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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025.

☐ **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, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $49.6 million.

The number of shares of the registrant's Common Stock outstanding as of March 26, 2026 was 39,533,227 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OS THERAPIES INCORPORATED

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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 owned by their respective owners. Solely for convenience, trademarks and trade names referred to in this annual report may appear without the ™ or ® symbols, but such an omission is 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 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. In the first quarter of 2025, we announced that our Phase IIb clinical trial achieved its primary endpoint with statistical significance. In October 2025, we announced final two-year overall survival data from the Phase IIb trial, in which 75% (27 of 36 evaluable patients) of OST-HER2-treated patients achieved two-year overall survival from the most recent pulmonary resection, compared with 40% in historical control patients ($p < 0.0001$). OST-HER2 was observed to be well-tolerated in the study. In January 2026, we announced positive immune biomarker data from the Phase IIb trial indicating that activation of immune blood biomarkers in the interferon gamma pathway correlated with, and was predictive of, overall survival, distinguishing long-term survivors (≥ two years) from short-term survivors (< one year). These biomarker findings are based on exploratory analyses and have not been validated as surrogate endpoints for clinical benefit. Based on the totality of the data generated to date, including the observed survival outcomes, safety profile and the significant unmet medical need in this patient population, we intend to engage with the FDA regarding potential regulatory pathways for OST-HER2.

We have engaged in ongoing regulatory interactions with the FDA, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), and the European Medicines Agency (EMA) regarding the clinical and biomarker data for OST-HER2 in recurrent, fully resected pulmonary metastatic Osteosarcoma. Following submission of the Non-Clinical and Chemistry, Manufacturing & Controls (CMC) modules of our Biologics License Application (BLA) to the FDA at the end of January 2026, we anticipate submitting the clinical BLA module following an expected Type B meeting with the FDA in the second quarter of 2026 and completing conditional Marketing Authorization Application (MAA) submissions to both the MHRA and the EMA in the second quarter of 2026. We also anticipate releasing additional biomarker data in the second quarter of 2026 to further characterize immune pathway activation and its relationship to clinical outcomes. We expect to initiate confirmatory clinical studies in the third quarter of 2026 in support of conditional approval pathways. If OST-HER2 receives approval under the FDA's Accelerated Approval Program prior to September 30, 2029, we would become eligible to receive a Priority Review Voucher under the Rare Pediatric Disease Designation Program.

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 an 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.

Pipeline of Our Product Candidates

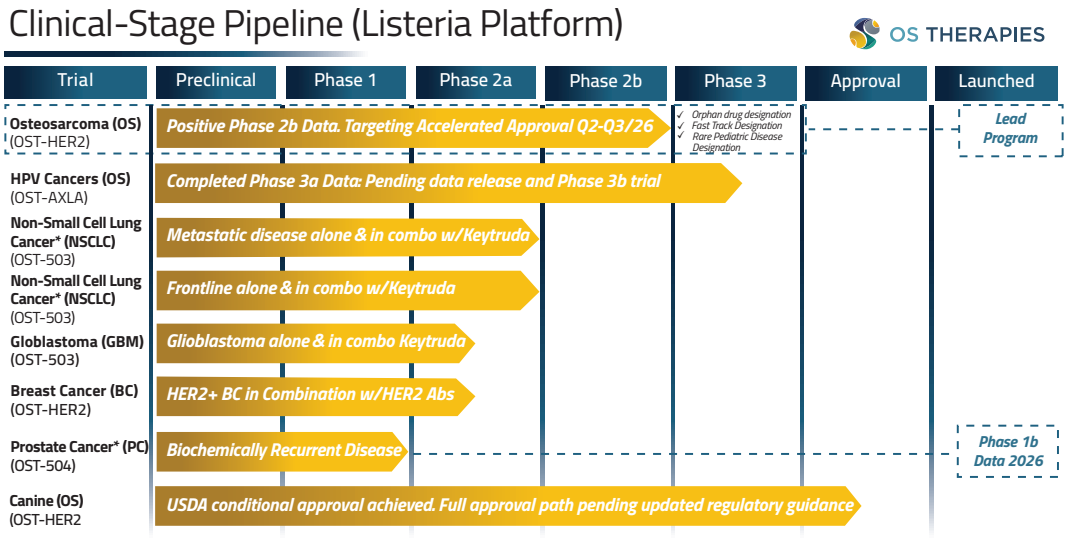
We have built a pipeline of product candidates targeting multiple indications for solid cancers. Our pipeline includes two drug technologies: (i) OST-HER2, an off-the-shelf immunotherapy, which is a type of cancer treatment that helps one's immune system fight cancer, comprised of a genetically weakened 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.

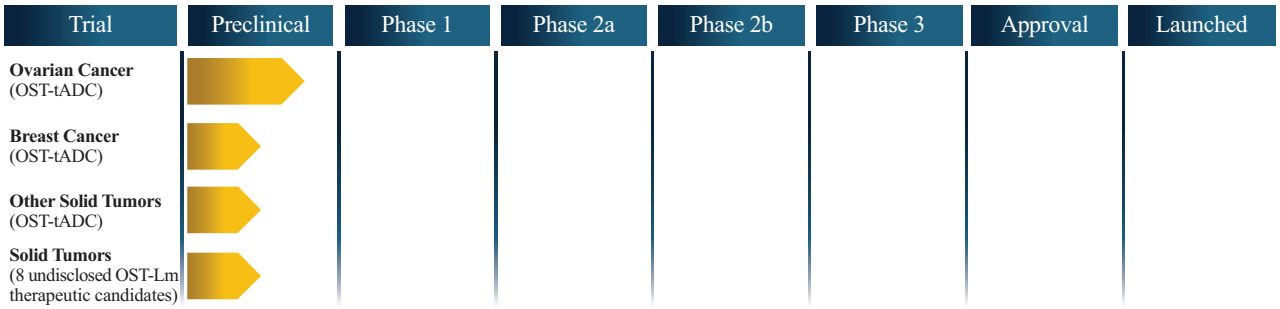
OST-HER2 has received an orphan drug designation in the United States. The FDA may designate a biologic product as an orphan product if it is intended to treat a rare disease or condition, which generally is defined as having a patient population of fewer than 200,000 individuals in the United States. Osteosarcoma has an incidence rate of 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. Such designations by the FDA do not convey any advantages in, 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 adapters 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. 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.



Preclinical Pipeline (Listeria & ADC Platform)



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 Acquisition of HER2 and *Lm*-Related Assets

On April 9, 2025, pursuant to the terms of an Asset Purchase Agreement, dated as of January 28, 2025 (the "HER2 Purchase Agreement"), between us and Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc. ("Ayala")), we completed the acquisition of the *Lm*-based immune-oncology programs and related intellectual property assets (the "HER2 Assets") from Ayala. The HER2 Assets include two investigational new drug applications ("IND") with the FDA: (i) ADXS-503 for non-small cell lung cancer; and (ii) ADXS-504 for prostate cancer.

Our OS-Focused Clinical Trials and Studies

We and our former 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, we initiated a Phase IIb clinical trial to evaluate the safety and efficacy of our OST-HER2 product candidate in patients following complete surgical resection of recurrent pulmonary metastatic Osteosarcoma. The study was sponsored by us and conducted by George Clinical, Inc. A total of 41 eligible patients between the ages of 12 and 39 were enrolled, with full enrollment completed in October 2023. Patients received a total of 16 intravenous infusions of OST-HER2 administered over a 48-week treatment period. The trial was conducted at major hospitals across 21 clinical sites in 18 U.S. states. The treatment phase has been completed, and patients continue to be followed prospectively for long-term survival.

The primary endpoint of the study was 12-month event-free survival ("EFS"), defined as the proportion of patients who remained recurrence-free at 12 months following surgical resection. EFS outcomes were compared to a best available historical control derived from published U.S. literature (the "Published Control"), with recurrence assessments conducted every three months in accordance with standard of care. In the first quarter of 2025, we announced that the study met its primary endpoint with statistical significance. Specifically, 33% of OST-HER2-treated patients (n=41) were event-free at 12 months compared to 20% in the Published Control population, representing a 13-percentage point absolute improvement over historical outcomes.

Secondary endpoints included overall survival and safety. In October 2025, we announced final two-year overall survival data. Among 36 evaluable patients, 75% (27 of 36) were alive two years following their most recent pulmonary resection compared to 40% in the Published Control population ($p < 0.0001$). Earlier interim analyses demonstrated 12-month overall survival of 91% for OST-HER2-treated patients compared to 80% in the Published Control, and 24-month overall survival of 61% compared to 40%, respectively. Survival assessments were conducted at three-month intervals. The study was not powered as a randomized controlled trial, and comparisons were made against published historical data rather than a contemporaneous control arm.

Safety was assessed throughout the treatment period and follow-up using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE). OST-HER2 was generally well tolerated. No treatment-emergent adverse events classified as CTCAE Grade 5 (death) were reported. Adverse events were monitored during the 48-week treatment period, with ongoing follow-up for survival and long-term safety.

In January 2026, we announced results from exploratory biomarker analyses evaluating immune activation markers in peripheral blood. Activation of biomarkers within the interferon gamma pathway was observed to correlate with overall survival outcomes and distinguished long-term survivors (≥ two years) from short-term survivors (< one year). These biomarker analyses were exploratory in nature, were not pre-specified as primary or secondary endpoints, and have not been validated as surrogate endpoints for clinical benefit.

Although the Phase IIb trial met its primary endpoint and demonstrated favorable overall survival outcomes relative to historical controls, the study was conducted as an open-label trial and did not include a randomized, contemporaneous control arm. Comparisons to historical controls are subject to inherent limitations, including potential differences in patient populations, standards of care, supportive therapies and assessment methodologies, and such comparisons may not be predictive of results in a randomized controlled trial. We intend to continue engaging with the FDA regarding potential regulatory pathways for OST-HER2. However, there can be no assurance that the FDA will determine that the results of the Phase IIb trial are sufficient to support submission or approval of a BLA. The FDA may require additional clinical data, including data from a randomized Phase III clinical trial, prior to approval. The necessity, scope and design of any additional trials will depend on future regulatory interactions and formal FDA determinations.

Phase Ib Clinical Trial. From September 2015 through May 2017, Advaxis, Inc. ("Advaxis") sponsored and conducted a Phase Ib clinical trial evaluating ADXS-HER2 (also known as ADXS31-164), the intellectual property rights to which we subsequently acquired from Ayala for further development and commercialization as our OST-HER2 product candidate. The Phase Ib study was a multicenter, open-label, dose-escalation trial designed to evaluate safety and tolerability, determine the maximum tolerated dose ("MTD"), and establish a recommended Phase II dose. The study enrolled 12 adult patients with advanced, HER2-expressing solid tumors. Patients received escalating intravenous doses of ADXS-HER2 administered every three weeks during a 12-week treatment cycle. Clinical sites were located at hospitals in Colorado, Michigan, North Carolina, Pennsylvania and Texas. Following completion of study treatment, all 12 patients entered a three-year surveillance period to monitor for potential *Listeria monocytogenes*-related complications.

The primary endpoints were safety and tolerability, including the incidence of dose-limiting toxicities ("DLTs") during the first four months of treatment and the frequency and severity of adverse events, assessed using the CTCAE, including Grade 4 events (life-threatening consequences). Secondary endpoints included (i) objective tumor response rate (complete or partial response) as assessed by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and immune-related RECIST (ir-RECIST), and (ii) immunologic response parameters measured through serial peripheral blood collection and analysis of peripheral blood mononuclear cells and serum biomarkers.

No dose-limiting toxicities were observed at the highest dose level evaluated (1×10^9 colony-forming units ("CFU")), and no maximum tolerated dose was reached. ADXS-HER2 administered intravenously at 1×10^9 CFU appeared to be generally well tolerated in the 12 treated and evaluable subjects. No objective tumor responses (complete or partial responses) were observed in this late-stage, heavily pre-treated patient population. Based on the observed safety and tolerability profile, 1×10^9 CFU was selected as the recommended Phase II dose.

This Phase Ib study was primarily designed to assess safety and dose selection and was not powered or intended to evaluate clinical efficacy. Accordingly, the absence of objective tumor responses in this small, heterogeneous patient population should be interpreted in the context of the study's dose-escalation design and safety-focused objectives.

Preclinical Animal Study. From July 2012 through September 2015, a prior licensee of Advaxis sponsored and conducted a preclinical study evaluating ADXS-HER2 in 18 companion canines with HER2-positive appendicular Osteosarcoma following standard-of-care treatment (amputation and chemotherapy). This study is sometimes referred to as a Phase I veterinary clinical study. We subsequently acquired the intellectual property rights to ADXS-HER2 constructs for further development and commercialization as OST-HER2.

Canine appendicular Osteosarcoma is recognized in scientific literature as a spontaneous large-animal model with biological and clinical similarities to pediatric Osteosarcoma. In this study, ADXS-HER2 was administered in the setting of minimal residual disease following definitive surgical and chemotherapeutic management. Outcomes were compared to a historical control cohort treated with amputation and chemotherapy alone.

Results published in 2016 in Clinical Cancer Research (Mason, N. et al., "Immunotherapy with a HER2-Targeting Listeria Induces HER2-Specific Immunity and Demonstrates Potential Therapeutic Effects in a Phase I Trial in Canine Osteosarcoma") reported improvements in overall survival and metastatic disease progression relative to the historical control group. Reported overall survival rates at one, two and three years were 77.8%, 67% and 56%, respectively, for ADXS-HER2-treated dogs, compared to 55%, 28% and 22%, respectively, for historical controls. Median survival time was 956 days in the ADXS-HER2-treated group compared to 423 days in the historical control group (hazard ratio 0.33; 95% confidence interval 0.136 – 0.802; p = 0.014). A reduction in the incidence of metastatic disease was also reported relative to historical controls. 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. These findings were generated in a small, non-randomized veterinary study using historical controls. Animal study results are not necessarily predictive of clinical outcomes in humans.

Following completion of the study, an application for conditional licensure of ADXS-HER2 for the treatment of canine Osteosarcoma was submitted to the United States Department of Agriculture ("USDA"). In December 2017, ADXS-HER2 was granted a conditional license for veterinary use in dogs one year of age and older diagnosed with Osteosarcoma. As the current owner of the ADXS-HER2 constructs, we held the conditional license for OST-HER2. The conditional license permitted limited commercial distribution while additional data was to be generated to support full licensure. We subsequently allowed the conditional license to lapse in connection with manufacturing process improvements and a strategic reassessment of our development priorities. We may seek a new conditional license in the future following engagement with a USDA-licensed contract manufacturer. Full USDA licensure would require submission of additional data, including studies addressing safety, purity, potency, effectiveness, metabolism and shedding in canines. We are currently evaluating potential future development strategies with respect to the veterinary indication. There can be no assurance that we will seek or obtain future USDA licensure.

Preclinical Development. Our OST-HER2 product candidate is also being evaluated for potential development in additional HER2-expressing solid tumor indications, including breast, esophageal and lung cancers. These programs are currently in the preclinical stage. The scope of additional preclinical development required, if any, will depend on multiple factors, including the totality of available clinical and nonclinical data, the specific tumor indication pursued, the design of any subsequent clinical protocol (including whether additional cohorts are incorporated into a follow-on or master protocol) and feedback from the FDA and other regulatory authorities. While OST-HER2 has been evaluated clinically in Osteosarcoma, regulatory authorities may require additional preclinical pharmacology, toxicology, biodistribution or other nonclinical studies to support initiation of clinical trials in different tumor types. The extent of any such requirements will depend on regulatory determinations regarding the sufficiency and applicability of existing data to the proposed indications. There can be no assurance that additional preclinical studies will not be required prior to initiating clinical trials in breast, esophageal, lung or other solid tumor indications, or that existing clinical data will be deemed sufficient to support expansion into those indications.

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:

- We may consider out-licensing OST-HER2 to animal health companies for veterinary use in dogs diagnosed with Osteosarcoma, one year of age or older, consistent with prior conditional licensure and preclinical data.
- 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.
- Complete pre-clinical and toxicology trials with the lead drug candidate for OST-tADC (OST-tADC-A, Exatecan-silanol-FRa) and submit an IND to initiate a Phase I trial in ovarian cancer and other folate receptor alpha-overexpressing tumors, including endometrial cancer and certain Osteosarcomas. We believe that positive results from preclinical and GLP toxicology studies may also facilitate potential out-licensing opportunities for SiLinker and CAPs drug products, without limiting therapeutic development.
- Establish global commercial, clinical and medical affairs infrastructure to support the potential launch and commercialization of OST-HER2-based therapies and related product candidates.

Through these strategies, we aim to leverage our OST-HER2 and OST-tADC platforms to develop a diversified oncology pipeline across multiple tumor types, while maintaining flexibility to pursue both human and veterinary indications, and to capture value through partnerships, out-licensing and clinical expansion.

Expansion Opportunities

We may seek to expand our business through acquisitions, in-licensing of complementary products or technologies, or the acquisition of companies with complementary capabilities. 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 believe there is continued interest from larger pharmaceutical companies in biotechnology firms developing next-generation therapies, including ADCs, due in part to the potential of these therapies to address unmet medical needs in oncology. Advances in ADC technology, including combinations with immunotherapies and other targeted agents, have broadened the potential applications for these modalities, which we may consider as part of our expansion strategy.

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 two granted U.S. utility patents and one granted Japanese patent. These patents were originally developed at the University of Pennsylvania and were owned either solely by the University or jointly with Advaxis. We acquired all rights, title and interest in these patents from Advaxis pursuant to an assignment, which enables us to develop, manufacture and commercialize OST-HER2 without reliance on in-licensing from Advaxis. See "*Our Licensing Obligations — 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 six 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
- 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; MD candidate at David Geffen School of Medicine at UCLA; Osteosarcoma Survivor
- Mac Tichenor — President of Osteosarcoma Institute
- Tony Trent — President of The Tyler Trent Foundation
- Serena Subada — OST-HER2 Trial Participant

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.
- Colin Goddard, Ph.D. — Chairman at BlinkBio, 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 Obligations

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 allowed us to utilize Advaxis' ADXS-HER2 construct patents to develop and commercialize ADXS-HER2, our lead product candidate (OST-HER2). On April 9, 2025, we acquired from Ayala (formerly Advaxis) the HER2 Assets. In connection with such acquisition, the amended and restated development, license and supply agreement was terminated.

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.

Biolacuna Ltd. We have contracted with Biolacuna Ltd, a global life sciences advisory firm, to assist with the following agencies requirements to register OST-HER2 and gain approval of its use in the respective regions:

- European Medicines Agency (EMA, Europe);
- Medicines Evaluation Board (MEB, Netherlands);
- Medicines and Healthcare products Regulatory Agency (MHRA, United Kingdom); and
- U.S. Food and Drug Administration (FDA, United States).

University of Pennsylvania. On April 9, 2025, we acquired from Ayala the HER2 Assets. Pursuant to the terms of the HER2 Purchase Agreement, the amended and restated development, license and supply agreement with Advaxis terminated. In connection with the acquisition of the HER2 Assets, we were assigned by Ayala a license agreement with the Trustees of the University of Pennsylvania covering the use of HER2 construct patents. Under the terms of the license agreement, we are required to pay an annual license fee to the Trustees of the University of Pennsylvania. We are obligated to pay a royalty equal to 1.5% of net 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 such licensing agreement.

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

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, owning, co-owning and filing 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.

