Item 601(b)(10)(iv) of Regulation S-K, certain portions of this exhibit have been redacted. Redacted information is indicated by [***].

# Indicates a management contract or any compensatory plan, contract or arrangement.

(b) The exhibits required by Item 601 of Regulation S-K are filed herewith or incorporated herein by reference. Please see the Index to Exhibits to this annual report, which is incorporated into this Item 15(b) by reference.

(c) All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

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.

Date: March 31, 2025

OS THERAPIES INCORPORATED

By: /s/ Paul A. Romness
Paul A. Romness
Chairman, President and
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Christopher P. Acevedo
Christopher P. Acevedo
Chief Financial Officer
(Principal Financial and Accounting
Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Paul A. Romness and Christopher P. Acevedo, and each of them, his or her true and lawful attorney in fact and agent, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and conforming all that said attorney in fact and agent or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Paul A. Romness Paul A. Romness, MPH	Chairman, President, Chief Executive Officer and Director (principal executive officer)	March 31, 2025
/s/ Christopher P. Acevedo Christopher P. Acevedo	Chief Financial Officer (principal financial officer and principal accounting officer)	March 31, 2025
/s/ John Ciccio John Ciccio	Director	March 31, 2025
/s/ Avril McKean Dieser Avril McKean Dieser	Director	March 31, 2025
/s/ Karim Galzahr Karim Galzahr	Director	March 31, 2025
/s/ Olivier R. Jarry Olivier R. Jarry	Director	March 31, 2025
/s/ Theodore F. Search, Pharm.D. Theodore F. Search, Pharm.D.	Director	March 31, 2025