As confidentially submitted with the Securities and Exchange Commission on November 23, 2022
This draft registration statement has not been filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

OS THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware		**82-5118368**
(State or other jurisdiction of incorporation or organization)	Primary SIC Code	(IRS Employer Identification No.)

15825 Shady Grove Road, Suite 135, Rockville, MD 20850
(Address of principal executive offices, including zip code)

410-297-7793
(Registrant's telephone number, including area code)

Paul Romness
Chief Executive Officer
OS Therapies, Inc.
15825 Shady Grove Road Suite 135 Rockville, MD 20850
410-297-7793
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Bruce Rosetto Greenberg Traurig, P.A. 777 South Flagler Drive, Suite 300 East West Palm Beach, FL, 33401 (561) 650-7900	Ralph V. De Martino Cavas Pavri Johnathan Duncan ArentFox Schiff, LLP 1717 K Street, NW Washington, DC 20006

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the Registration Statement filed with the Securities and Exchange Commission becomes effective. [This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS
SUBJECT TO COMPLETION
DATED [ ], 2022

OS THERAPIES

OS THERAPIES, INC.

SHARES OF CLASS A COMMON STOCK

We are offering shares of our Class A common stock. This is our initial public offering and no public market currently exists for our Class A common stock. We expect the initial public offering price to be between $ and $ per share. We intend to apply to list our Class A common stock on either the New York Stock Exchange ("NYSE") American or Nasdaq Capital Market under the symbol "OSTX".

Following this offering, we will have one class of common stock: Class A common stock.

We are an "emerging growth company" and "smaller reporting company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Our business and investment in our common stock involves significant risks. These risks are described under the caption "Risk Factors" beginning on page 9 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	*Total*
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to OS Therapies, Inc.	$	$

(1) See the section entitled ''Underwriting'' beginning on page 120 of this prospectus for additional information regarding compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to additional shares of our Class A common stock, solely to cover over-allotments, if any, at the public offering price less the underwriting discounts.

The underwriters expect to deliver the shares of Class A common stock on or about , 202 .

The date of this prospectus is , 2022

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 (the "Registration Statement") that we are filing with the U.S. Securities and Exchange Commission ("SEC"). Unless otherwise mentioned or unless the context requires otherwise, when used in throughout this prospectus, and the Registration Statement of which this prospectus forms a part, the terms "OS Therapies," "OST," the "Company," "we," "us," and "our" refer to OS Therapies, Inc.

The Registration Statement of which this prospectus forms a part includes exhibits that provide more detail of the matters discussed in this prospectus. A prospectus supplement may also add, update or change information included in this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such prospectus supplement modifies or supersedes such statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus. You should rely only on the information contained in this prospectus and any applicable prospectus supplement. See "*Where You Can Find More Information.*"

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or any accompanying prospectus supplement. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any applicable prospectus supplement. You should assume that the information appearing in this prospectus or any prospectus supplement is accurate only as of the date on the front of those documents only, regardless of the time of delivery of this prospectus or any applicable prospectus supplement, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein are or will be filed, as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under "*Where You Can Find More Information.*"

We are not, and the Underwriters are not, offering to sell or seeking offers to purchase these securities in any jurisdiction where the offer or sale is not permitted. We and the Underwriters have not done anything that would permit this offering or possession or distribution of this Prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this Prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities as to distribution of the Prospectus outside of the United States.

INDUSTRY AND MARKET DATA

The industry and market data and certain other statistical information used throughout this prospectus are from our own research, surveys or studies conducted by third parties and industry or general publications. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

RISK FACTOR SUMMARY

An investment in our securities involves substantial risk. Our ability to execute on our strategy also is subject to certain risks. The risks described under the heading "*Risk Factors*" immediately following the Summary below 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. Some of the more significant challenges and risks we face include the following:

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.
- Even if we consummate this offering, we will need to raise substantial additional funding, and 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.
- We have identified conditions and events that raise 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 lead product candidates, [OST31-164 (AKA: OST-HER2)/OST-TDC]. We may not be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals both for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.
- Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- A Breakthrough Therapy Designation by the FDA for our current or future product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our current or future product candidates will receive marketing approval.
- We may not be able to obtain or maintain Orphan Drug Designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.
- Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.
- Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.

- Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.
- Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

Risks Related to Intellectual Property

- If we 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 granted patents we may own or in-license 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 of our Operations

- In our industry especially, our future success depends on our ability to retain key 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.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our Common Stock. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

Overview

OS Therapies, Inc. is a clinical, development, and discovery stage therapeutic company focused on the identification, development, and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. OS Therapies Inc. is a Delaware corporation incorporated on June 24, 2019. We are based in Rockville, Maryland.