Following our acquisition of the HER2 Assets from Ayala, we now own or co-own certain patents covering our lead product candidates. We also in-license patents and patent applications for our other core candidate, OST-tADC, from BlinkBio, Inc. We co-own with the University of Pennsylvania the intellectual property related to OST-HER2, which includes two granted U.S. utility patents, one granted Japanese patent, and two additional foreign patents and pending applications, with expected expiration between 2029 and 2035, excluding any potential patent term extensions. We hold exclusive rights to patents and patent applications covering the commercial manufacturing of OST-HER2 and our broader *Listeria*-based immunotherapy platform, including two granted U.S. utility patents, one pending U.S. patent application, 11 granted foreign patents and 12 pending foreign applications. These patents are expected to expire in 2038, with one U.S. patent expiring in 2040 after patent term adjustment. The intellectual property licensed from BlinkBio, Inc. includes six granted U.S. utility patents and multiple foreign patents and pending applications covering methods of use for silicon-based drug conjugates and silanol-based therapeutic payloads, with expected expiration between 2036 and 2037, excluding any potential patent term extensions.

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 own, co-own or 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 own, co-own or 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, co-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 pre-clinical 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

Before initiating clinical trials in humans, a sponsor must complete preclinical development activities, which generally include laboratory evaluations of product chemistry, manufacturing, formulation and stability, as well as *in vitro* and animal studies designed to assess pharmacology, toxicology and potential safety risks. Nonclinical safety studies intended to support an IND application are required to comply with applicable GLP regulations.

To initiate human clinical trials in the United States, a sponsor must submit an IND to the FDA. An IND contains, among other things, results of preclinical studies, manufacturing and analytical data, any available clinical data or relevant literature, and a proposed clinical trial protocol. The IND submission process is intended to allow the FDA to assess whether the investigational product is reasonably safe to evaluate in humans and whether the proposed clinical trial protocol is appropriate.

An IND becomes effective 30 days after receipt by the FDA unless the FDA, within that 30-day period, places the proposed clinical trial on full or partial clinical hold due to safety concerns or deficiencies in the submission. If a clinical hold is imposed, the sponsor must address the FDA's concerns to the agency's satisfaction before the clinical trial may proceed. Accordingly, submission of an IND does not guarantee that the FDA will permit a clinical trial to begin. Certain long-term nonclinical studies, such as reproductive toxicity or carcinogenicity studies, may continue after an IND becomes effective.

Clinical Trials

Clinical trials must be conducted in accordance with applicable federal statutes and regulations governing drug development and human subject research, as well as in compliance with Good Clinical Practice ("GCP") requirements, which are international ethical and scientific quality standards intended to protect the rights, safety and welfare of human subjects and to ensure the integrity and reliability of clinical trial data. Clinical trials must also be conducted pursuant to protocols that detail, among other things, the study objectives, inclusion and exclusion criteria, dosing regimen, safety monitoring procedures, and statistical analysis plans designed to evaluate efficacy and safety endpoints.

Clinical trials are typically conducted at multiple geographically dispersed sites to support generalizability of the data and to enable the FDA to evaluate the overall benefit-risk profile of the investigational product and determine whether it satisfies the applicable statutory standard for approval. Clinical data generated in these trials form the basis for the product labeling, if approved.

In the United States, each clinical trial must be reviewed and approved by an Institutional Review Board ("IRB") prior to initiation. An IRB is a duly constituted body established to review and monitor biomedical research involving human subjects and has authority to approve, require modifications to, or disapprove research in order to protect the rights and welfare of trial participants. In foreign jurisdictions, clinical trials are subject to review and approval by independent ethics committees or similar regulatory authorities in accordance with applicable local laws and regulations.

The FDA may impose a clinical hold at any time before or during a clinical trial if it identifies safety concerns or determines that the investigation is not being conducted in accordance with applicable statutory or regulatory requirements. A clinical hold may delay or suspend a trial until the identified deficiencies are satisfactorily addressed. Similarly, an IRB may suspend or terminate a trial at its institution for non-compliance with applicable legal or regulatory requirements or IRB determinations, or if it determines that the research presents an unexpected serious risk to subjects.

Investigational products used in clinical trials must be manufactured in accordance with applicable current good manufacturing practice ("cGMP") requirements under federal law and related regulations. While full commercial-scale validation is not required during early development, manufacturing controls must be sufficient to ensure product identity, strength, quality and purity appropriate for the stage of development. As clinical development progresses, regulatory expectations for manufacturing controls and validation generally increase.

Marketing Approval

Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from the applicable regulatory authorities. We have not received approval to market any of our current product candidates. We expect to rely on third-party contract research organizations and regulatory consultants to assist us in preparing and submitting marketing applications and navigating the regulatory review process. Securing regulatory approval requires the submission of extensive preclinical and clinical data, as well as supporting information, to the relevant regulatory authorities for each therapeutic indication and line of treatment to establish the product candidate's safety, efficacy, and, in the case of biologics, purity and potency. Securing regulatory approval also requires the submission of detailed information regarding the drug manufacturing process and, in most cases, inspection of manufacturing facilities by the applicable regulatory authority.

The process required by the FDA before a drug or biologic product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory studies and, as applicable, animal studies;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product for its intended use or uses;
- pre-approval inspection of manufacturing facilities and, in certain cases, clinical trial sites; and
- FDA review and approval of a marketing application, such as an NDA or BLA, which must occur before a drug or biologic product may be commercially marketed or sold.

We are not permitted to market our current or future product candidates in the United States until we receive approval of an NDA or BLA from the FDA, as applicable. In the European Economic Area, we must receive a marketing authorization from the European Commission following review by the European Medicines Agency, and in other foreign jurisdictions, we must obtain approval from comparable regulatory authorities prior to commercialization.

Post-Market Requirements

If the FDA or comparable foreign regulatory authorities approve 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, continued compliance with cGMPs, and compliance with GCPs for any clinical trials conducted post-approval. Regulatory approvals may also be subject to limitations on the approved indications, conditions of approval, or requirements for additional post-marketing studies, including Phase IV clinical trials and ongoing safety surveillance.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or issues with our manufacturing processes or third-party manufacturers, or failure to comply with regulatory requirements, may result in, among other things:

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

To produce our product candidates for clinical trials and any products for commercial purposes, either at our own facilities or at third-party facilities, we and our third-party vendors must comply with applicable cGMP requirements. As part of our ongoing quality and process improvement efforts, we routinely assess our quality systems and implement enhancements as necessary to maintain compliance with applicable regulations. Regulatory authorities, including the FDA and comparable foreign authorities, may inspect our facilities to confirm compliance.

Animal Health Products

Certain U.S. federal agencies oversee the regulation of animal health products, including the FDA, the USDA and, as applicable, the U.S. Environmental Protection Agency ("EPA"). The FDA Center for Veterinary Medicine regulates animal pharmaceuticals under the Federal Food, Drug, and Cosmetic Act. The EPA regulates certain pesticidal products intended for use in or on animals.

The USDA, through the Animal and Plant Health Inspection Service ("APHIS") and the Center for Veterinary Biologics ("CVB"), regulates veterinary biologics, including vaccines, diagnostics and immunomodulators, under the Virus-Serum-Toxin Act. APHIS oversees the importation, interstate movement and environmental release of veterinary biologics, while the CVB evaluates the safety, purity, potency and efficacy of these products prior to licensure.

The CVB's licensure process for veterinary biologics generally includes:

- Pre-License Evaluation. Review of the manufacturer's application and supporting data on safety, efficacy, and quality, which may include laboratory and field studies.
- Licensing Decision. Granting a license if regulatory requirements are met, or requesting additional data if necessary.
- Labeling Review. Approval of product labeling, including indications, dosage, administration, contraindications, and warnings.

- Manufacturing Standards. Establishment and enforcement of requirements for facilities, equipment, and procedures, with inspections to ensure compliance.
- Post-Licensure Surveillance. Ongoing monitoring for safety or efficacy concerns, and requirements for reporting adverse events or conducting post-marketing studies.

Conditional licenses may be granted for veterinary biologics in special circumstances, such as limited markets or unmet needs, if the product demonstrates a reasonable expectation of safety and efficacy. Products with conditional licensure may be marketed under specific restrictions and are subject to follow-up studies to support full licensure. The CVB continues to monitor licensed products, enforce manufacturing standards, and may require additional data, inspections, or post-marketing studies as needed to ensure ongoing safety and efficacy.

Other Healthcare Laws

If we begin commercializing any of our current or future product candidates, our operations will be subject to a variety of U.S. federal, state and foreign healthcare laws and regulations. These laws govern, among other things, the recommendation, prescribing, marketing, distribution and reimbursement of biopharmaceutical products. Healthcare providers, including physicians, play a central role in prescribing and recommending drugs for which we obtain marketing approval. Our arrangements with healthcare providers, payors and other customers are subject to requirements designed to ensure the integrity of these interactions.

U.S. federal laws include, among others, the Anti-Kickback Statute, which prohibits offering or receiving remuneration to induce or reward the referral or recommendation of products reimbursable under federal healthcare programs, and the False Claims Act, which imposes penalties for submitting, or causing the submission of, false or fraudulent claims to the federal government. Analogous state laws may impose similar requirements, including reporting obligations for payments or other transfers of value to healthcare providers.

Healthcare reform legislation also influences coverage, pricing and reimbursement for biopharmaceutical products. In the United States, statutes such as the Affordable Care Act and the Inflation Reduction Act, as well as other federal and state programs, establish requirements for Medicaid and Medicare drug rebates, coverage determinations, pricing transparency and other programmatic matters. States may also adopt regulations affecting pricing, reimbursement and product access, including measures that encourage importation, bulk purchasing or competitive bidding. Similar legislative and regulatory frameworks exist in other countries, where foreign authorities regulate drug approval, reimbursement and healthcare coverage.

Compliance with these laws and regulations informs our commercial programs, interactions with healthcare providers and payors, product labeling and pricing strategies. Government authorities may update, amend or reinterpret these laws, which can affect operational requirements for biopharmaceutical companies.

Privacy and Data Protection Laws

Our operations may involve the collection, use, storage and transmission of personal information, including health-related data obtained in connection with clinical trials, research activities and other business operations. As a result, we are subject to a variety of federal, state, and foreign privacy and data protection laws and regulations.

HIPAA and HITECH. In the United States, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), establishes standards for the privacy and security of protected health information maintained by healthcare providers, health plans and healthcare clearinghouses, as well as their business associates. These laws impose requirements relating to the use, disclosure and safeguarding of individually identifiable health information, including administrative, physical, and technical safeguards and breach notification obligations. HIPAA and HITECH also provide for civil and criminal penalties for violations and authorize enforcement by the U.S. Department of Health and Human Services and, in certain circumstances, state attorneys general.

International Data Protection Laws. Outside the United States, privacy and data protection laws regulate the processing of personal information, including health-related data. For example, the European Union's General Data Protection Regulation ("GDPR") establishes requirements governing the collection, processing, storage and transfer of personal data and imposes obligations on organizations that process such data. The GDPR includes restrictions

on cross-border data transfers and provides individuals with certain rights regarding their personal data. The United Kingdom has adopted a similar regulatory framework under the UK GDPR and the Data Protection Act 2018. Compliance with these frameworks may affect how we collect, process, and transfer personal data in connection with our operations in Europe and other jurisdictions.

U.S. State Privacy Laws. Several U.S. states have enacted comprehensive privacy laws that regulate the collection and use of personal information. For example, the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act ("CPRA"), provides California residents with rights regarding their personal information and imposes obligations on covered businesses relating to disclosures, consumer rights requests, and limitations on certain uses or sharing of personal data. These laws are enforced by state authorities and may provide private rights of action in certain circumstances. Additional states have adopted or are considering similar privacy legislation.

Compliance with these privacy and data protection requirements may affect how we design our clinical trial activities, information systems, data processing practices and contractual arrangements with third parties that process personal information on our behalf.

Environmental Regulations

Our operations, facilities and product development activities are subject to a variety of U.S. federal, state, local and foreign environmental, health and safety laws and regulations. These requirements govern, among other things, air emissions, wastewater discharges, the use and storage of hazardous substances, the generation and disposal of hazardous and non-hazardous waste, and the remediation of environmental contamination.

Our research and development and manufacturing-related activities involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials, and may generate hazardous waste. We typically rely on third-party contractors for the transport, treatment and disposal of these materials and wastes.

Environmental regulatory authorities, including the EPA and comparable state and foreign agencies, administer laws and regulations relating to pollution control, environmental protection and workplace health and safety. These requirements address, among other matters, emissions to air, discharges to land or water, and the handling, storage, transportation and disposal of regulated materials. Compliance with these laws and regulations is an ongoing component of our operations and facility management.

Pricing Regulations and Third-Party Coverage and Reimbursement

The requirements governing regulatory approval, pricing and reimbursement for pharmaceutical and biologic products vary significantly among countries. In some jurisdictions, governmental authorities regulate or approve the price of a drug before it can be marketed, while in others pricing reviews occur after marketing authorization. In many foreign markets, prescription drug pricing remains subject to ongoing governmental oversight even after initial approval. As a result, the timing of commercial launch and the price at which products may be marketed can be influenced by regulatory review and reimbursement determinations.

The commercial success of any of our current or future product candidates will depend, in part, on the availability of coverage and reimbursement from government healthcare programs, private health insurers and other third-party payors. These payors determine whether a product will be covered under a particular health plan and establish reimbursement levels. In making these determinations, payors typically consider factors such as the product's safety and efficacy, clinical value, medical necessity and cost-effectiveness.

Healthcare systems in the United States and other countries increasingly emphasize cost containment. Government authorities and third-party payors employ a range of mechanisms to manage pharmaceutical expenditures, including coverage limitations, formulary controls, negotiated discounts and rebates, and utilization management tools. These policies may influence product pricing, prescribing practices and reimbursement levels.

In the United States, coverage and reimbursement decisions for many medicines under the Medicare program are administered by the Centers for Medicare & Medicaid Services ("CMS"), a component of the U.S. Department of Health and Human Services. CMS policies often inform reimbursement approaches adopted by private payors and other healthcare programs.

Trade Laws

Our global operations are subject to various U.S. and foreign laws and regulations relating to anti-corruption, anti-money laundering, export controls, economic sanctions and other international trade matters (collectively, "Trade Laws"). These laws generally prohibit companies and their employees, agents and other representatives from offering, authorizing or providing improper payments or other benefits to government officials or private parties in order to obtain or retain business or secure an improper advantage.

In the course of our business, we may interact with government agencies, government-affiliated hospitals, universities and other public institutions, including in connection with clinical trials, regulatory approvals and research collaborations. We may also engage third parties, such as contract research organizations, consultants and other service providers, to support these activities. Trade Laws may apply to our activities and to those conducted on our behalf by such third parties.

Compliance with applicable Trade Laws informs our internal policies, procedures and contractual arrangements with third parties engaged in our operations in the United States and internationally.

Our Competition

The biotechnology and pharmaceutical industries are highly competitive and characterized by rapid technological advancement, evolving regulatory requirements, and significant research and development efforts. We face competition from large pharmaceutical companies, biotechnology companies, academic institutions, government agencies and other research organizations that are developing or commercializing therapies for cancer and rare diseases, including Osteosarcoma.

While we are not currently aware of any adjuvant therapy for Osteosarcoma intended for use in pediatric patients that is further advanced in development than OST-HER2, a number of organizations are developing therapies that may compete with our product candidates. These include product candidates under development by companies such as AstraZeneca and Y-mAbs Therapeutics, as well as programs being pursued by academic and research institutions, including MD Anderson Cancer Center.

Competition in this industry is based on a number of factors, including the ability to successfully develop product candidates, demonstrate safety and efficacy in clinical trials, obtain regulatory approvals, secure intellectual property protection, establish manufacturing capabilities, obtain reimbursement from third-party payors and successfully commercialize approved products.

Human Capital and Employees

As of March 26, 2026, 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

PIPE Financing

On December 24, 2024, we entered into a Securities Purchase Agreement (the "PIPE Purchase Agreement") with certain institutional and accredited investors, substantially all of whom were existing stockholders, to issue immediately separable units (the "Units"), each consisting of one share of Series A senior convertible preferred stock ("Series A Preferred Stock") and one warrant to purchase one share of common stock (each, a "Series A Warrant"). The Units were sold at $4.00 per Unit (the "PIPE Financing"). At two closings on December 31, 2024 and January 14, 2025, we issued an aggregate of 1,775,750 shares of Series A Preferred Stock and Series A Warrants exercisable into 1,775,750 shares of common stock, generating gross proceeds of approximately $7.1 million before fees and expenses.

Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as exclusive placement agent for the issuance and sale of the securities in the PIPE Financing. Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as exclusive placement agent. In connection with the PIPE Financing, we paid Brookline cash fees totaling $159,685 and $79,723 to Brookline and Brookline's selected dealer, respectively, plus warrants to purchase an aggregate of 59,848 shares of common stock (the "Agent Warrants").

The PIPE Purchase Agreement required stockholder approval under NYSE American rules for issuances that could exceed 20% of common stock outstanding as of December 24, 2024. On April 9, 2025, we held a Special Meeting of Stockholders, at which the issuance of shares upon (i) conversion of the Series A Preferred Stock, (ii) exercise of the Series A Warrants, and (iii) exercise of the Agent Warrants, in each case without regard to any limits on conversion or exercise therein and in amounts collectively equal to or exceeding 20% of our common stock outstanding as of December 24, 2024 (including upon the operation of applicable price reset and anti-dilution provisions and/or the reduction of conversion prices and exercise prices), was approved by our stockholders.

Acquisition of HER2 Assets

On April 9, 2025, we completed the acquisition of the HER2 Assets from Ayala. The HER2 Assets include two INDs with the FDA: (i) ADXS-503 for non-small cell lung cancer; and (ii) ADXS-504 for prostate cancer. In consideration for the purchase of the HER2 Assets, we agreed to assume certain specified liabilities and to pay an aggregate purchase price of $8,000,000, which was paid as follows: (i) $400,000 to Ayala ($150,000 of which was transferred upon signing of the HER2 Purchase Agreement and the remainder on the closing date); (ii) $100,000 to a third party on behalf of Ayala on the closing date; and (iii) $7,500,000 worth of shares of our common stock, or 4,774,637 shares based on the volume-weighted average price of our common stock over the 30 trading days immediately preceding the closing date.

ATM Equity Offering Program and Sales

On August 8, 2025, we entered into an at market issuance sales agreement (the "Sales Agreement") with B. Riley Securities, Inc. and JonesTrading Institutional Services LLC (each, a "Sales Agent" and, together, the "Sales Agents") relating to shares of our common stock. Pursuant to the Sales Agreement, we may offer and sell shares of our common stock from time to time having an aggregate offering price of up to $18,000,000 through or to the Sales Agents. We will pay each of the Sales Agents a total commission for its services in acting as agent in the sale of common stock up to 3.0% of the gross sales price per share of all shares sold through it as agent under the Sales Agreement. The amount of proceeds we will receive will depend upon the actual number of shares of our common stock sold and the market price at which such shares are sold. Because there is no minimum offering amount required as a condition to close a sale, the actual total public offering amount, commissions and proceeds to us are not determinable at this time. Sales of our common stock under the Sales Agreement are being made pursuant to a prospectus supplement filed with the SEC on August 25, 2025. As of March 26, 2026, we have sold an aggregate of 282,679 shares of our common stock for aggregate gross proceeds of $530,162 pursuant to the Sales Agreement.

Warrant Exercise Inducement and Exchange Offers

On July 11, 2025, we completed a final closing of a warrant exercise inducement and exchange offer (the "First Inducement Offering"). On September 2, 2025, we closed on a second warrant exercise inducement and exchange offer (the "Second Inducement Offering"). On January 14, 2026, we closed on a third warrant exercise inducement and exchange offer (the "Third Inducement Offering" and, collectively with the First Inducement Offering and Second Inducement Offering, the "Inducement Offerings"). The First Inducement Offering and Second Inducement Offering were made to holders of certain of our Series A Warrants to purchase shares of our common stock having a then current exercise price of $1.12 per share.

Pursuant to certain inducement offer letter agreements, holders of Series A Warrants exercised for cash their Series A Warrants to purchase an aggregate of 7,154,338 shares of our common stock at the then current exercise price of $1.12 per share and in exchange we issued to such holders new warrants (the "New Warrants") to purchase up to an aggregate of 7,154,338 shares of our common stock at an exercise price of $3.00 per share, subject to adjustment as provided therein. The New Warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date.

The Third Inducement Offering was made to less than 10 accredited investors that held New Warrants to purchase up to an aggregate of 5,382,148 shares of our common stock having a then current exercise price of $3.00 or $2.10 per share. Pursuant to certain inducement offer letter agreements, such holders of New Warrants exercised for cash their New Warrants to purchase 2,499,558 shares of our common stock at a reduced exercise price of $1.40 per share and in exchange we issued to such holders new warrants (the "2026 Warrants") to purchase up to an aggregate of 2,499,558 shares of our common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. The 2026 Warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date.

We engaged a SEC-registered broker dealer and FINRA member (the "Solicitation Agent") to act as our exclusive warrant solicitation agent in connection with the Inducement Offerings and paid the Solicitation Agent a cash fee equal to 5.0%, 1.5% and 8.0% of the total gross cash proceeds received from the exercise by the holders of their respective warrants in connection with the First Inducement Offering, Second Inducement Offering and Third Inducement Offering, respectively. We also paid the Solicitation Agent $15,000 and $25,000 for its reasonable legal and other expenses in connection with the First Inducement Offering and Third Inducement Offering, respectively.

The gross proceeds to us from the Inducement Offerings, before deducting transaction fees and other offering expenses, were approximately $11.5 million. We are using the net proceeds from the Inducement Offerings to support U.S. and international regulatory and pre-commercial efforts aimed at securing marketing authorizations for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic Osteosarcoma, provide funding for our wholly owned subsidiary OS Animal Health's proposed spin-off transaction preparations, and for general corporate purposes.

The shares of common stock underlying the New Warrants have been registered for resale under the Securities Act. We agreed to file a registration statement on Form S-3 (or other appropriate form, including on Form S-1, if we are not then eligible to register securities on Form S-3) providing for the resale of the shares of common stock issued or issuable upon exercise of the 2026 Warrants within 30 calendar days of March 2, 2026, and to use commercially reasonable efforts to have such registration statement declared effective by the SEC within 60 calendar days (or within 90 calendar days in case of "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time no holder owns any 2026 Warrants or shares of common stock issuable upon exercise thereof and (ii) the Delegend Date (as defined in the inducement offer letter agreements entered into in connection with the Third Inducement Offering).

Privately Negotiated Warrant Exercise Inducement and Exchange Agreements

From January 10, 2026 through February 2026, we entered into privately negotiated inducement offer letters, pursuant to which certain remaining holders of our New Warrants exercised for cash their New Warrants to purchase an aggregate of 123,216 shares of our common stock at a reduced exercise price of $1.40 per share and in exchange we issued new warrants to purchase up to an aggregate of 123,216 shares of our common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. Such new warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date. We received gross proceeds of approximately $172,502 from the exercise of these New Warrants.

We agreed to file a registration statement on Form S-3 (or other appropriate form, including on Form S-1, if we are not then eligible to register securities on Form S-3) providing for the resale of the shares of common stock issued or issuable upon exercise of these warrants on or before March 30, 2026, and to use commercially reasonable efforts to have such registration statement declared effective by the SEC within 60 calendar days (or within 90 calendar days in case of "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time no holder of these warrants owns any such warrants or shares of common stock issuable upon exercise thereof and (ii) the Delegend Date (as defined in the privately negotiated inducement offer letters).

2026 Bridge Financing

On March 4, 2026, pursuant to a securities purchase agreement (the "Bridge SPA"), we issued to certain accredited investors in a private placement transaction (i) 10.0% original issue discount unsecured convertible promissory notes in an aggregate principal amount of $2,200,000 (the "Bridge Notes") and (ii) warrants to purchase up to an aggregate of 1,666,667 shares of our common stock (the "Bridge Warrants" and such private placement transaction, the "Bridge Financing"), for aggregate gross proceeds of $2,000,000, before deducting placement agent fees and other Bridge Financing expenses. The Bridge Notes mature on March 4, 2027 and accrue interest at a rate of 4.0% per annum. The Bridge Warrants were immediately exercisable upon issuance, expire five years from the date of issuance and have an exercise price of $1.40 per share, subject to adjustment as provided therein.

The Bridge Notes were sold at a 10% original issue discount, such that for each $100,000 invested by a purchaser, such purchaser received a Bridge Note in the principal amount of $110,000. The Bridge Notes are convertible into shares of our common stock under certain circumstances. If we complete a "Qualified Offering," defined as a registered public offering or registered direct offering resulting in at least $2.5 million in gross proceeds from new money investments, the outstanding principal, together with all accrued and unpaid interest, will automatically convert into the securities sold in such offering at the offering price. Additionally, prior to any such Qualified Offering or repayment of the Bridge Notes, holders may elect to convert the Bridge Notes, in whole or in part, into shares of our common stock at a conversion price equal to 90% of the average daily volume-weighted average price of our common stock during the 10 trading days immediately preceding the holder's conversion notice, subject to adjustment.

We intend to use the net proceeds of the Bridge Financing to fund clinical development activities, including ongoing and planned clinical trials, and advance our research and development programs, as well as for working capital and general corporate purposes.

We engaged a SEC-registered broker dealer and FINRA member to act as the exclusive placement agent for the Bridge Financing. In connection with the Bridge Financing, we paid to the placement agent (a) a cash fee equal to 7.0% of the aggregate gross cash proceeds received by us in connection with the Bridge Financing and (b) a one-time expense reimbursement of $25,000 for its legal and other expenses incurred in connection with the Bridge Financing.

We agreed to file a registration statement on Form S-3 (or Form S-1 if we are not then eligible to register securities for Form S-3) by April 3, 2026 to register for resale the shares of our common stock issuable upon conversion of the Bridge Notes and exercise of the Bridge Warrants, and to use commercially reasonable efforts to cause such registration statement to become effective within 60 calendar days (or 90 calendar days in the case of a "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time that no investor owns any Bridge Notes, Bridge Warrants or shares underlying such Bridge Notes and Bridge Warrants or (ii) the Legend Removal Date (as defined in the Bridge SPA).

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 approval for, or successfully commercialize, any of our current or future product candidates.
- Delays or difficulties in enrolling patients in clinical trials could delay regulatory approval and increase development costs.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for both 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 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, EMA or other regulatory authorities 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.
- 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 owned, co-owned or in-licensed 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 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 achieve profitability depends on our ability to generate revenue from product sales. To date, while we have generated interest in potential research collaborations, we have not generated any commercial revenue from our product candidates, including our lead product candidate OST-HER2 and our OST-tADC platform. We do not expect to generate revenue from drug sales in the near future. We will not generate revenue unless and until we successfully complete the development of, obtain regulatory approval for, and commercialize one or more of our product candidates. Our lead product candidate, OST-HER2, has completed a Phase IIb clinical trial in patients with recurrent, fully resected pulmonary metastatic Osteosarcoma and we are currently pursuing regulatory interactions with the FDA and regulatory authorities in the United Kingdom and European Union regarding potential approval pathways. These pathways may include the FDA's Accelerated Approval Program and conditional approval pathways in other jurisdictions. However, there can be no assurance that any such approvals will be granted, that confirmatory trials will be successful or that we will ultimately be able to commercialize OST-HER2. Our OST-tADC platform remains in the preclinical stage of development.

Even if we pursue these regulatory pathways, we face significant risks and uncertainties that may prevent us from generating revenue, including, but not limited to:

- our ability to attract and retain qualified scientific, clinical and management personnel;
- our ability to successfully develop our product candidates, including completing preclinical studies and clinical trials, generating positive safety and efficacy data, and conducting any confirmatory trials that may be required to support accelerated or conditional approvals;
- our ability to obtain regulatory approval for our product candidates from the FDA and other regulatory authorities;
- the costs, timing and uncertainties associated with advancing additional development programs we may identify internally or through collaborations or other strategic arrangements;
- our ability to identify, develop and utilize biomarkers that support regulatory submissions or demonstrate clinical benefit;
- our ability to establish and maintain relationships with third-party manufacturers and suppliers for clinical and potential commercial supply, and to accurately forecast and meet supply requirements;

- our ability to enter into and maintain collaboration, licensing, manufacturing, distribution and other strategic arrangements on favorable terms;
- our ability to establish commercialization capabilities, obtain adequate reimbursement and coverage from third-party payors, and achieve market acceptance among physicians, patients and payors if our products are approved;
- our ability to compete effectively with existing or future therapies; and
- our ability to obtain, maintain and enforce intellectual property protection and regulatory exclusivity for our product candidates.

In addition, while OST-HER2 has received Rare Pediatric Disease Designation and we may become eligible to receive a Priority Review Voucher if certain regulatory approvals are obtained within specified timeframes, there can be no assurance that we will meet the requirements to receive such a voucher or that it will provide any financial or strategic benefit to us.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we may never generate significant revenue from product sales or achieve profitability.

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

Since our inception, we have devoted substantially all of our resources to the research and development of our product candidates, including OST-HER2 and our OST-tADC platform. As a result, we have incurred significant operating losses and negative cash flows from operations. For each of the years ended December 31, 2025 and 2024, we incurred operating losses and negative cash flows from operations. Since July 2018, we have financed our operations primarily through public and private offerings of our securities, from which we have raised aggregate gross proceeds of approximately $41.1 million. We have not generated any revenue from product sales and do not expect to do so unless and until one or more of our product candidates receives regulatory approval and is successfully commercialized. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our historical losses, together with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our expenses are expected to increase substantially as we:

- advance the development of our product candidates, including completing preclinical studies and conducting clinical trials, including any confirmatory trials that may be required to support potential regulatory approvals;
- prepare regulatory submissions and continue interactions with regulatory authorities in the United States and internationally;
- manufacture clinical trial materials and establish or expand relationships with third-party manufacturers to support clinical development and potential commercialization;
- continue research and development activities to expand and advance our product pipeline, including our OST-tADC platform;
- seek regulatory approval for our product candidates and prepare for potential commercialization;
- expand our internal capabilities, including hiring additional scientific, clinical, regulatory and management personnel;
- maintain, expand, and protect our intellectual property portfolio; and
- incur additional legal, accounting, insurance, investor relations and other expenses associated with operating as a public company.

As a result, we will need to generate significant revenue to achieve profitability, and we may never achieve or sustain profitability.

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 biopharmaceutical product candidates is capital intensive and subject to significant uncertainty. We are currently advancing our lead product candidate, OST-HER2, toward potential regulatory submission and approval, and our OST-tADC platform remains in preclinical development. We expect our expenses to increase substantially as we continue to support regulatory interactions, prepare for potential BLA submissions, conduct additional analyses, initiate any required confirmatory clinical trials, and expand our research and development activities. If OST-HER2 receives regulatory approval, we also expect to incur significant costs related to commercialization, including manufacturing scale-up, sales, marketing, distribution and medical affairs, whether independently or with collaborators.

Our capital requirements will depend on many factors, including regulatory outcomes, the scope and timing of any additional clinical trials that may be required by regulatory authorities, the costs of manufacturing and process development for our product candidates, the pace of expansion into additional indications or geographies, and our ability to establish collaborations or strategic partnerships. In particular, despite the positive results from our Phase IIb clinical trial, regulatory authorities may require additional clinical data, including from randomized controlled trials, which would significantly increase our funding needs and extend development timelines.

We will require substantial additional capital to support our ongoing operations and execute our business strategy. However, we may be unable to obtain financing on acceptable terms, or at all. Market conditions, including volatility in the biotechnology sector, and our clinical, regulatory and commercial progress may adversely impact our ability to raise capital. If we are unable to secure adequate funding when needed, we may be required to delay, reduce or terminate development programs, including for OST-HER2 or our OST-tADC platform, limit our ability to pursue additional indications or regulatory approvals in other jurisdictions, delay or forgo commercialization efforts, or curtail our operations, any of which could materially harm 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 securities offerings, including our at-the-market offering program, 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 incurred significant operating losses and negative cash flows from operations since our inception and expect to continue to incur substantial losses for the foreseeable future as we advance the development of our product candidates, including OST-HER2, and continue preclinical development of our OST-tADC platform. To date, we have financed our operations primarily through the issuance of equity and equity-linked securities, including common stock, preferred stock, convertible promissory notes and warrants in public and private offerings.

We do not currently generate product revenue and do not expect to generate any product revenue in the near term. In addition, we do not expect our existing collaboration or licensing arrangements, if any, to provide significant cash inflows sufficient to fund our operations. Our ability to generate revenue, if any, will depend on the successful development, regulatory approval and commercialization of our product candidates, which is subject to significant uncertainty and may not occur.

As a result of our recurring losses from operations, negative cash flows, and net capital deficiency, our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements expressing substantial doubt about our ability to continue as a going concern for at least 12 months from the date of issuance of the consolidated financial statements. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will need to raise substantial additional capital to fund our 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 acceptable terms. If we are unable to raise additional capital or otherwise address our liquidity needs, we may be required to significantly delay, scale back or discontinue the development of our product candidates, including OST-HER2, or otherwise curtail our operations. In such case, there can be no assurance that we will be able to continue as a going concern. In addition, the inclusion of a going concern explanatory paragraph in our auditor's report may adversely affect our ability to obtain financing on acceptable terms, or at all, and could negatively impact the market price of our common stock.

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, 2025 and 2024, we had federal and state NOLs of approximately $33,561,091 and $22,236,580, respectively, federal and state research and development tax credits of $268,568 and $268,568, respectively, and general business credit carryforwards of approximately $3,492,199 and $1,672,876, 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 products approved for sale and may never successfully develop marketable product candidates. Our business depends heavily on the successful development, regulatory approval, and commercialization of our current and future immunotherapy product candidates for Osteosarcoma, of which our lead candidate, OST-HER2, is in Phase IIb clinical development. OST-tADC remains in preclinical development and will require substantial additional preclinical and clinical testing, as well as regulatory approvals, before we may commercialize it. The preclinical studies and clinical trials of our product candidates, as well as the manufacturing and marketing of any approved product, are subject to extensive and rigorous regulation by government authorities in the United States, the European Economic Area (EEA), and other jurisdictions in which we intend to test or market our product candidates. Before obtaining regulatory approvals, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for its intended indication. Drug development is a lengthy, expensive, and uncertain process, and delay or failure can occur at any stage. Even with sufficient funding, there can be no assurance that any of our product candidates will be successfully developed, approved, or commercialized.

We cannot market our product candidates in the United States without approval of a BLA from the FDA, in the EEA without approval of a MAA from the EMA, or in other foreign jurisdictions without the requisite approvals. Obtaining regulatory approval is complex, time-consuming, costly, and uncertain, and the FDA, EMA, or other foreign authorities may delay, limit, or deny approval for many reasons, including but not limited to:

- inability to demonstrate that our product candidates are safe and effective for their target indications;
- preclinical or clinical trial results that fail to meet required statistical or clinical significance;
- disagreement with the number, design, size, conduct, or implementation of our studies;
- requests to conduct additional preclinical studies or clinical trials;
- non-approval of formulation, labeling, or specifications;
- actions by CROs that materially adversely affect study results;
- regulatory authorities' determination that our data are insufficient to demonstrate that clinical benefits outweigh safety risks;
- disagreement with our interpretation of study data;
- non-acceptance of data generated at certain study sites;
- advisory committee recommendations that are negative or impose conditions;
- requirements to implement a Risk Evaluation and Mitigation Strategy (REMS);
- determinations that manufacturing processes or facilities do not comply with regulatory requirements, including cGMPs; or
- changes in regulatory policies, requirements, or procedures.

Many of these factors are beyond our control and could prevent or delay regulatory approval, limit the indications for which a product may be approved, or impose significant post-approval obligations. Any such setback could materially and adversely affect our business, prospects, and ability to generate revenue.

Delays or difficulties in enrolling patients in clinical trials could prevent or delay regulatory approval and increase development costs.

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. This challenge is particularly significant because we are focused on patients with rare Osteosarcoma, which has a relatively low prevalence, with an incident rate of approximately 1,000 individuals affected per year in the United States. Identifying patients who meet our eligibility criteria, including those with specific molecular or driver gene profiles, may be difficult and could lead to slower-than-expected enrollment. 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.

While we successfully enrolled 41 patients in our Phase IIb clinical trial of OST-HER2, patient enrollment in future trials may be slower or more limited due to the rarity of the disease, competition for patients from other clinical trials, or other factors outside our 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.

Failure to enroll a sufficient number of patients in future trials could result in significant delays, increased development costs, or the need to suspend or abandon one or more clinical trials. Such delays may also impair our ability to seek participation in expedited regulatory programs, such as the FDA's priority review or fast track designations, and could materially impact the timing, cost, and success of regulatory approvals and commercialization.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for both 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 is 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, EMA or other regulatory authorities 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 have submitted the required information to the FDA in order to re-establish ODD for OST-HER2 in 2026. 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 may be entitled to a period of marketing exclusivity, during which the FDA or EMA generally cannot approve another marketing application for the same active ingredient for the same indication. The applicable period is seven years in the United States and ten years in the European Union, although EU exclusivity may be reduced to six years if a drug no longer meets the orphan criteria or is considered sufficiently profitable. 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 drug supply to meet patient needs.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition. Drugs with different active ingredients can be approved for the same condition, and the FDA or EMA may approve the same drug for the same condition if a later product demonstrates clinical superiority, such as being safer, more effective, or making a major contribution to patient care. In addition, we may not be the first to obtain marketing approval for a particular orphan indication. Approval of another product for the same active ingredient and indication could prevent or delay our ability to obtain orphan drug exclusivity, materially affecting our competitive position.

Regulatory authorities may also revise orphan drug regulations or policies, and it is uncertain how any such changes could impact our business or exclusivity rights.

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 within the timeframe required by the applicable statutory provisions or if future law changes eliminate or further modify the PRV Program.

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 current law, as amended by the Consolidated Appropriations Act, 2026, the PRV Program is authorized through September 30, 2029. The FDA may not award PRVs under this program after that date. Eligibility for a PRV generally requires both rare pediatric

disease designation and approval of a marketing application for the designated rare pediatric disease. Even if OST-HER2 receives rare pediatric disease designation and is ultimately approved, we may not receive a PRV if the BLA is not approved in time to meet statutory requirements or if the PRV Program is subsequently modified or allowed to expire. In addition, even if we are eligible for and obtain a PRV, there can be no assurance that we will be able to realize significant value from the voucher, as the market for PRVs and their perceived value may vary over time and may be affected by changes in regulatory policies, business conditions or the supply of available PRVs.

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 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 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 lead core product candidate OST-HER2 and our other core product candidate OST-tADC, both targeting 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.

Although a larger number of Osteosarcoma patients reside outside the United States, our ability to generate meaningful revenues in those jurisdictions may be limited due to pricing controls, reimbursement limitations, and other market access challenges.

The incidence of new cases of Osteosarcoma is approximately 1,000 individuals annually in the United States and approximately 20,000 globally. Although the global patient population is larger, our ability to generate revenues outside the United States may be limited by pricing regulations, reimbursement restrictions, and market access barriers. In many countries, particularly in the European Union and other developed markets, the pricing of prescription pharmaceuticals is subject to governmental control, and pricing and reimbursement approvals may be required prior to or following marketing authorization. Pricing negotiations with governmental authorities can be lengthy and may delay the commercial launch of a product candidate. In some jurisdictions, obtaining reimbursement or pricing approval may require the submission of health economic data or the conduct of additional clinical studies to demonstrate cost-effectiveness relative to existing therapies. If reimbursement for our product candidates is unavailable, limited in scope, or subject to significant restrictions, or if pricing is set at unsatisfactory levels, our ability to generate revenues in those markets may be materially adversely affected. In addition, in certain regions, including parts of Africa and the Middle East, limited healthcare infrastructure and diagnostic capabilities may constrain our ability to identify and treat patients, thereby limiting commercial opportunities. In the United States, there have been significant efforts to control drug pricing. For example, the Inflation Reduction Act of 2022 introduced measures that allow the federal government to negotiate prices for certain drugs under Medicare and impose rebates tied to inflation. These and other pricing reforms may reduce the prices we are able to charge for any approved products and adversely affect our revenues.

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 and constantly evolving. 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, biotechnology companies, academic institutions, government agencies and other public and private research organizations worldwide. Some of these competitors currently market or are actively developing therapies for rare diseases and cancers, including Osteosarcoma, and some programs may be based on scientific approaches that are similar to ours, while others may employ entirely different approaches.

Specifically, 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 programs from AstraZeneca, Y-mAbs Therapeutics, MD Anderson Cancer Center and others. The competitive landscape is dynamic: competitors' programs may advance or be discontinued, and new entrants may emerge, which could materially affect our ability to capture or maintain market share.

Many of the companies against which we are competing or may compete in the future have significantly greater financial, technical, regulatory and commercial resources than we do, including greater expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement, and marketing approved drugs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in further consolidation and concentration of resources among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors may also compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and enrolling patients in 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, and in many countries, the pricing review period begins after marketing approval is granted. In certain markets, including the European Union, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval. As a result, we may obtain marketing approval for a product candidate in a particular country but be subject to price regulations that delay commercial launch or limit 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 approved.

In the United States, there have been significant legislative and regulatory efforts to control drug pricing. For example, the Inflation Reduction Act of 2022 includes provisions that permit the U.S. Department of Health and Human Services, through the CMS, to negotiate prices for certain high-expenditure drugs covered under Medicare, impose inflation-based rebates, and redesign certain aspects of the Medicare Part D program. While the full implementation and long-term impact of these measures are still evolving, they may reduce the prices we are able to charge for any approved products and adversely affect our revenues and profitability. Additional federal or state healthcare reform measures may also be adopted in the future that could further impact pricing and reimbursement.

Our ability to successfully commercialize any current or future product candidates will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments are available from government authorities, private health insurers, and other organizations. Government authorities and other third-party payors decide which medications they will cover and establish reimbursement levels. Factors payors consider in determining reimbursement include whether the product is a covered benefit, safe and effective, medically necessary, appropriate for the patient, and cost-effective, and whether it is considered experimental or investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have sought to control costs by limiting coverage, setting reimbursement levels, requiring rebates and discounts, and challenging the prices charged for drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize or, if coverage is available, the level of reimbursement. Reimbursement levels 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 comparable foreign regulatory authorities. 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, manufacturing, and distribution. Reimbursement rates may vary based on the use of the drug, the clinical setting, and comparisons to lower-cost therapies, and may be incorporated into bundled payments for other services. Net prices for drugs may also be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. In the United States, coverage and reimbursement decisions for Medicare are made by CMS, and private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement practices. Our inability to obtain timely and adequate coverage and reimbursement for any approved products could have a material adverse effect on our business, financial condition, and results of operations.

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 and continue to consider legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates, restrict or regulate post-approval activities, and affect our ability to profitably commercialize any products for which we obtain marketing approval. Changes in regulations, statutes, or the interpretation of existing requirements could require, among other things: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of products; or (iv) additional recordkeeping, reporting, or compliance obligations. Any such changes could adversely affect our operations and increase our costs.

In the United States, there have been significant efforts to control healthcare costs and drug pricing. For example, the Inflation Reduction Act of 2022 includes provisions that, among other things, allow the U.S. Department of Health and Human Services to negotiate prices for certain drugs covered under Medicare, impose inflation-based rebates, and redesign certain aspects of the Medicare Part D program. The implementation and long-term effects of these measures are still evolving, but they may reduce the revenues we are able to generate from any approved products. In addition, other federal and state legislative and regulatory proposals aimed at controlling drug pricing, increasing transparency, or reforming reimbursement systems have been introduced and may be enacted in the future.

Our revenue prospects may also 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, pricing, coverage, or reimbursement may negatively impact our business, financial condition, and results of operations. We cannot predict the likelihood, nature, or extent of future healthcare reform measures or their potential impact on our business. If we or any third parties we engage are unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties fail to maintain regulatory compliance, we may lose any regulatory approvals that we may obtain and 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 significant penalties and adversely affect our business.

Although we do not currently have any products on the market, if we begin commercializing our current or future product candidates, we will become subject to additional healthcare statutory and regulatory requirements and enforcement by federal, state, and foreign governmental authorities. Healthcare providers, including physicians, play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our arrangements with healthcare providers, third-party payors, and customers will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business and financial relationships through which we market, sell, and distribute our products. Restrictions under applicable federal and state healthcare laws and regulations include, among others, the following:

- the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward referrals or the purchase, order, or recommendation of any good or service reimbursable under federal or state healthcare programs such as Medicare, Medicaid, and TRICARE. The term "remuneration" has been interpreted broadly to include anything of value, and a person or entity need not have actual knowledge of the statute or specific intent to violate it to be found in violation;
- the federal False Claims Act imposes civil and criminal penalties, including through whistleblower (qui tam) actions, against individuals or entities for knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government or for making false statements to avoid an obligation to pay money to the government. Manufacturers may be held liable even when they do not submit claims directly if they are deemed to "cause" the submission of false claims. The statute provides for treble damages and significant per-claim penalties, and has been used to pursue a wide range of pharmaceutical company activities, including alleged improper promotional practices, off-label promotion, and pricing-related conduct;

- HIPPA imposes criminal and civil liability for executing schemes to defraud healthcare benefit programs or making false statements in connection with the delivery of or payment for healthcare benefits, items, or services;
- federal physician payment transparency requirements (commonly referred to as the Open Payments program) require manufacturers of drugs, biologics, and medical supplies reimbursable under federal healthcare programs to report annually to the U.S. Department of Health and Human Services information regarding payments and other transfers of value to physicians, certain non-physician healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such individuals;
- HIPAA, as amended by HITECH, and its implementing regulations, impose obligations on covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, including breach notification requirements and expanded enforcement authority; and
- analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, transparency laws, and data privacy and security laws, many of which differ from federal requirements and may not be preempted, thereby complicating compliance efforts.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. The regulatory and enforcement environment in the healthcare industry remains active, and governmental authorities have increased their focus on compliance with these laws. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, or case law. If our operations are found to be in violation of any of these laws or any other applicable regulations, we may be subject to significant civil, criminal, and administrative penalties, including damages, fines, exclusion from government-funded healthcare programs such as Medicare and Medicaid, and the curtailment or restructuring of our operations. In addition, if any of the physicians or other providers or entities with whom we do business are found to be non-compliant, they may be subject to sanctions, which could also adversely affect our business.

We may face potential liability and increased regulatory scrutiny if we obtain, use or fail to adequately protect identifiable patient health information in connection with our clinical trials and operations.

In the course of our clinical development activities, we may obtain or have access to sensitive personally identifiable information, including protected health information, from clinical trial participants, healthcare providers, research institutions, contract research organizations, and other third parties. While most healthcare providers and research institutions are subject to privacy and security regulations under HIPPA, as amended by HITECH, we may, depending on the nature of our relationships, be deemed a business associate or otherwise contractually subject to certain HIPAA obligations. Even where we are not directly subject to HIPAA, we may be subject to criminal liability under HIPAA in certain circumstances, including if we knowingly obtain or misuse individually identifiable health information in a manner that violates applicable law.

In addition, we are or may become subject to a variety of other federal, state, and foreign privacy and data protection laws and regulations that govern the collection, use, storage, disclosure, and protection of personal information. These include, for example, U.S. state privacy laws such as the CCPA, as amended by the CPRA, and similar laws in other jurisdictions, as well as international data protection regulations such as the European Union's GDPR, to the extent we conduct clinical trials or otherwise process personal data outside the United States. These laws are complex, evolving, and may impose significant compliance obligations, including requirements related to consent, data minimization, cross-border data transfers, breach notification, and individual rights.

We and our collaborators, including CROs, CMOs, and other third-party service providers, may also be subject to data breach notification laws and consumer protection laws that require us to notify affected individuals, regulatory authorities, and others in the event of a data breach involving personal information. Failure to comply with these requirements could result in significant penalties, litigation, and reputational harm. We face an increasing risk of cybersecurity incidents and data breaches, including those resulting from unauthorized access, system failures,

or cyberattacks. Any such incident could compromise the confidentiality, integrity, or availability of our data, including clinical trial data, disrupt our operations, delay our development programs, and expose us to regulatory enforcement actions and liability. Ensuring compliance with applicable privacy, data protection, and cybersecurity laws and regulations may require us to expend substantial resources. Claims that we or our third-party partners have violated individuals' privacy rights or failed to adequately protect personal information, even if unfounded, could be costly to defend and could result in adverse publicity, which could materially harm our business, financial condition, and results of operations.

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, a rare disease. 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 limited number of patients with the diseases we are targeting, our ability to achieve meaningful revenue will depend on our ability to accurately identify eligible patients, successfully commercialize our product candidates, and capture a significant share of the addressable market. Our estimates of the number of patients who may be eligible for treatment with OST-HER2 or any of our other current or future product candidates are based on a variety of sources, including published literature, clinical experience, and internal analyses, and may prove to be inaccurate. Although we have completed enrollment in our Phase IIb clinical trial for OST-HER2, which enrolled a limited number of patients consistent with the rare nature of the disease, our understanding of the addressable patient population remains subject to significant uncertainty. New studies or real-world data may change the estimated incidence, prevalence, or treatable population for osteosarcoma, and the number of patients ultimately eligible for our therapies may be lower than expected. In addition, identifying, diagnosing, and referring patients with osteosarcoma, particularly in earlier stages or in certain geographic regions, can be challenging, and we may not be successful in reaching all patients who could potentially benefit from our therapies. Even if we obtain regulatory approval and achieve meaningful market penetration, the small size of the target patient population may limit our ability to generate sufficient revenue to achieve or sustain profitability.

Furthermore, because there are limited standard-of-care treatments specifically directed at Osteosarcoma, the pricing and reimbursement landscape for OST-HER2 and any other product candidates we may develop is uncertain. While therapies for rare diseases may in some cases support premium pricing, there can be significant variability in reimbursement decisions by governmental authorities and third-party payors. If we are unable to obtain adequate reimbursement at levels sufficient to support our anticipated commercial infrastructure, our ability to successfully market and sell OST-HER2 and any of our other current or future product candidates would 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 and timing, 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 are party to licensing arrangements with the Trustees of the University of Pennsylvania and BlinkBio, 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. However, identifying appropriate partners is competitive, and the negotiation of these arrangements is complex, time-consuming, and resource-intensive. Potential partners may be unwilling to commit to such transactions on acceptable terms, or at all, particularly if they determine that our product candidates do not have sufficient clinical validation, commercial potential, or likelihood of regulatory approval. Even if we are successful in entering into such arrangements, we may not realize the anticipated benefits. Strategic transactions typically involve significant risks, including the potential for loss of control over

certain development or commercialization activities, reliance on third parties to meet development, regulatory and commercialization milestones, disagreements or disputes with partners, which could delay or terminate development programs, reduced economic returns as a result of profit-sharing, milestone payments or royalties, and the diversion of management attention and internal resources.

In addition, these transactions may require us to incur substantial costs, record non-recurring charges, assume contingent liabilities, or issue equity securities that dilute our existing stockholders. If we are unable to successfully identify and execute strategic transactions, or if any such transactions fail to achieve their intended objectives, our ability to advance our product candidates, including OST-HER2 and our other programs, may be adversely affected, and our business, financial condition and results of operations could be materially harmed.

As a result, we may not realize the anticipated benefits of our existing collaboration and licensing arrangements or any future strategic transactions, including partnerships, acquisitions, or licensing arrangements, particularly if we are unable to effectively integrate such arrangements with our existing operations and company culture. Any such failure could delay development timelines, disrupt our business, or otherwise adversely affect our results of operations. In addition, we cannot assure that any strategic transaction or collaboration will generate the expected revenues, cost savings, or other anticipated benefits that justified our entry into such arrangement. Further, delays in identifying or entering into new collaboration or strategic partnership agreements with respect to our current or future product candidates may delay or limit the development and commercialization of such product candidates, including in specific geographies or for particular indications, which could materially 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 the third parties from whom we in-license intellectual property are unable to obtain, maintain, protect, or enforce patent and other intellectual property rights for our technology and product candidates, or if the scope of such protection is not sufficiently broad, our competitors could develop and commercialize similar or identical technologies and products, and our ability to successfully commercialize our product candidates may be impaired.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal and factual questions, and has been the subject of extensive litigation in recent years. Our commercial success depends in part on our ability, and the ability of our licensors and other partners, to obtain, maintain, protect, and enforce intellectual property rights in the United States and other jurisdictions for our current and future product candidates, including OST-HER2, OST-tADC, our non-core programs, and our proprietary technologies and know-how.

We rely on a combination of owned, co-owned and in-licensed patents and patent applications to protect our intellectual property. For example, we in-license and co-own certain intellectual property relating to OST-HER2 from the University of Pennsylvania, and we in-license intellectual property relating to OST-tADC from BlinkBio, Inc. The intellectual property we own includes six 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 2029 and 2038, 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 required to successfully commercialize our product candidates may be unavailable or limited. We cannot assure that any of the patents we own or in-license, or any pending patent applications, will issue with claims of sufficient scope to protect our product candidates or provide a meaningful competitive advantage. If the scope or strength of our intellectual property protection is reduced or challenged, it could adversely affect our ability to attract collaborators or commercial partners.

Third parties may have developed or may develop technologies that compete with ours, and they may have filed or may file patent applications, or may obtain patents, that overlap with or conflict with our intellectual property. Because patent applications are typically not published until 18 months after filing and scientific publications often lag behind discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in our patents or pending applications. As a result, the validity, enforceability, scope, and commercial value of our intellectual property cannot be predicted with certainty.

Even if our patents are issued, they may be challenged, invalidated, narrowed, or held unenforceable in administrative proceedings or litigation in the United States or abroad. Such challenges could result in the loss of exclusivity, freedom to operate, or other competitive advantages. Furthermore, given the time required for clinical development and regulatory review, patent protection for our product candidates may expire before or shortly after commercialization, thereby limiting our ability to realize the full commercial value of our intellectual property. Any failure to obtain, maintain, protect, or enforce our intellectual property rights, or any loss or narrowing of such rights, could allow third parties to use our technology or develop competing products and could materially adversely affect 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, co-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, co-own or in-license. In addition, any patents we may own, co-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, co-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, co-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 or co-own. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own, co-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 or co-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, co-own or in-license. Even if we detect infringement by a third-party of any patents we may own, co-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, co-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, co-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, co-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, co-own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own, co-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, co-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, co-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 26, 2026, 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, 2025 due inadequate segregation of duties as a result of limited personnel and insufficient written policies and procedures for accounting, information technology and financial reporting (no control procedures in place). 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 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.

Use of artificial intelligence, machine learning and algorithmic tools involves risks that could materially and adversely affect our business, results of operations and development timelines.

We use, and expect to increasingly use, artificial intelligence ("AI"), machine learning ("ML") and other data-driven models to support discovery, clinical trial design and operations, manufacturing planning, and other aspects of our business. The effectiveness of these systems depends on the quality and completeness of the underlying data, proper training and validation of models, human oversight, and adherence to applicable regulatory expectations. Errors, bias, software vulnerabilities, or misuse of AI, ML, or other algorithmic tools could compromise scientific conclusions, produce flawed clinical trial protocols, generate inaccurate operational or manufacturing forecasts, or result in breaches of data integrity or privacy. Such events could delay development, regulatory review, or commercialization, or could otherwise adversely affect patient safety.

Regulatory authorities, including FDA, the EMA and other global agencies, are increasingly scrutinizing the use of AI and ML in drug development, including claims regarding AI-assisted decision making. If our public statements regarding AI capabilities are inaccurate, incomplete, or become outdated, or if regulators adopt new

expectations regarding AI governance, model validation, data transparency, or reporting in drug development, we could face investigations, enforcement actions, fines, or litigation. Such regulatory scrutiny could also require operational rework, additional documentation or validation, and delays in regulatory submissions or approvals.

In addition, malfunction, misuse, bias, or inaccuracies in AI, ML, or other algorithmic tools could materially and adversely affect the quality and reliability of our research and development programs, clinical data, manufacturing processes, and commercial operations. Any of these outcomes could materially delay development timelines, increase costs, negatively impact regulatory review, and reduce our ability to successfully develop, obtain marketing approval for, or commercialize our product candidates, which could have a material adverse effect on our business, financial condition, and prospects.

Geopolitical events, trade restrictions, sanctions and export controls could adversely affect our clinical operations, supply chain, data flows and financial transactions.

Our development, manufacturing, and supply chains, as well as certain aspects of our research and clinical programs, may be adversely affected by geopolitical events, including military conflicts, escalating international tensions, trade or investment restrictions, sanctions regimes, export controls, or retaliatory measures by foreign governments. Such actions could limit our ability, or the ability of our CROs, CMOs and other third-party partners, to source active pharmaceutical ingredients, starting materials, consumables, equipment, or software, to transfer biological materials, clinical samples, or data across international borders, or to make or receive payments in affected jurisdictions.

Geopolitical events may also increase cybersecurity threats targeting life sciences companies, potentially compromising sensitive research, patient data, or operational systems. Any of these factors could result in delays in our clinical trials, interruptions in the supply of materials or products, increased costs, or the need to rapidly identify and qualify alternative suppliers, manufacturing sites, or trial locations. Such disruptions could materially and adversely affect our business, results of operations, development timelines, and prospects for successfully developing and commercializing our product candidates.

Risks Related to Our Common Stock

A significant number of additional shares of our common stock may be issued pursuant to outstanding preferred stock, warrants, stock options and convertible securities, which issuances could substantially dilute existing stockholders and may depress the market price of our common stock.

We have issued, and may issue in the future, a significant number of shares of our common stock upon the conversion or exercise of outstanding preferred stock, warrants, stock options and other convertible securities.

In connection with the PIPE Financing completed in December 2024 and January 2025, we issued shares of our Series A Preferred Stock, each share of which is convertible into a number of shares of common stock at a conversion ratio equal to (x) the original issue price of the Series A Preferred Stock divided by (y) the conversion price of the Series A Preferred Stock. The Series A Preferred Stock was initially convertible at a 1:1 ratio, subject to adjustment as set forth in the Certificate of Designation, Preferences, Rights and Limitations of Series A Senior Convertible Preferred Stock. The number of shares of common stock into which the Series A Preferred Stock may be converted is also subject to potential increase pursuant to applicable resets and anti-dilution adjustments.

During 2025 and the first quarter of 2026, we completed three warrant exercise inducement and exchange transactions pursuant to which holders exercised certain existing warrants for cash and received new warrants to purchase a number of shares of our common stock equal to the number of shares received upon such exercise. In March 2026, we completed the Bridge Financing that included the issuance of the Bridge Notes and the Bridge Warrants. The Bridge Notes are convertible into shares of our common stock under certain circumstances. If we complete a "Qualified Offering," defined as a registered public offering or registered direct offering resulting in at least $2.5 million in gross proceeds from new money investments, the outstanding principal, together with all accrued and unpaid interest, will automatically convert into the securities sold in such offering at the offering price. Additionally, prior to any such Qualified Offering or repayment of the Bridge Notes, holders may elect to convert the Bridge Notes, in whole or in part, into shares of our common stock at a conversion price equal to 90% of the average daily volume-weighted average price of our common stock during the 10 trading days immediately preceding the holder's conversion notice, subject to adjustment.

As of the date of this Form 10-K, (i) 1,401,786 shares of our common stock are issuable upon the conversion of outstanding shares of our Series A Preferred Stock, with a conversion ratio of 3.571429 per share, (ii) 10,399,522 shares of our common stock are issuable upon the exercise of outstanding warrants, (iii) 6,771,250 shares of our common stock are issuable upon the exercise of outstanding and vested stock options under our 2023 Incentive Compensation Plan and (iv) 1,392,805 shares of our common stock are issuable upon the conversion of outstanding Bridge Notes (assuming full conversion of such notes into common stock at a conversion price of $1.39, which was the closing price of our common stock on March 26, 2026).

As a result of these features, declines in the market price of our common stock or future issuances of securities at lower prices could result in additional shares of our common stock becoming issuable upon conversion or exercise of these securities. The issuance of such shares would substantially dilute the ownership interests and voting power of existing stockholders.

In addition, we have agreed, or may agree, to file registration statements covering the resale of shares of common stock issuable upon conversion or exercise of these securities. The availability of a significant number of shares for sale in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and make it more difficult for us to raise additional capital in the future.

Sales of a substantial number of shares of our common stock, including those issued pursuant to the Sales Agreement, could cause the market price of our common stock to decline.

The sale of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could cause the market price of our common stock to decline. Although we cannot predict the exact number of shares that may be sold pursuant to the Sales Agreement or the price at which any sales may occur, the issuance and sale of up to $17,469,838 of our common stock pursuant to the Sales Agreement may result in the issuance of 12,568,228 additional shares (based on an assumed offering price of $1.39 per share, the closing price of our common stock on the NYSE American on March 26, 2026). Based on our shares outstanding as of March 26, 2026, and assuming full issuance of such shares, we would have 52,101,455 shares of common stock outstanding (excluding any shares issuable upon the conversion or exercise, as applicable, of outstanding convertible notes, preferred stock, warrants, or stock options). A substantial majority of the outstanding shares of our common stock are, and all of the shares sold pursuant to the Sales Agreement upon issuance will be, freely tradable without restriction or further registration under the Securities Act, unless such shares are owned or purchased by "affiliates" as that term is defined in Rule 144 under the Securities Act.

In addition, as of the date of this Form 10-K, there were outstanding (i) 392,500 shares of Series A Preferred Stock convertible into an aggregate of 1,401,786 shares of common stock, (ii) warrants to purchase an aggregate of 10,399,522 shares of common stock, (iii) options to purchase an aggregate of 6,771,250 shares of our common stock, of which options to purchase 2,866,750 shares of our common stock were then exercisable, and (iv) $2,200,000 in aggregate principal amount of convertible notes convertible into 1,392,805 shares of common stock (including the conversion of accrued interest and assuming a conversion price of $1.39, which was the closing price of our common stock on March 26, 2026). The shares of our common stock issuable upon conversion or exercise, as applicable, of such securities may be immediately eligible for resale in the open market. Any such sales, or the perception that such sales could occur, could cause the market price of our common stock to decline and may make it more difficult for us to raise capital in the future.

It is not possible to predict the aggregate proceeds resulting from sales made under the Sales Agreement.

Subject to certain limitations in the Sales Agreement and compliance with applicable law, we have the discretion to deliver a placement notice to the Sales Agents at any time throughout the term of the Sales Agreement. The number of shares that are sold through the Sales Agents, if any, after delivering a placement notice will fluctuate based on a number of factors, including the market price of our common stock during the sales period, the limits we set with the Sales Agents in any applicable placement notice, and the demand for our common stock during the sales period. Because the price per share of each share sold will fluctuate during the sales period, it is not currently possible to predict the aggregate proceeds to be raised in connection with those sales.

The common stock offered pursuant to the Sales Agreement will be sold in "at the market offerings," and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares pursuant to the Sales Agreement at different times will likely pay different prices, and so may experience different levels of dilution and different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and number of shares sold pursuant to the Sales Agreement. In addition, subject to the final determination by our board of directors, there is no minimum or maximum sales price for shares to be sold pursuant to the Sales Agreement. Investors may experience a decline in the value of the shares they purchase pursuant to the Sales Agreement as a result of sales made at prices lower than the prices they paid.

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 8.3% of the outstanding shares of common stock of our company, and other executive officers and directors beneficially own another approximately 3.4% 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 11.7% 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 6 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 26, 2026, there were 111 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, 2025 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	6,771,250	1.83	3,228,750
Total	6,771,250	$ 1.83	3,228,750

Sales of Unregistered Securities

During the year ended December 31, 2025, we did not issue any securities that were not registered under the Securities Act and that have not been previously disclosed in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

During the year ended December 31, 2025, 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 consolidated financial statements and related notes appearing elsewhere in this annual report. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking

statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this annual report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 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. In the first quarter of 2025, we announced that our Phase IIb clinical trial achieved its primary endpoint with statistical significance. In October 2025, we announced final two-year overall survival data from the Phase IIb trial, in which 75% (27 of 36 evaluable patients) of OST-HER2-treated patients achieved two-year overall survival from the most recent pulmonary resection, compared with 40% in historical control patients ($p < 0.0001$). OST-HER2 was observed to be well-tolerated in the study. In January 2026, we announced positive immune biomarker data from the Phase IIb trial indicating that activation of immune blood biomarkers in the interferon gamma pathway correlated with, and was predictive of, overall survival, distinguishing long-term survivors (≥ two years) from short-term survivors (< one year). These biomarker findings are based on exploratory analyses and have not been validated as surrogate endpoints for clinical benefit. Based on the totality of the data generated to date, including the observed survival outcomes, safety profile and the significant unmet medical need in this patient population, we intend to engage with the FDA regarding potential regulatory pathways for OST-HER2.

We have engaged in ongoing regulatory interactions with the FDA, the United Kingdom MHRA, and the EMA regarding the clinical and biomarker data for OST-HER2 in recurrent, fully resected pulmonary metastatic Osteosarcoma. Following submission of the Non-Clinical and CMC modules of our BLA to the FDA at the end of January 2026, we anticipate submitting the clinical BLA module following an expected Type B meeting with the FDA in the second quarter of 2026 and completing conditional MAA submissions to both the MHRA and the EMA in the second quarter of 2026. We also anticipate releasing additional biomarker data in the second quarter of 2026 to further characterize immune pathway activation and its relationship to clinical outcomes. We expect to initiate confirmatory clinical studies in the third quarter of 2026 in support of conditional approval pathways. If OST-HER2 receives approval under the FDA's Accelerated Approval Program prior to September 30, 2029, we would become eligible to receive a Priority Review Voucher under the Rare Pediatric Disease Designation Program.

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 an OST-tADC platform, a next generation 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.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses,

and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on 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 consolidated 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 consolidated 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 PIPE Financing in December 2024 and January 2025 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. 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 in 2024.

In April 2025, after stockholder approval was obtained, this warrant liability was closed to stockholders' equity. The following assumptions were made as of April 9, 2025 based on stockholder approval in the model for the aggregate warrants: (1) a fixed exercise price of $1.12 per share, which automatically reset and resulted in a reclassification of the warrant liability on April 9, 2025 to equity per ASC 815; (2) then-current common stock price of $1.34 per share on April 9, 2025; (3) discount rate of 4.06%; and (4) expected stock price volatility of 23.26%.

Components of Our Results of Operations

Revenue. We did not recognize revenues for the years ended December 31, 2025 and 2024.

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, 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 as of December 31, 2025 and 2024 was $375,000 and $375,000, 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 recognized income tax benefits for the net operating losses ("NOLs") incurred or the research and development ("R&D") tax credits generated each year due to uncertainty regarding the realization of these benefits.

As of December 31, 2025 and 2024, we had federal NOLs of $33,561,091 and $22,236,580, respectively. Our 2019 NOL carryforward of $292,144 will expire in tax years through 2037. NOLs generated in tax years 2020 and later may carry forward indefinitely; however, the deductibility of such NOLs is subject to certain limitations under the Code. Accordingly, we have established a full valuation allowance to offset our deferred tax assets due to uncertainty regarding the realization of these benefits.

Our issuances of common stock have resulted in ownership changes as defined by Section 382 of the Code. We have not yet performed a formal Section 382 study, and it is possible that a future analysis in 2026 could conclude that a substantial portion, or potentially all, of our NOL and R&D tax credit carryforwards may be limited or rendered unusable under Sections 382 and 383 of the Code. As a result, a portion of these carryforwards could expire unused. We are subject to U.S. federal tax examinations for the year 2021, given that NOL carryforwards from 2019 and subsequent years may be applied to current or future tax returns.

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

Results of Operations

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

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

	December 31,	
	2025	**2024**
Expenses:		
Research and development expenses	$ 16,360,725	$ 2,839,060
General and administrative	12,344,976	3,974,786
Total operating expenses	28,705,701	6,813,846
Loss from operations	(28,705,701)	(6,813,846)
Other income (expenses):		
Interest income	249	—
Interest expense	—	(2,051,839)
Non-operating income	—	33,997
Non-operating expenses	(1,472,995)	(51,250)
Change in fair value of warrant liability	1,424,603	—
Total other income (expense)	(48,143)	(2,069,092)
Net loss	**(28,753,844)**	**(8,882,938)**

Research and Development Expenses. Research and development expenses were approximately $16.4 million for the year ended December 31, 2025, compared to approximately $2.8 million for the year ended December 31, 2024. The increase was primarily driven by higher vendor costs related to our ongoing efforts to pursue FDA approval for our Phase IIb clinical trial and the preparation of data for submission to various global regulatory authorities. This increase was partially offset by a reduction in vendor expenses associated with our OST-tADC platform technology.

For the years ended December 31, 2025 and 2024, our direct research and development expenses related to OST-HER2 primarily consisted of laboratory fees, vendor costs, and staff payroll. In 2025, these expenses included approximately $1.6 million for laboratory fees and clinical support related to Phase IIb clinical trial preparation, $12.7 million for advisor fees, and $0.2 million for legal costs associated with the completion of IND-enabling studies. Direct research and development expenses related to our OST-tADC platform were approximately $0.0 million for both the years ended December 31, 2025 and 2024.

General and Administrative Expenses. General and administrative expenses were approximately $12.3 million for the year ended December 31, 2025, compared to approximately $4.0 million for the year ended December 31, 2024. The increase was primarily due to higher marketing and investor relations costs of $2.4 million, as well as advisory fees of $3.3 million and legal fees of $1.6 million incurred in connection with the PIPE Financing and equity line of credit that was terminated.

Interest Expense. Interest expense was approximately $0.0 million for the year ended December 31, 2025, compared to approximately $2.0 million for the year ended December 31, 2024.

Liquidity and Capital Resources

Operating Losses

Since our inception, we have incurred significant operating losses. Our ability to generate sufficient product revenue to achieve profitability will depend on the successful development and eventual commercialization of our product candidates. For the years ended December 31, 2025 and 2024, we reported net losses of approximately

$28.7 million and $8.6 million, respectively, and had accumulated deficits of approximately $67.2 million and $38.0 million, respectively. We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future.

As of December 31, 2025 and 2024, we had cash of approximately $0.3 million and $5.5 million, respectively. To date, we have primarily funded our operations through the sale of our securities in public offerings and private placements and warrant exercise inducement and exchange transactions, generating total gross proceeds of approximately $41.1 million as of March 26, 2026. We believe that the net proceeds from these transactions, together with our existing cash, will be sufficient to fund our operating expenses and capital expenditures for at least the next twelve months.

Cash Flows

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

	December 31,	
(In thousands)	**2025**	**2024**
Cash used in operating activities	$ (14,239)	$ (7,283)
Cash used in investing activities	(466)	—
Cash provided by financing activities	9,442	12,777
Net (decrease) increase in cash	$ (5,263)	$ 5,494

Operating Activities

For the years ended December 31, 2025 and 2024, net cash used in operating activities was approximately $14.2 million and $7.3 million, respectively. This primarily reflected net losses of approximately $28.8 million and $8.9 million, partially offset by non-cash charges of approximately $5.4 million and $1.7 million, respectively, and net cash provided by changes in operating assets and liabilities of approximately $9.1 million and $(0.1) million, respectively.

The changes in operating assets and liabilities for the years ended December 31, 2025 and 2024 primarily consisted of: an increase (decrease) in accounts payable of approximately $8.3 million and $(1.1) million, respectively; an increase in accrued interest of approximately $0.0 million and $0.6 million, respectively; and changes in accrued expenses of approximately $0.9 million and $0.4 million, respectively.

For the years ended December 31, 2025 and 2024, non-cash charges were primarily due to changes in the fair value of our warrant liability of $(1.4) million and $0.0 million, respectively, as well as common stock issued for services and stock-based compensation of approximately $4.87 million and $0.3 million, respectively, and amortization of non-cash prepaids of $1.0 million and $0.0 million, respectively. Changes in accounts payable, accrued expenses and other current liabilities, and prepaid expenses and other current assets in each period primarily reflected the growth of our business, the advancement of our research programs, and the timing of vendor invoicing and payments.

Investing Activities

For the years ended December 31, 2025 and 2024, net cash used in investing activities was approximately $0.5 million and $0.0 million, respectively.

Financing Activities

For the years ended December 31, 2025 and 2024, net cash provided by financing activities was approximately $9.4 million and $12.8 million, respectively. During 2025, cash inflows included approximately $1.1 million from our PIPE Financing and approximately $8.4 million from our warrant exercise inducement and related exchange and sale of common stock.

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.

PIPE Financing

On December 24, 2024, we entered the PIPE Purchase Agreement with certain institutional and accredited investors, substantially all of whom were existing stockholders, pursuant to which we issued an aggregate of 1,775,750 shares of Series A Preferred Stock and Series A Warrants exercisable into 1,775,750 shares of common stock, generating gross proceeds of approximately $7.1 million before fees and expenses. In connection with the PIPE Financing, we paid Brookline cash fees totaling $159,685 and $79,723 to Brookline and Brookline's selected dealer, respectively, plus Agent Warrants to purchase an aggregate of 59,848 shares of common stock.

ATM Equity Offering Program and Sales

On August 8, 2025, we entered into the Sales Agreement with the Sales Agents relating to shares of our common stock. Pursuant to the Sales Agreement, we may offer and sell shares of our common stock from time to time having an aggregate offering price of up to $18,000,000 through or to the Sales Agents. We will pay each of the Sales Agents a total commission for its services in acting as agent in the sale of common stock up to 3.0% of the gross sales price per share of all shares sold through it as agent under the Sales Agreement. The amount of proceeds we will receive will depend upon the actual number of shares of our common stock sold and the market price at which such shares are sold. Because there is no minimum offering amount required as a condition to close a sale, the actual total public offering amount, commissions and proceeds to us are not determinable at this time. Sales of our common stock under the Sales Agreement are being made pursuant to a prospectus supplement filed with the SEC on August 25, 2025. As of March 26, 2026, we have sold an aggregate of 282,679 shares of our common stock for aggregate gross proceeds of $530,162 pursuant to the Sales Agreement.

Warrant Exercise Inducement and Exchange Offers

On July 11, 2025, we completed a final closing of the First Inducement Offering. On September 2, 2025, we closed on the Second Inducement Offering. On January 14, 2026, we closed on the Third Inducement Offering.

In connection with the First Inducement Offerings and Second Inducement Offering, and pursuant to certain inducement offer letter agreements, holders of Series A Warrants exercised for cash their Series A Warrants to purchase an aggregate of 7,154,338 shares of our common stock at the then current exercise price of $1.12 per share and in exchange we issued to such holders New Warrants to purchase up to an aggregate of 7,154,338 shares of our common stock at an exercise price of $3.00 per share, subject to adjustment as provided therein. The New Warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date.

The Third Inducement Offering was made to less than 10 accredited investors that held New Warrants to purchase up to an aggregate of 5,382,148 shares of our common stock having a then current exercise price of $3.00 or $2.10 per share. Pursuant to certain inducement offer letter agreements, such holders of New Warrants exercised for cash their New Warrants to purchase 2,499,558 shares of our common stock at a reduced exercise price of $1.40 per share and in exchange we issued to such holders 2026 Warrants to purchase up to an aggregate of 2,499,558 shares of our common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. The 2026 Warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date.

We engaged the Solicitation Agent to act as our exclusive warrant solicitation agent in connection with the Inducement Offerings and paid the Solicitation Agent a cash fee equal to 5.0%, 1.5% and 8.0% of the total gross cash proceeds received from the exercise by the holders of their respective warrants in connection with the First Inducement Offering, Second Inducement Offering and Third Inducement Offering, respectively. We also paid the Solicitation Agent $15,000 and $25,000 for its reasonable legal and other expenses in connection with the First Inducement Offering and Third Inducement Offering, respectively.

The gross proceeds to us from the Inducement Offerings, before deducting transaction fees and other offering expenses, were approximately $11.5 million. We are using the net proceeds from the Inducement Offerings to support U.S. and international regulatory and pre-commercial efforts aimed at securing marketing authorizations for OST-HER2 in the prevention or delay of recurrent, fully resected, pulmonary metastatic Osteosarcoma, provide funding for our wholly owned subsidiary OS Animal Health's proposed spin-off transaction preparations, and for general corporate purposes.

Privately Negotiated Warrant Exercise Inducement and Exchange Agreements

From January 10, 2026 through February 2026, we entered into privately negotiated inducement offer letters, pursuant to which certain remaining holders of our New Warrants exercised for cash their New Warrants to purchase an aggregate of 123,216 shares of our common stock at a reduced exercise price of $1.40 per share and in exchange we issued new warrants to purchase up to an aggregate of 123,216 shares of our common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. Such new warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date. We received gross proceeds of approximately $172,502 from the exercise of these New Warrants.

2026 Bridge Financing

On March 4, 2026, pursuant to the Bridge SPA, we issued to certain accredited investors in the Bridge Financing (i) Bridge Notes in an aggregate principal amount of $2,200,000 and (ii) Bridge Warrants to purchase up to an aggregate of 1,666,667 shares of our common stock, for aggregate gross proceeds of $2,000,000, before deducting placement agent fees and other Bridge Financing expenses. The Bridge Notes mature on March 4, 2027 and accrue interest at a rate of 4.0% per annum. The Bridge Warrants were immediately exercisable upon issuance, expire five years from the date of issuance and have an exercise price of $1.40 per share, subject to adjustment as provided therein.

The Bridge Notes were sold at a 10% original issue discount, such that for each $100,000 invested by a purchaser, such purchaser received a Bridge Note in the principal amount of $110,000. The Bridge Notes are convertible into shares of our common stock under certain circumstances. If we complete a "Qualified Offering," defined as a registered public offering or registered direct offering resulting in at least $2.5 million in gross proceeds from new money investments, the outstanding principal, together with all accrued and unpaid interest, will automatically convert into the securities sold in such offering at the offering price. Additionally, prior to any such Qualified Offering or repayment of the Bridge Notes, holders may elect to convert the Bridge Notes, in whole or

in part, into shares of our common stock at a conversion price equal to 90% of the average daily volume-weighted average price of our common stock during the 10 trading days immediately preceding the holder's conversion notice, subject to adjustment.

We intend to use the net proceeds of the Bridge Financing to fund clinical development activities, including ongoing and planned clinical trials, and advance our research and development programs, as well as for working capital and general corporate purposes.

We engaged a SEC-registered broker dealer and FINRA member to act as the exclusive placement agent for the Bridge Financing. In connection with the Bridge Financing, we paid to the placement agent (a) a cash fee equal to 7.0% of the aggregate gross cash proceeds received by us in connection with the Bridge Financing and (b) a one-time expense reimbursement of $25,000 for its legal and other expenses incurred in connection with the Bridge Financing.

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

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, 2025, 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 "*Financing Activities — BlinkBio*" above for more information on the BlinkBio Convertible Note.

Biolacuna Ltd. We have contracted with Biolacuna Ltd, a global life sciences advisory firm, to assist with the following agencies requirements to register OST-HER2 and gain approval of its use in the respective regions:

- European Medicines Agency (EMA, Europe);
- Medicines Evaluation Board (MEB, Netherlands);
- Medicines and Healthcare products Regulatory Agency (MHRA, United Kingdom); and
- U.S. Food and Drug Administration (FDA, United States).

For the year ended December 31, 2025, we paid $11,629,063 in consulting fees, which includes refundable value-added tax ("VAT") expenses. As of December 31, 2025, accounts payable related to consulting fees and VAT totaled $6,468,216.

University of Pennsylvania. On April 9, 2025, we acquired from Ayala the HER2 Assets. Pursuant to the terms of the HER2 Purchase Agreement, the amended and restated development, license and supply agreement with Advaxis terminated. In connection with the acquisition of the HER2 Assets, we were assigned by Ayala a license agreement with the Trustees of the University of Pennsylvania covering the use of HER2 construct patents. Under the terms of the license agreement, we are required to pay an annual license fee to the Trustees of the University of Pennsylvania. In April 2025, we paid a fee of $266,317 for the year ended December 31, 2025. In addition, we are obligated to pay a royalty equal to 1.5% of net 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 such licensing agreement.

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 consolidated 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 CONSOLIDATED 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 consolidated balance sheets of OS Therapies Incorporated and its subsidiaries (collectively, the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, stockholders' equity (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, 2025 and 2024, 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 30, 2026

OS Therapies Incorporated
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash	$ 269,830	$ 5,533,527
Prepaid expenses	63,082	—
Total Current Assets	332,912	5,533,527
Long-Term Assets		
Fixed assets (net)	2,490	5,270
Patent (net of amortization)	6,504,132	—
Total-Long Term Assets	6,506,622	5,270
TOTAL ASSETS	$ 6,839,534	$ 5,538,797
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable	$ 9,936,387	$ 1,662,068
Accrued expenses	1,415,002	521,010
Accrued payroll and payroll taxes – related party	36,792	97,257
Accrued payroll and payroll taxes	1,279	—
Preferred dividends payable	375,000	375,000
Warrant liability	—	1,971,975
Total Current Liabilities	11,764,460	4,627,310
Long-Term Liabilities		
TEDCO grant	100,000	100,000
Total Long-Term Liabilities	100,000	100,000
Total Liabilities	11,864,460	4,727,310
Commitments and contingencies (See Note 6)		
MEZZANINE EQUITY:		
Series A Convertible Preferred Stock, par value $0.001, 2,500,000 shares authorized; 392,500 and 1,775,750 issued and outstanding, respectively	1,070,705	4,078,025
Total Mezzanine Equity	1,070,705	4,078,025
STOCKHOLDERS' DEFICIT		
Common Stock A, par value $0.001, 150,000,000 shares authorized; 37,113,082 and 20,869,908 issued and outstanding, respectively	37,116	20,870
Preferred Stock, par value $0.001, 5,000,000 shares authorized; 0 and 0 shares outstanding, respectively	—	—
Additional paid-in capital	61,053,472	35,144,967
Accumulated deficit	(67,186,219)	(38,432,375)
Total Stockholders' Deficit	(6,095,631)	(3,266,538)
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	$ 6,839,534	$ 5,538,797

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

OS Therapies Incorporated
Consolidated Statements of Operations
For the Years Ended December 31, 2025 and 2024

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024
OPERATING EXPENSES		
Research and development	$ 16,360,725	$ 2,839,060
General and administrative	12,344,976	3,974,786
Loss from operations	(28,705,701)	(6,813,846)
OTHER INCOME/EXPENSE		
Interest income	249	—
Interest expense	—	(2,051,839)
Non-operating income	—	33,997
Non-operating expenses	(1,472,995)	(51,250)
Change in fair value of warrant liability	1,424,603	—
TOTAL OTHER INCOME/EXPENSE	(48,143)	(2,069,092)
NET LOSS	(28,753,844)	(8,882,938)
Cumulative Series A preferred stock dividend requirement	—	(31,250)
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS	$ (28,753,844)	$ (8,914,188)
Weighted average # of shares	29,253,292	6,950,100
Basic and diluted loss per common share outstanding	$ (0.98)	$ (1.28)

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

OS Therapies Incorporated
Consolidated Statements of Stockholders' Deficit
For the Years Ended December 31, 2025 and 2024

	Common Stock CS – Shares	CS – Par	Preferred Stock Shares Par	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
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)	—	—
Issuance of Common Stock to Investment Advisor	32,500	33	—	—	129,968	—	130,000
Surrender of Common Stock Investors	(669,958)	(669)	—	—	669	—	—
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
Net Loss	—	—	—	—	—	(8,882,938)	(8,882,938)
Balances, December 31, 2024	20,869,908	$ 20,870	—	$ —	$ 35,144,967	$ (38,432,375)	$ (3,266,538)
Commitment shares issued for Equity Line of Credit	157,407	157	—	—	568,078	—	568,235
Common Stock issued for Services	450,000	450	—	—	4,599,054	—	4,599,504
Stock-based compensation	—	—	—	—	4,265,374	—	4,265,374
Conversion of Preferred Shares Mezzanine Equity to Common Stock	4,939,808	4,939	—	—	3,725,181	—	3,730,120
Issuance of Common Stock for Patent License	4,774,637	4,776	—	—	6,393,239	—	6,398,015
Sale of Common Stock to Investors	282,679	282			529,878		530,160
Conversion of Warrants to Common Stock	5,638,643	5,639	—	—	7,138,562	—	7,144,201
Warrants Liability Reclass Preferred Stock	—	—	—	—	878,153	—	878,153
Warrants exercised and proceeds received, shares pending issuance	—	—	—	—	1,579,870	—	1,579,870
Net Loss	—	—	—	—	—	(28,753,844)	(28,753,844)
Balances, December 31, 2025	37,113,082	$ 37,113	—	$ —	$ 61,053,475	$ (67,186,219)	$ (6,095,631)

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

OS Therapies Incorporated
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2025 and 2024

	December 31, 2025	December 31, 2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (28,753,844)	$ (8,882,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	363,085	2,780
Amortization of debt discounts issuance and warrants	—	1,425,679
Shares issued for services	—	25,000
Shares issued for interest expense	—	8,523
Change in value of warrant liabilities	(1,424,603)	—
Commitment shares issued for equity line of credit	568,235	—
Common shares issuance for services	595,841	—
Stock-based compensation	4,265,957	268,300
Amortization of non-cash prepaids	1,037,631	
Adjustments to reconcile net loss to net cash used in operating activities:		
Accounts payable	8,274,316	(1,053,331)
Accrued expenses	893,992	358,510
Accrued interest on convertible notes	—	613,605
Accrued Payroll and payroll taxes	(59,186)	(48,423)
Net cash used in operating activities	**(14,238,576)**	**(7,282,295)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Patent License Acquisition	(466,423)	—
Net cash used in investing activities	**(466,423)**	**—**
CASH FLOWS FROM FINANCING ACTIVITIES		
Prepaid warrants (net of fees)	530,162	—
Common stock issuance (net of fees)	7,858,140	—
Short-term borrowings	—	250,000
Short-term loan repayments	—	(250,000)
Sale of preferred stock	1,053,000	6,050,000
Initial public offering (net of fees)	—	5,225,840
Net proceeds from conversion of debt A, B, C, D, E & F	—	1,501,000
Net cash provided by financing activities	**9,441,302**	**12,776,840**
Net change in cash	(5,263,697)	5,495,545
Cash – beginning of period	5,533,527	38,982
Cash – end of period	**$ 269,830**	**$ 5,533,527**
Cash paid for interest	$ —	$ —
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Discount on notes payable – redemption premium	$ —	$ 750,500
Dividends payable	—	31,250
Deemed dividend on Series A convertible preferred stock	—	1,971,975
Mezzanine equity conversion (net of costs)	3,730,121	—
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
Conversion of make-whole liability to common stock	—	130,000
Clawback of common stock for over issuance	—	(670)
Common stock issued for patent purchase	6,398,015	—
Reclassification of warrants liability to equity	878,153	—
Shares issued for prepaid services	$ 1,100,713	$ —

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

OS Therapies Incorporated
Notes to the Consolidated Financial Statements
For the Years Ended December 31, 2025 and 2024

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, 2025, there is one ongoing clinical trial for Osteosarcoma therapy.

OS Animal Health Corp — Subsidiary

On June 25, 2025, the Company formed OS Animal Health Corp, a Delaware corporation and wholly owned subsidiary. The subsidiary had minimal activity during the year ended December 31, 2025, consisting primarily of investor relations and audit-related expenses. During this period, the Company entered into a license agreement with the subsidiary, pursuant to which it granted the subsidiary rights to use the HER2 Assets (as defined below).

OS Therapies UK LTD — Subsidiary

On August 29, 2025, the Company formed OS Therapies UK LTD, a United Kingdom corporation and wholly owned subsidiary. This subsidiary serves as the Company's research and development arm and had substantial operating activity during 2025. The Company has transitioned its research and development activities to this subsidiary and intends to enter into an intercompany loan agreement, which is currently pending.

Liquidity

The Company has prepared its consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred significant net losses and negative cash flows from operations. During the year ended December 31, 2025, the Company incurred a net loss of $28.8 million and used $14.2 million in cash for operating activities.

As of December 31, 2025, the Company had cash and cash equivalents of $269,830. Management has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. The Company's current cash balance is insufficient to fund operations. During 2025, the Company incurred significant expenses, primarily related to activities in preparation for potential regulatory approvals by the U.S. Food and Drug Administration and other regulatory authorities. The Company expects vendor and related costs associated with these efforts to total approximately $25.0 million and continue into 2026. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional capital to fund its research and development and future operations. Management's plans to mitigate these conditions include:

- Equity and Debt Financing: The Company is actively seeking additional capital through public or private equity offerings or debt financings.

However, there can be no assurance that the Company will be successful in sequestering additional financing on favorable terms, or at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated 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.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries and majority-owned subsidiaries. The Company consolidates all entities in which it has a controlling interest.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its consolidated 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, 2025 and December 31, 2024, JPMorgan Chase Bank checking account had $233,490 and $5,216,354, respectively, and the JPM Chase savings account had $20,269 and $20,021, respectively. As of December 31, 2025 and December 31, 2024, Silicon Valley Bank checking account had $6,071 and $287,173, respectively, and the SVB money market account had $10,000 and $10,000, respectively. The JPM Chase and SVB checking accounts were in excess of the FDIC limits for the year ended December 31, 2024.

Redeemable Preferred Stock and Mezzanine Equity

The Company's Series A Senior Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), is classified as mezzanine equity in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480 ("ASC 480") due to its redemption features upon the occurrence of a deemed liquidation event, including (i) a merger or consolidation or (ii) the sale, lease, transfer, or other disposition of substantially all of the Company's assets. Proceeds from the issuance were allocated between the Series A Preferred Stock and the accompanying warrants to purchase shares of common stock (the "Series A Warrants") on a relative fair value basis. Of the initial $6,050,000 in proceeds, a portion was allocated to the Series A Warrants, with the residual allocated to the Series A Preferred Stock. Similarly, of the subsequent $1,053,000 in proceeds, a portion was allocated to the Series A Warrants, with the residual allocated to the Series A Preferred Stock.

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 consolidated 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.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Patent Amortization

On April 9, 2025, in connection with the HER2 Purchase Agreement (as defined below), the Company acquired the HER2 Assets (as defined below) from Ayala (as defined below), including the assignment by Ayala of a license agreement with the Trustees of the University of Pennsylvania. These intangible assets are amortized on a straight-line basis over their estimated useful lives, with amortization recorded quarterly. Amortization expense for the years ended December 31, 2025 and 2024 was $360,305 and $0, respectively.

Patent and License Acquisition

On April 9, 2025, pursuant to the terms of an Asset Purchase Agreement, dated as of January 28, 2025 (the "HER2 Purchase Agreement"), between the Company and Ayala Pharmaceuticals, Inc. (formerly Advaxis, Inc.) ("Ayala"), the Company completed the acquisition of the *Lm*-based immune-oncology programs and related intellectual property assets (the "HER2 Assets") from Ayala, including the assignment by Ayala of a license agreement with the Trustees of the University of Pennsylvania. The transaction was accounted for as an asset acquisition in accordance with ASC 805.

In connection with the acquisition, the Company assumed certain specified liabilities and paid an aggregate purchase price of $8,000,000, with a fair value of $6,864,438, consisting of: (i) $400,000 to Ayala ($150,000 of which was transferred upon signing of the HER2 Purchase Agreement and the remainder on the closing date); (ii) $100,000 to a third party on behalf of Ayala on the closing date; and (iii) $7,500,000 worth of shares of common stock, or 4,774,637 shares based on the volume-weighted average price of the Company's common stock over the 30 trading days immediately preceding the closing date of $1.5708. The fair value of the common stock issued was determined using the closing price of $1.34 per share on April 9, 2025, resulting in a total equity value of $6,398,014 and a corresponding reduction in total purchase consideration. The fair value of the purchase consideration is summarized below:

Cash	$	400,000
Legal fees paid on behalf of Ayala		66,424
Company common stock (4,774,637 shares at $1.34 per share)		6,398,014
Total fair value of consideration transferred	$	6,864,438

The acquired intangible assets consist primarily of a portfolio of patents and related licenses, including patents covering "Compositions and Methods for Evaluating Potency of Listeria-Based Immunotherapeutics," which underpin the Company's lead programs. These patents have an effective filing date of April 19, 2019 and an estimated remaining useful life of approximately 14 years. The assets are amortized on a straight-line basis over their estimated useful lives. Amortization expense was $360,305 and $0 for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, expected future amortization expense is as follows:

Year		
2026	$	496,972
2027		496,972
2028		496,972
2029		496,972
2030		496,972
2031 and thereafter		4,019,272
Total	$	6,504,132

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

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, 2025 or the year ended December 31, 2024.

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. As of December 31, 2025 and 2024, the Company had no capitalized deferred offering costs. Upon the completion of the Company's initial public offering on August 2, 2024, all deferred offering costs were charged to stockholders' deficit.

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 with a term of 12 months or less, the Company recognizes lease expense on a straight-line basis over the lease term. The Company's current lease arrangements qualify for this short-term lease exemption and are expensed as incurred. The Company did not renew its prior lease due to landlord restrictions related to renovations of the premises and has temporarily relocated its primary office to 115 Pullman Crossing Road, Suite #103, Grasonville, Maryland 21638. This space, which serves as the primary office of the Company's Chief Financial Officer, is being provided at no cost. In May 2024, the Company entered into a month-to-month lease agreement with JLabs for general office space in New York City, primarily for meetings and use by staff when visiting. The monthly lease payment was $750 and increased to $787.50 effective January 1, 2025.

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

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 consolidated 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.

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 consolidated 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, 2025 and December 31, 2024, the Company had no unrecognized uncertain income tax positions.

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 9,900,522	$ 6,559,791
General business credit carryover	3,045,651	1,672,876
R&D credit (available for payroll tax offset)	268,568	268,568
Subtotal	13,214,741	8,501,235
Valuation allowance	(13,214,741)	(8,501,235)
Total deferred tax assets	$ —	$ —

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	December 31, 2025	December 31, 2024
Series A Senior Convertible Preferred Stock	1,401,786	—
Underwriter/Placement Agent Warrants	319,711	280,448
Inducement Warrants	7,154,338	—
Prepaid Common Stock Not Issued	1,441,518	—
Series A Warrants	—	1,512,500
Total	10,317,353	1,792,948

The Series A Convertible Preferred Stock issued on December 31, 2024, is not reflected in the table above as of December 31, 2024, because stockholder approval was required for the issuance of common stock upon conversion. Stockholder approval was obtained on April 9, 2025, for the issuance of the shares of common stock underlying the Series A Preferred Stock, which is classified as mezzanine equity, and for the Series A Warrants. Upon approval, the conversion price of the Series A Preferred Stock and the exercise price of the Series A Warrants were automatically adjusted to $1.12 per share, based on the volume-weighted average price of the Company's common stock for the

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

10 trading days immediately preceding April 9, 2025. This adjustment established a conversion multiplier of 3.571429 common shares per preferred share. As of December 31, 2025, 392,500 non-converted shares of Series A Preferred Stock were outstanding, which, using the conversion multiplier, are exercisable into 1,401,786 shares of common stock.

As of December 31, 2025, a total of 319,711 shares of common stock were underlying outstanding underwriter and placement agent warrants, consisting of 112,000 shares issued in connection with the Company's initial public offering and 207,711 shares issued to placement agents in connection with the PIPE financing in December 2024 and January 2025.

During the Company's two warrant exercise and inducement offerings, held June 23 to July 10, 2025, and August 29 to September 1, 2025, warrant holders who exercised their existing warrants received new warrants with an exercise price of $3.00 per share. In total, warrants to purchase 7,154,338 shares of common stock were exercised in exchange for new warrants to purchase an equal number of shares.

Warrant holders who pre-funded conversions during the August 29 to September 30, 2025 offering received an aggregate of 937,500 prepaid shares of common stock and additionally funded 504,018 prepaid shares, resulting in a total of 1,441,518 prepaid warrants.

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).

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, 2025 and December 31, 2024, the carrying value of the warrant liability in the aggregate was $0 and $1,971,975, respectively (See Note 8).

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.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

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 Series A 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 recently issued accounting pronouncements and plans to adopt ASU 2024-03, Disaggregated Income Statement Disclosure, in the notes to its audited financial statements for the year ending December 31, 2026.

In December 2023, the FASB issued final guidance in ASU No. 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For the public business entities, the guidance is effective for annual periods beginning after December 15, 2024.

No other recently issued accounting pronouncements are expected to have a material impact on the Company's financial statements at this time.

NOTE 3 — RELATED PARTY TRANSACTIONS

Accrued Payroll

As of December 31, 2025 and 2024, the Company had payroll payable to the CEO of $36,792 and $8,871, respectively, and related payroll taxes payable of $1,279 and $88,386, respectively. During the years ended December 31, 2025 and 2024, the Company made advances on payroll payable, and the CEO repaid amounts previously advanced.

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

Balance December 31, 2023	$ 191,198
Advances during 2024	222,875
Repayment	(414,073)
Balance December 31, 2024	$ —
Advances during 2025	134,184
Repayments 2025	(134,184)
Balance December 31, 2025	$ —

NOTE 3 — RELATED PARTY TRANSACTIONS (cont.)

During the second and third quarters of 2024, the Company issued paychecks to Paul Romness, CEO, representing the remaining balance of backpay, net of all 2024 payroll advances. Payroll taxes related to both backpay and regular compensation were fully paid. All related-party payroll advances to Mr. Romness, previously recorded as employee advances, were fully repaid during 2025. The balance of related-party payroll advances for Mr. Romness was $0 during 2025. All advances for 2024 were repaid in full as of December 31, 2024.

Related Parties — Convertible Debt

Mill River Partners LLC, an entity affiliated with Ted Search and John Ciccio, members of the Company's board of directors, held convertible notes with face amounts of $0 as of December 31, 2025, and December 31, 2024. These notes were converted into shares of the Company's common stock upon the closing of the Company's initial public offering on August 2, 2024.

Related Party Accounting Fees

As of December 31, 2025 and 2024, the Company had accounts payable of $0 and $26,765, respectively, to Shore Accountants MD Inc., an outside accounting firm that provides payroll, bookkeeping, and tax preparation services. Shore Accountants MD Inc. is wholly owned by Christopher Acevedo, the Company's Chief Financial Officer.

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, 2025 Carrying Amount	December 31, 2024 Carrying Amount
A	10%	10/31/2024	None	80% – 87.5%	$ —	$ —
B	6%	10/31/2024	None	80%	$ —	$ —
C	6%	10/31/2024	None	80%	$ —	$ —
D	6%	10/31/2024	None	50%	$ —	$ —
E	6%	10/31/2024	None	50%	$ —	$ —
F	6%	10/31/2024	None	50%	$ —	$ —
BlinkBio	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

NOTE 4 — CONVERTIBLE DEBT (cont.)

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 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.

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 263,499 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

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 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% 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.

NOTE 4 — CONVERTIBLE DEBT (cont.)

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 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.

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 1,288,500 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

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 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% 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 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.

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 986,250 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

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 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 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 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.

NOTE 4 — CONVERTIBLE DEBT (cont.)

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 500,000 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

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 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 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 Convertible 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 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 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.

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 262,500 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

NOTE 4 — CONVERTIBLE DEBT (cont.)

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 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 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 Convertible 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 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 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.

As of December 31, 2025 and 2024, the balance of the convertible notes was $0 and $0, respectively, as the notes were converted into 773,805 shares of the Company's common stock in connection with the closing of the Company's initial public offering on August 2, 2024.

Redemption Liability

The fair value of the redemption liability was 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 June 30, 2024. The fair value of the redemption liability

NOTE 4 — CONVERTIBLE DEBT (cont.)

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 resulting redemption liability was amortized over the remaining life of the notes using interest rates of 10% for Group A and 6% for Groups B — F. Group A notes had a fixed term of three years, while Groups B — F had variable terms ranging from 12 months to three years. The Company retained the option to negotiate extended maturity dates for Groups B — F. 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.

Fees Associated with Convertible Debt Raise

The fees associated with the issuance of the convertible notes for Groups A, B, C and D consist of legal and investment banking fees. No related parties received any portion of these fees. These fees are capitalized and amortized over the life of the respective convertible notes using an effective interest rate of 10% for Group A and 6% for Groups B, C and D.

Make-whole liability — Shares due Noble Capital

In March 2020, the Company entered into an advisory agreement with Noble Capital under which, in lieu of cash compensation, the Company agreed to issue 4% of its common stock, subject to an anti-dilution clause. The make-whole liability represents shares earned due to adjustments under the anti-dilution provision during 2020 and 2021. As of year-end 2021, the Company held an aggregate of 233,202 shares, valued at $408,413, after issuing 200,000 shares in 2020. Advisory fee expense of $152,482 was recorded in 2021 to reflect the share value earned under the anti-dilution provision. In 2022, 70,624 shares were set aside to satisfy the anti-dilution clause, with an associated advisory fee expense of $282,496 recognized.

On July 1, 2023, the make-whole liability for Noble Capital was contractually nullified and unwound, and the adjustment was reflected in the Consolidated Statements of Stockholders' Deficit.

In September 2024, Noble Capital and the Company settled various investment fees in dispute, as well as shares related to the anti-dilution clause that had expired. Under the settlement, Noble Capital received 320,033 shares of common stock and $50,000 in cash.

Make-whole liability — Shares Officers & Directors

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

On March 1, 2023, the Company hired Alan Musso, former CFO, and as part of his compensation, awarded him 12,500 shares of common stock at $4.00 per share, totaling $50,000. This amount was reflected in the Company's make-whole stock liability.

Upon Mr. Musso's resignation on June 30, 2023, Christopher Acevedo, the current CFO, assumed the role and was awarded the balance of Mr. Musso's shares following the successful completion of the Company's initial public offering.

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

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	Former Director	20,000	80,000	July 1, 2022
		32,500	$ 130,000	

NOTE 4 — CONVERTIBLE DEBT (cont.)

All make-whole shares due to directors and officers were issued in October 2024. As a result, the balance of the make-whole stock liability was $0 as of December 31, 2025 and December 31, 2024.

Warrants for Placement Agent — Noble Capital

In March 2020, the Company entered into an advisory agreement with Noble Capital, under which, in lieu of cash remuneration, it was granted a 10% warrant fee in addition to cash compensation for debt raises from investments procured by Noble Capital. The warrants have a five-year term, with an exercise price equal to the average price paid by the convertible debt holders in each respective debt raise round.

The warrants earned were as follows:

- 2020: 248,855 warrants, valued at $248,855
- 2021: 213,782 warrants, valued at $427,564
- 2022: 162,644 warrants, valued at $325,288

No warrants were earned from 2023 through December 31, 2024. Warrants issued in 2020, 2021, and 2022 were accounted for as a discount to the related convertible debt, with the discount amortized over the life of the debt. Debt discount accretion expense for these warrants was $0 for the year ended December 31, 2025, and $49,840 for the year ended December 31, 2024. The total unamortized warrant discount was $0 as of both December 31, 2025 and December 31, 2024.

In September 2024, Noble Capital warrant holders exercised 116,313 warrants in a cashless transaction, and in December 2024, the remaining 294,977 warrants were exercised in a reduced cashless transaction, resulting in the issuance of common stock.

Warrants for Underwriter and Placement Agents — Brookline Capital Markets and Ceros Financial Services, Inc.

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. The warrant became exercisable 180 days after July 31, 2024, expires on July 31, 2029, and has an exercise price of $4.40 per share.

On December 24, 2024, in connection with the Company's Purchase Agreement, Brookline earned warrants initially exercisable for 39,918 shares at $4.40 per share. These warrants were subsequently adjusted to 156,821 shares at an exercise price of $1.12 per share, subject to further adjustment as provided in the agreement. The warrants are exercisable for five years from April 9, 2025. As of December 31, 2025, warrants to purchase 156,821 shares remained outstanding.

Ceros, in connection with the same Purchase Agreement, earned warrants initially exercisable for 13,951 shares at $4.40 per share, which were subsequently adjusted to 54,807 shares at $1.12 per share, also subject to further adjustment under the agreement. These warrants are exercisable for five years from April 9, 2025. As of December 31, 2025, 52,872 warrants remained outstanding.

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 — COMMITMENTS AND CONTINGENCIES

Employee Commitments

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

Rental Agreement

The Company rents a virtual office on a month-to-month basis at JLabs in New York, New York, a facility owned by Johnson & Johnson. The current monthly rent is $787.50. Rent expense for the years ended December 31, 2025 and 2024 was $10,390 and $1,750, respectively.

License Obligation and Manufacturing Agreements

Advaxis (now Ayala)

In September 2018, the Company entered into an exclusive license agreement with Advaxis, Inc., as amended, under which it acquired the rights to develop and commercialize the Advaxis HER2 Construct, including related patents.

Under the agreement, all milestone payments were non-refundable, non-creditable and payable only once upon the achievement of the corresponding milestone. As of December 31, 2020, the first milestone was achieved and paid ($1,550,000) in January 2021. The second milestone was completed and paid ($1,375,000) in May 2021. No milestone payments were made for the year ended December 31, 2025 or December 31, 2024. The license agreement was terminated upon the Company's purchase of the HER2 Assets from Ayala on April 9, 2025, which included a payment of $400,000 and the issuance of common stock as consideration.

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 or 2025. The Company is currently conducting early-stage research on the licensed drug, including studies to support future toxicology evaluations. A payment schedule for future milestones is summarized below.

NOTE 6 — COMMITMENTS AND CONTINGENCIES (cont.)

	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 years ended December 31, 2025 and 2024.

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 was required to pay to George Clinical certain fees described in the fee schedule below. The total budget under the agreement was approximately $2,436,928. For the years ended December 31, 2025 and 2024, the total research and development expenses recorded in the statement of operations was $0 and $86,687, 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

NOTE 6 — COMMITMENTS AND CONTINGENCIES (cont.)

George Clinical tracked and invoiced the Company for the number of task units completed and pass-through costs were invoiced each month in arrears based on actual costs without mark-up. The PTC Advance Fee was used to offset final pass-through fees payable. As of December 31, 2025, the balance payable to George Clinical was $0, and the services agreement has terminated in accordance with its terms. All fees due under the agreement have been satisfied, and no further obligations to the vendor remain.

Biolacuna Ltd

The Company has contracted with Biolacuna Ltd, a global life sciences advisory firm, to assist with the following agencies requirements to register OST-HER2 and gain approval of its use in the respective regions:

- European Medicines Agency (EMA, Europe);
- Medicines Evaluation Board (MEB, Netherlands);
- Medicines and Healthcare products Regulatory Agency (MHRA, United Kingdom); and
- U.S. Food and Drug Administration (FDA, United States).

For the year ended December 31, 2025, the Company paid $11,629,063 in consulting fees, which includes refundable value-added tax (VAT) expenses. As of December 31, 2025, accounts payable related to consulting fees and VAT totaled $7,323,386.

Trustees of the University of Pennsylvania

On April 9, 2025, the Company acquired from Ayala the HER2 Assets. Pursuant to the terms of the HER2 Purchase Agreement, the amended and restated development, license and supply agreement with Advaxis terminated. In connection with the acquisition of the HER2 Assets, the Company was assigned by Ayala a license agreement with the Trustees of the University of Pennsylvania covering the use of HER2 construct patents. Under the terms of the license agreement, the Company is required to pay an annual license fee to the Trustees of the University of Pennsylvania. In April 2025, the Company paid a fee of $266,317 for the year ended December 31, 2025. In addition, the Company is obligated to pay a royalty equal to 1.5% of net 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 such licensing agreement.

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 recently participated in an arbitration hearing related to a claim

NOTE 6 — COMMITMENTS AND CONTINGENCIES (cont.)

brought by its former investment advisor concerning underwriter compensation for the Company's initial public offering in August 2024 and any subsequent equity offerings during the following 12 months. The hearing concluded on November 7, 2025, and the arbitrators issued a ruling on January 28, 2026, awarding the former investment advisor $1,055,428 and their attorneys $308,804.88. The Company also incurred $15,128.32 in arbitration-related fees.

The total amount of $1,379,361.20 has been accrued in the Company's financial statements as of December 31, 2025 and is recorded as Other expense, payable in 2026. The Company does not intend to challenge the ruling. In accordance with ASC 450, the obligation is considered both probable and reasonably estimable.

NOTE 7 — EQUITY

Common Stock

In 2021, the Company's common stock was initially split into two classes: 50,000,000 shares of Class A common stock, $0.001 par value per share ("Class A Common Stock"), and 20,000,000 shares of Class B common stock, $0.001 par value per share ("Class B Common Stock"). On February 9, 2024, the Company combined the two classes under the name common stock with 50,000,000 shares authorized. On October 21, 2025, stockholders approved an increase in authorized common stock from 50,000,000 to 150,000,000 shares. As of December 31, 2025 and 2024, the Company had 37,113,082 and 20,869,908 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.

During the three months ended March 31, 2025, the Company issued (i) 157,407 shares of common stock in connection with its equity line of credit, (ii) 300,000 shares of common stock to a scientific and technical advisor in exchange for scientific and technical services, which will be amortized over a 12-month period with the remaining balance in prepaid expenses, and (iii) 20,000 shares of common stock to an advisor in exchange for services.

During the three months ended June 30, 2025, the Company issued (i) 3,962,129 shares of common stock in connection with conversions of Series A Preferred Stock, (ii) 2,164,215 shares of common stock in connection with the purchase of the HER2 Assets, (iii) 2,166,381 pre-funded warrants in connection with the purchase of the HER2 Assets, (iv) 10,000 shares of common stock to an advisor in exchange for services and (v) 2,181,257 shares of common stock in connection with the Company's warrant exercise inducement and exchange offering.

During the three months ended September 30, 2025, the Company issued (i) 977,679 shares of common stock in connection with conversions of Series A Preferred Stock, (ii) 2,507,386 shares of common stock in connection with the Company's warrant exercise inducement and exchange offering and (iii) 120,000 shares of common stock to an advisor in exchange for services. Additionally, the Company received $1,050,000 in gross proceeds, which was recorded as additional paid-in capital, from the exercise of Series A Warrants to purchase 937,500 shares of common stock, which were issued subsequent to September 30, 2025.

During the three months ended December 31, 2025, the Company issued (i) 950,000 shares of common stock in connection with its warrant exercise inducement and exchange offering related to pre-funded warrants, (ii) 2,610,422 shares of common stock upon exercise of the pre-funded warrant issued in connection with the purchase of the HER2 Assets, and (iii) 282,679 shares of common stock sold pursuant to the Company's ATM program.

Additionally, in three months ended December 31, 2025, the Company received $1,426,109 in gross proceeds from the exercise of Series A Warrants to purchase 1,441,518 shares of common stock at a future date. These proceeds were recorded as additional paid-in capital and are reflected in the Company's warrant register.

NOTE 7 — EQUITY (cont.)

Preferred Stock

In 2021, the Company authorized 5,000,000 shares of Preferred Stock, of which 1,400,000 were designated as Series A Preferred Stock. A total of 1,302,082 shares of Series A Preferred Stock were issued, which carried a 5% cumulative dividend and liquidation preference over common stock. Dividends were computed at 5% of the principal annually and recorded monthly.

On February 9, 2024, all outstanding Series A Preferred Stock was converted into common stock on a one-for-two basis pursuant to the filing of the Company's third amended and restated certificate of incorporation. As of that date, the Company had 5,000,000 shares of authorized Preferred Stock, with none outstanding.

The Series A Preferred Stock dividend for the year ended December 31, 2025 was $0, and for the year ended December 31, 2024 was $31,250, resulting in a total accrued dividend payable of $375,000 as of December 31, 2025.

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.

Stock Options

The following table summarizes the common stock options issued to employees and consultants for services during the year ended December 31, 2025:

	Common Stock Options			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Years	Intrinsic Value
Outstanding at January 1, 2025	2,866,750	$ 1.86	4.92	—
Granted	3,904,500	$ 1.80	5.00	—
Forfeited	—	—	—	—
Exercised	—	—	—	—
Outstanding at December 31, 2025	6,771,250	$ 1.83	4.43	—
Exercisable at December 31, 2025	2,866,750	$ 1.86	3.92	—

NOTE 7 — EQUITY (cont.)

The fair value of the options granted during the year ended December 31, 2025 was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2025
Volatility (based on peer companies)	112%
Risk Free Interest Rate	3.55%
Dividends	None
Estimated Life in years	2.88

During the years ended December 31, 2025 and 2024, the Company recognized combined share-based compensation expense of $4,265,374 and $268,300, respectively, related to these common stock options. At the Company's annual meeting on October 21, 2025, stockholders approved an amendment to the Company's 2023 Incentive Compensation Plan, increasing the shares of common stock authorized for issuance thereunder from 4 million to 10 million.

NOTE 8 — 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 Preferred Stock, and (ii) a Warrant to purchase one share of common stock, 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. On January 14, 2025 the Company sold and issued an additional 263,250 Units. The gross proceeds from the second closing to the Company, before deducting transaction fees and other estimated expenses, was $1,053,000.

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. $1,971,975 of the initial cash proceeds of $6,050,000 were allocated to the Warrants and $4,078,025 of the residual proceeds were allocated to the Series A Preferred Stock. $330,781 of the additional cash proceeds of $1,053,000 were allocated to the Warrants and $722,219 of the residual proceeds were allocated to the Series A Preferred Stock from the January 14, 2025 settlement, with all the same terms as the first settlement above.

From April 9, 2025 through December 31, 2025, Mezzanine Equity converted into 4,939,808 shares of common stock. Of the original 1,775,750 shares of Series A Preferred Stock, 273,750 and 1,383,250 shares were converted during the three- and nine-month periods ended December 31, 2025, respectively. As of December 31, 2025, 392,500 shares of Series A Preferred Stock remain outstanding, convertible into 1,401,786 shares of common stock.

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 the 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.

NOTE 8 — REDEEMABLE PREFERRED STOCK, MEZZAINE EQUITY AND WARRANT LIABILITY (cont.)

The following assumptions were made as of December 31, 2024 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 December 31, 2024, (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 on December 31, 2024. The following assumptions were made as of January 14, 2025 in the model: (1) a variable exercise price with a floor of $4.40 per share, (2) current common stock price of $4.16 per share on January 14, 2025, (3) discount rate of 4.59%, and (4) expected stock price volatility of 25.77%. As of January 14, the carrying value of the 263,250 issued warrants was $330,781.

The following assumptions were made as of April 9, 2025 based on stockholder approval in the model for the aggregate warrants: (1) a fixed exercise price of $1.12 per share, which automatically reset and resulted in a reclassification of the warrant liability on April 9, 2025 to equity per ASC 815; (2) then-current common stock price of $1.34 per share on April 9, 2025; (3) discount rate of 4.06%; and (4) expected stock price volatility of 23.26%.

As of December 31, 2025, the carrying value of the Warrant liability in aggregate was $0. For the year ended December 31, 2025, the Company recorded a gain on the change in fair value of the Warrant Liability in the amount of $1,424,603 and a $878,153 deduction due to reclassification to equity. As of December 31, 2025 and December 31, 2024, the carrying value of the Warrant liability in aggregate was $0 and $1,971,975, respectively.

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. The following tables reflect the allocation of the cash proceeds and changes in Warrant Liability in the consolidated statement of operations as of and for the period from December 31, 2024 to December 31, 2025.

	As of December 31, 2025
Cash proceeds	$ 7,103,000
Fair value of Warrant liability	(2,302,756)
Residual value allocated to Series A Preferred Stock	(4,800,244)
Unallocated cash proceeds	$ —

	For the year ended December 31, 2025
Warrant Liability as of December 31, 2024	$ 1,971,975
Additional Warrant Liability on January 14, 2025	330,781
Gain on the change in fair value of Warrant Liability as of March 31, 2025	(1,122,561)
Warrant Liability as of March 31, 2025	1,180,195
Gain on the change in fair value of Warrant Liability as of April 9, 2025	(302,042)
Stockholder approval on April 9, 2025 – warrants turn into Equity	(878,153)
Warrant Liability as of December 31, 2025	$ —

NOTE 9 — 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.

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2025 and 2023:

	December 31, 2025	December 31, 2024
OPERATING EXPENSES		
Research and development	$ 16,360,725	$ 2,839,060
General and administrative	12,344,976	3,974,786
Loss from operations	(28,705,701)	(6,813,846)
OTHER INCOME (EXPENSE)		
Interest income	249	—
Interest expense	—	(2,051,839)
Non-operating income	—	33,997
Non-operating expenses	(1,472,995)	(51,250)
Change in fair value of warrant liability	1,424,603	—
TOTAL OTHER INCOME (EXPENSE)	(48,143)	(2,069,092)
NET LOSS	(28,753,844)	(8,882,938)

NOTE 10 — SUBSEQUENT EVENTS

Third Warrant Exercise Inducement and Exchange Offering — On January 14, 2026, the Company closed on a third warrant exercise inducement and exchange offer (the "Third Inducement Offering"). The Third Inducement Offering was made to less than 10 accredited investors that held certain existing warrants to purchase up to an aggregate of 5,382,148 shares of the Company's common stock having a then current exercise price of $3.00 or $2.10 per share. Pursuant to certain inducement offer letter agreements, such holders exercised for cash their warrants to purchase 2,499,558 shares of the Company's common stock at a reduced exercise price of $1.40 per share and in exchange the Company issued to such holders new warrants to purchase up to an aggregate of 2,499,558 shares of common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. Such new warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date. The gross proceeds to the Company from the Third Inducement Offering, before deducting transaction fees and other offering expenses, were approximately $3.5 million.

The Company agreed to file a registration statement on Form S-3 (or other appropriate form, including on Form S-1, if not then eligible to register securities on Form S-3) providing for the resale of the shares of common stock issued or issuable upon exercise of the new warrants issued within 30 calendar days of March 2, 2026, and to use commercially reasonable efforts to have such registration statement declared effective by the SEC within 60 calendar days (or within 90 calendar days in case of "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time no holder owns any new warrants or shares of common stock issuable upon exercise thereof and (ii) the Delegend Date (as defined in the inducement offer letter agreements entered into in connection with the Third Inducement Offering).

NOTE 10 — SUBSEQUENT EVENTS (cont.)

Privately Negotiated Warrant Exercise Inducement and Exchange Agreements — From January 10, 2026 through February 2026, the Company entered into privately negotiated inducement offer letters, pursuant to which certain remaining holders of existing warrants exercised for cash their warrants to purchase an aggregate of 74,108 shares of common stock at a reduced exercise price of $1.40 per share and in exchange the Company issued new warrants to purchase up to an aggregate of 74,108 shares of common stock at an exercise price of $1.40 per share, subject to adjustment as provided therein. Such new warrants are immediately exercisable from the date of issuance and have a term of exercise of five years from such date. The Company received gross proceeds of approximately $103,750 from the exercise of these warrants.

The Company agreed to file a registration statement on Form S-3 (or other appropriate form, including on Form S-1, if not then eligible to register securities on Form S-3) providing for the resale of the shares of common stock issued or issuable upon exercise of these warrants on or before March 30, 2026, and to use commercially reasonable efforts to have such registration statement declared effective by the SEC within 60 calendar days (or within 90 calendar days in case of "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time no holder of these warrants owns any such warrants or shares of common stock issuable upon exercise thereof and (ii) the Delegend Date (as defined in the privately negotiated inducement offer letters).

Bridge Financing — On March 4, 2026, pursuant to a securities purchase agreement (the "Bridge SPA"), the Company issued to certain accredited investors in a private placement transaction (i) 10.0% original issue discount unsecured convertible promissory notes in an aggregate principal amount of $2,200,000 (the "Bridge Notes") and (ii) warrants to purchase up to an aggregate of 1,666,667 shares of common stock (the "Bridge Warrants" and such private placement transaction, the "Bridge Financing"), for aggregate gross proceeds of $2,000,000, before deducting placement agent fees and other Bridge Financing expenses. The Bridge Notes mature on March 4, 2027 and accrue interest at a rate of 4.0% per annum. The Bridge Warrants were immediately exercisable upon issuance, expire five years from the date of issuance and have an exercise price of $1.40 per share, subject to adjustment as provided therein.

The Bridge Notes were sold at a 10% original issue discount, such that for each $100,000 invested by a purchaser, such purchaser received a Bridge Note in the principal amount of $110,000. The Bridge Notes are convertible into shares of common stock under certain circumstances. If the Company completes a "Qualified Offering," defined as a registered public offering or registered direct offering resulting in at least $2.5 million in gross proceeds from new money investments, the outstanding principal, together with all accrued and unpaid interest, will automatically convert into the securities sold in such offering at the offering price. Additionally, prior to any such Qualified Offering or repayment of the Bridge Notes, holders may elect to convert the Bridge Notes, in whole or in part, into shares of common stock at a conversion price equal to 90% of the average daily volume-weighted average price of the Company's common stock during the 10 trading days immediately preceding the holder's conversion notice, subject to adjustment.

The Company agreed to file a registration statement on Form S-3 (or Form S-1 if not then eligible to register securities for Form S-3) by April 3, 2026 to register for resale the shares of common stock issuable upon conversion of the Bridge Notes and exercise of the Bridge Warrants, and to use commercially reasonable efforts to cause such registration statement to become effective within 60 calendar days (or 90 calendar days in the case of a "full review" by the SEC) following its initial filing and to keep such registration statement effective at all times until the earlier of (i) the time that no investor owns any Bridge Notes, Bridge Warrants or shares underlying such Bridge Notes and Bridge Warrants or (ii) the Legend Removal Date (as defined in the Bridge SPA).

Regulatory Meetings — During early 2026, the Company continued its regulatory engagement with the U.S. Food and Drug Administration ("FDA") related to its Biologics License Application ("BLA") for OST-HER2. As outlined in recent press releases, this included planned interactions with the FDA, including a Type D meeting that was elevated to a Type B pre-BLA meeting. These activities are consistent with the Company's ongoing regulatory efforts. The Company does not believe these interactions currently have a measurable impact on its consolidated financial statements; however, the outcome of these discussions may affect future development timelines and regulatory strategy.

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, 2025, 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, 2025 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 as a result of limited personnel and insufficient written policies and procedures for accounting, information technology and financial reporting (no control procedures in place) and insufficient number of personnel with appropriate levels of accounting knowledge and experience in U.S. GAAP.

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, 2025 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 26, 2026.

Name	Age	Position
Executive Officers and Key Employees:		
Paul A. Romness, MPH	60	Founder, Chairman, President and Chief Executive Officer
Robert G. Petit, Ph.D.	66	Chief Medical Officer and Chief Scientific Officer
Christopher P. Acevedo	63	Chief Financial Officer
Gerald Commissiong	43	Chief Business Officer
Non-Executive Directors:		
John Ciccio	45	Director
Avril McKean Dieser	52	Director
Karim Galzahr	52	Director
Olivier R. Jarry	64	Director
Theodore F. Search, Pharm.D.	44	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, Chairman, President and Chief Executive Officer, 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), Olivier R. Jarry 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.

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.

Insider Trading Policy

Our board of directors has not adopted a formal insider trading policy governing the purchase, sale and/or other disposition of our securities by the Company, our directors, officers, employees and consultants that is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable NYSE American listing standards. While we do not currently have a written insider trading policy, it is our policy to comply, and to seek to enforce compliance by our directors, officers, employees and consultants, with insider trading laws, rules and regulations, and any applicable NYSE American listing standards, when engaging in transactions in the Company's securities. Our board of directors intends to adopt an insider trading policy during 2026.

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 each of Paul A. Romness, Christopher P. Acevedo, Robert G. Petit, John Ciccio, Karim Galzahr, Olivier Jarry, Avril McKean Dieser and Theodore F. Search filed late a Form 4 with respect to stock option award grants that occurred on October 21, 2025.

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, 2025 and 2024 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers for the year ended December 31, 2025 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.

Our executive compensation program is designed to attract, retain and motivate high-quality executive leadership by providing compensation that is competitive and appropriately aligned with our stage of development and long-term strategic objectives. We operate in a highly competitive and capital-intensive industry where the ability to recruit and retain experienced leadership is critical to advancing our pipeline and delivering value to stockholders. Given our size, scale and market capitalization, our compensation approach reflects the need to manage cash resources prudently while incentivizing performance and long-term value creation. Accordingly, we place significant emphasis on equity-based compensation to align the interests of our executives with those of our stockholders and to promote a culture of ownership. We seek to provide compensation opportunities that reward progress toward our scientific, regulatory and operational milestones, while maintaining the flexibility to adapt our program as we grow and our needs evolve as a public company.

Through December 31, 2025, the compensation of our named executive officers consisted of annual base salaries, equity-based awards granted under our 2023 Incentive Compensation Plan and, in certain instances, transaction-based cash bonuses approved by our board of directors. Our named executive officers, like all full-time employees, are also eligible to participate in our health and welfare benefit plans. We periodically review our executive compensation program, including our compensation philosophy and compensation arrangements, and adjust them as we deem appropriate in light of our evolving business needs and market conditions.

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, 2025 and 2024.

Name and principal position	Year	Salary ($)	Bonus ($)[1]	Option awards ($)[2]	Non-Equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Paul A. Romness, MPH	2025	480,000	242,168	1,220,000	—	—	1,942,168
President and Chief Executive Officer	2024	480,000	200,000	984,000	—	—	1,664,000
Robert G. Petit, Ph.D.	2025	420,000	—	610,000	—	—	1,030,000
Chief Medical and Scientific Officer	2024	420,000	—	492,000	—	—	912,000
Christopher Acevedo	2025	36,000	—	244,000	—	—	280,000
Chief Financial Officer	2024	36,000	—	246,000	—	—	282,000

(1) The bonus for 2025 represents an incentive bonus approved by our board of directors and awarded to Mr. Romness for completion of our warrant inducement exercise and exchange transactions. The bonus for 2024 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 transaction with Square Gate Capital Master Fund, LLC — Series 3 in October 2024 and the PIPE Financing.

(2) The dollar amounts shown with respect to each of the named executive officers for the fiscal years ended December 31, 2025 and 2024 reflect the aggregate grant date fair value of option awards granted in the fiscal year indicated, computed in accordance with ASC 718. For a discussion of the assumptions we made in valuing the option awards, see "Note 2 — Significant Accounting Policies — Stock-Based Compensation" and "Note 7 — Equity" in the notes to our consolidated financial statements contained elsewhere in this Annual Report.

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 years ended December 31, 2025 and 2024, the annual base salary for each of Mr. Romness, Dr. Petit, and Mr. Acevedo was $480,000, $420,000 and $36,000, respectively. Mr. Acevedo's base salary reflects a part-time service arrangement during the periods presented.

Equity-Based Compensation. We grant equity-based awards to our named executive officers under our 2023 Incentive Compensation Plan to align their interests with those of our stockholders and to incentivize long-term value creation. We rely significantly on equity compensation to attract and retain highly qualified executives in a competitive market while preserving cash resources for research and development activities. Equity awards are designed to reward achievement of key value-driving milestones, including clinical development progress, regulatory advancement and operational execution, and to encourage a long-term focus on advancing our product candidates through the development pipeline. The size and terms of equity awards are determined by our board of directors, taking into account factors such as the executive's role and responsibilities, individual performance, market practices and our stage of development.

During the year ended December 31, 2025, Mr. Romness, Dr. Petit and Mr. Acevedo were granted options under our 2023 Incentive Compensation Plan to purchase 1,000,000 shares, 500,000 shares and 200,000 shares of common stock, respectively, each with an exercise price of $1.80 per share. During the year ended December 31, 2024, Mr. Romness, Dr. Petit and Mr. Acevedo were granted options to purchase 800,000 shares, 400,000 shares and 200,000 shares of common stock, respectively, each at an exercise price of $1.86 per share.

Employment Agreements and Arrangements

Paul A. Romness Employment Agreement

On February 21, 2023, Paul A. Romness, MPH entered into an employment agreement with us. 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 our 2023 Incentive Compensation 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 our 2023 Incentive Compensation 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, 2025, 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	12/05/2034	—	—	—	—
	—	1,000,000	—	1.80	10/21/2035	—	—	—	—
Robert G. Petit, Ph.D.	400,000	—	—	1.86	12/05/2034	—	—	—	—
	—	500,000	—	1.80	10/21/2035	—	—	—	—
Christopher P. Acevedo	200,000	—	—	1.86	12/05/2034	—	—	—	—
	—	200,000	—	1.80	10/21/2035	—	—	—	—

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. On October 21, 2025, at our 2025 annual meeting of stockholders, our stockholders approved an amendment to our plan to increase the number of shares authorized thereunder from 4,000,000 to 10,000,000. 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, 2025. 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 2025.

Name	Fees earned or paid in cash ($)	Fair value of options granted ($)[1]	All other compensation ($)	Total ($)
John Ciccio	—	170,800	—	170,800
Avril McKean Dieser	—	170,800	—	170,800
Karim Galzahr	—	170,800	—	170,800
Olivier R. Jarry	—	170,800	—	170,800
Theordore F. Search, Pharm.D.	—	170,800	—	170,800

(1) The dollar amounts shown with respect to each of non-executive director reflect the aggregate grant date fair value of option awards granted in 2025 and described below, computed in accordance with ASC 718. For a discussion of the assumptions we made in valuing the option awards, see "Note 2 — Significant Accounting Policies — Stock-Based Compensation" and "Note 7 — Equity" in the notes to our consolidated financial statements contained elsewhere in this Annual Report.

During the year ended December 31, 2025, each of our non-executive directors was granted options under our 2023 Incentive Compensation Plan to purchase 140,000 shares of common stock at an exercise price of $1.80 per share.

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 26, 2026 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. Under such rules, beneficial ownership includes any shares over which the individual has the sole or shared voting power or investment power and any shares that the individual has the right to acquire within 60 days of March 26, 2026, through the exercise of stock options, warrants or other convertible securities (including our Series A Preferred Stock) or any other right. Shares of our common stock that a person has the right to acquire within 60 days of March 26, 2026 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person (except with respect to the percentage ownership of all directors and executive officers as a group). 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, Maryland 21638.

As of March 26, 2026, we had 39,533,227 shares of common stock outstanding and 392,500 shares of Series A Preferred Stock outstanding, which are deemed to be convertible into 1,401,785 shares of common stock for voting purposes. The information in the following table regarding the beneficial owners of more than 5% of our common stock is based upon information supplied by our principal stockholders or set forth in Schedules 13D and 13G filed with the SEC. The determination that there were no other persons, entities or groups known to us to beneficially

own more than 5% of our outstanding common stock was based on a review of all statements filed with the SEC with respect to our company pursuant to Section 13(d) or 13(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percent of Outstanding Common Stock	Number of Shares of Series A Preferred Stock Beneficially Owned	Percent of Outstanding Series A Preferred Stock	Percent of Voting Power[1]
Executive Officers and Directors					
Paul A. Romness, MPH	3,273,000[2]	8.3%	—	—	8.0%
Robert G. Petit, Ph.D.	600,000[3]	1.5%	—	—	1.5%
Christopher P. Acevedo	309,375[4]	*	—	—	*
John Ciccio	277,917[5]	*	—	—	*
Avril McKean Dieser	42,500[6]	*	—	—	*
Karim Galzahr	—[7]	—	—	—	—
Olivier R. Jarry	40,000[8]	*	—	—	*
Theodore F. Search, Pharm.D.	277,918[9]	*	—	—	*
All directors and executive officers as a group (8 persons)	4,820,710	11.7%	—	—	11.4%

* Represents less than 1% of outstanding shares.

(1) Each share of common stock is entitled to one vote per share and each share of Series A Preferred Stock is entitled to one vote for each share of common stock into which it is convertible for voting purposes.

(2) Includes 800,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 1,000,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 1,000,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Romness is serving as an employee of the Company on each such date.

(3) Includes 400,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 500,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 100,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Petit is serving as an employee of the Company on each such date.

(4) Includes 200,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 200,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 100,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Acevedo is serving as an employee of the Company on each such date.

(5) Includes (i) 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, and (ii) 40,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 140,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 50,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Ciccio is serving as a director of the Company on each such date.

(6) Includes 40,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 140,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 50,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Ms. McKean Dieser is serving as a director of the Company on each such date.

(7) Excludes (i) 140,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 50,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Galzahr is serving as a director of the Company on each such date.

(8) Includes 40,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 140,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 50,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Mr. Jarry is serving as a director of the Company on each such date.

(9) Includes (i) 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, and (ii) 40,000 shares of common stock issuable pursuant to outstanding options, which are exercisable as of March 26, 2026, and excludes (i) 140,000 shares of common stock issuable pursuant to outstanding options, which vest in full on October 21, 2026, and (ii) 50,000 shares of common stock issuable pursuant to outstanding options, which vest in full on January 22, 2027, in each case provided that Dr. Search is serving as a director of the Company on each such date.

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, 2025, 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" And "Director Compensation."

Accrued Payroll

As of December 31, 2025 and 2024, we had payroll payable to the Paul A. Romness, our Chief Executive Officer, of $0 and $8,871, respectively, and related payroll taxes payable of $0 and $88,386, respectively. During the years ended December 31, 2025 and 2024, we made advances on payroll payable, and Mr. Romness repaid amounts previously advanced.

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

Balance December 31, 2023	$ 191,198
Advances during 2024	222,875
Repayment	(414,073)
Balance December 31, 2024	$ —
Advances during 2025	134,184
Repayments 2025	(134,184)
Balance December 31, 2025	$ —

During the second and third quarters of 2024, we issued paychecks to Mr. Romness, representing the remaining balance of backpay, net of all 2024 payroll advances. Payroll taxes related to both backpay and regular compensation were fully paid. All related-party payroll advances to Mr. Romness, previously recorded as employee advances, were fully repaid during 2025. The balance of related-party payroll advances for Mr. Romness was $0 during 2025. All advances for 2024 were repaid in full as of December 31, 2024.

Related Party Accounting Fees

As of December 31, 2025 and 2024, we had accounts payable of $0 and $26,765, respectively, to Shore Accountants MD Inc., an outside accounting firm that provides payroll, bookkeeping, and tax preparation services. Shore Accountants MD Inc. is wholly owned by Christopher P. 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-employee 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-employee 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.

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, 2025 and 2024 by MaloneBailey, LLP, our independent registered public accounting firm.

	2025	2024
Audit Fees[1]	$ 302,625	$ 255,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	7,008	—
Total Fees	$ 309,633	$ 255,000

(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 (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of OS Therapies Incorporated (incorporated herein by reference to Exhibit 3.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed June 7, 2024.
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of OS Therapies Incorporated (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-8 filed October 31, 2025).
3.4	Certificate of Designation of Rights, Preferences and Limitations of Series A Senior Convertible Preferred Stock of OS Therapies Incorporated (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 30, 2024).
3.5	Amended and Restated Bylaws of OS Therapies Incorporated (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed May 30, 2024.
3.6	Amendment No. 1 to the Amended and Restated Bylaws of OS Therapies Incorporated (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed August 15, 2025).
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 the Company's Registration Statement on Form S-1 filed May 30, 2024).
4.2	Form of Representative's Warrant (incorporated herein by reference to Exhibit 4.2 to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed June 13, 2024).
4.3	Form of Series A Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 30, 2024).
4.4	Form of Agent Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on December 30, 2024).
4.5	Form of Warrant for First and Second Inducement Offering (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 24, 2025).
4.6	Form of Warrant for the Third Inducement Offering (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 12, 2026).
4.7	Form of 10.0% Original Issue Discount Unsecured Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 6, 2026).
4.8	Form of Warrant for the Bridge Financing (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 6, 2026).
4.9*	Description of Registered Securities.
10.1#	OS Therapies Incorporated 2023 Incentive Compensation Plan, as amended (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 21, 2025).

Exhibit number	Description
10.2+	License Agreement, dated as of August 19, 2020, by and between OS Therapies Incorporated and BlinkBio, Inc. (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
10.3#	Employment Agreement, dated as of February 21, 2023, between OS Therapies Incorporated and Paul A. Romness, MPH (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
10.4#	Employment Letter, dated June 23, 2020, between OS Therapies Incorporated and Robert G. Petit, Ph.D. (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
10.5#	Form of Indemnification Agreement between OS Therapies Incorporated and each of its directors (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
10.6#	Employment Letter, dated January 1, 2023, between OS Therapies Incorporated and Christopher P. Acevedo (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed May 30, 2024).
10.7+	Securities Purchase Agreement, dated December 24, 2024, by and among OS Therapies Incorporated and the purchasers party thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 30, 2024).
10.8	Form of Registration Rights Agreement by and among OS Therapies Incorporated and the purchasers party thereto (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 30, 2024).
10.9	Amendment No. 1 to Securities Purchase Agreement and Amendment to Registration Rights Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 14, 2025).
10.10+	Asset Purchase Agreement, dated as of January 28, 2025, between OS Therapies Incorporated and Ayala Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 29, 2025).
10.11	Form of Inducement Offer Letter for the First Inducement Offering (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 24, 2025).
10.12	Form of Inducement Offer Letter for the Second Inducement Offering (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 2, 2025).
10.13	Form of Inducement Offer Letter for the Third Inducement Offering (incorporating herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 12, 2026).
10.14	At Market Issuance Sales Agreement, dated August 8, 2025, between OS Therapies Incorporated and B. Riley Securities, Inc. and JonesTrading Institutional Services LLC (incorporated herein by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed with the SEC on August 8, 2025).
10.15	Form of Securities Purchase Agreement for the Bridge Financing (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 6, 2026).
21.1*	List of Subsidiaries of the Registrant.
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 (incorporated herein by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on March 31, 2025).

Exhibit number	Description
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).

* Filed herewith.

** Furnished herewith.

\+ 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.

\# 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 30, 2026

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 30, 2026
/s/ Christopher P. Acevedo Christopher P. Acevedo	Chief Financial Officer (principal financial officer and principal accounting officer)	March 30, 2026
/s/ John Ciccio John Ciccio	Director	March 30, 2026
/s/ Avril McKean Dieser Avril McKean Dieser	Director	March 30, 2026
/s/ Karim Galzahr Karim Galzahr	Director	March 30, 2026
/s/ Olivier R. Jarry Olivier R. Jarry	Director	March 30, 2026
/s/ Theodore F. Search, Pharm.D. Theodore F. Search, Pharm.D.	Director	March 30, 2026