OS Therapies was founded on the vision of a single indication bio-pharmaceutical company focused on immunotherapy for osteosarcoma with the mission of addressing the significant need for new treatments in cancers of the bone in children and adults. Osteosarcoma is an extremely challenging and often aggressive cancer that has particular treatment challenges due to location, changing genotypes, and high recurrence rates. At OST, we are trying to answer the call for new treatments with our lead product candidate, OST31-164 (AKA: OST-HER2). OST intends to expand our pipeline beyond osteosarcoma with OST31-164 (AKA: OST-HER2) into other solid tumors with the same recurrence mechanism of action, including breast, esophageal and lung cancer. With the addition of the OST-Tunable Drug Conjugate (OST-TDC) platform, considered a next generation Antibody Drug Conjugate (ADC) technology, we will be targeting ovarian, lung, and pancreatic cancer. We also intend to investigate clinical indications for OST-TDC in osteosarcoma, furthering our founding mission.

Our Business

We are striving to be a leader in the field of Osteosarcoma and Tunable Drug Conjugates because of our technology. With OST31-164 (AKA: OST-HER2), there have not been any new treatment in Osteosarcoma in over 30 years — and results from initial canine trials have shown significant improvement in overall survival and disease progression. Canine and human osteosarcoma are almost genetically identical. In Humans, Osteosarcoma is an extremely rare cancer that primarily affects children and young adults. Our most advanced product candidate, OST31-164, will be the first adjuvant therapy for Osteosarcoma to be tested in children. This disease is difficult to diagnose, the standard of care following first line therapies is simply to screen and wait for possible recurrence/metastasis, which happens in approximately half of patients within 12-18 months of initial remittance. For those patients that do recur, metastasis is typically to the lungs and brain, with survival rates of ~14% over the next year. We hope that OST31-164 can delay or prevent recurrence of osteosarcoma in some patients.

Pipeline of Product Candidates

We have built a pipeline of product candidates targeting multiple indications for other solid cancers. Our pipeline includes two drug technologies: OST31-164 (AKA: OST-HER2), an off-the-shelf Immunotherapy comprised of a genetically weakened and modified strain of Listeria monocytogenes vector that secretes a fusion peptide of bacteria and HER-2 peptides, and OST-TDC — a next generation Tunable Antibody Drug Conjugate (ADC) plug-and-play platform that can carry various types of payloads, and features tunable pH sensitive silicone linkers (SiLinkers™) that can payloads including antibodies, chemotherapeutics, cytotoxins, and potentially mRNA treatments directly into and in the vicinity of solid tumors.

OST31-164 (AKA: OST-HER2): Our most advanced product candidate, OST31-164 (AKA: 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 form the bacteria. This drug product candidate is in Phase II Clinical Trials. OST31-164 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 ~1,000 individuals affected per year. 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, and other solid tumors.

OST-TDC: Our Tunable Drug Conjugate platform is currently in preclinical development. Each tunable drug conjugate contains four main components: ligand, payload cassette adaptor, linker, and payload. In addition, TDCs contain units to optimize physicochemical properties. The ligands are selected to bind to receptors overexpressed on cancer cells. Upon binding the TDC construct gets internalized into the cancer cell, where the payload is released, causing cell death. The payload cassette adaptors enable the stoichiometrical attachments of linkers and payloads. The SiLinkers™ represent a novel and pH-sensitive linker system. The SiLinker™ release profile can be tuned with proximal functional groups, resulting in payload release in the endosome, lysosome or the slightly acidic tumor microenvironment. The SiLinker™ system is compatible with a variety of payloads, and not limited to the employment of cytotoxic drug delivery. The first set of internal programs focus on the use of SiLinker™ and Conditionally Active Payloads (CAPs™) drug products. CAPs™ are cytotoxic drugs which on their own, due to their functional groups, cannot readily permeate cells at physiological pH; however, at the slightly acidic pH of the tumor-microenvironment, after some linker cleavage, these payloads readily permeate into cancer cells, resulting in an enhanced bystander effect. The lead program targets Folate Receptor alpha, which 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 as payloads. The discovery work is being carried out at Syngene.

From time to time, we may evaluate collaboration opportunities for our product candidates, We also expect to work opportunistically with pharmaceutical and biotechnology companies, as we have with Blinkbio Inc., 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.

Technology

We are in the process of building a fully integrated platform to accelerate the development of product candidates across multiple therapeutic areas. Our platform technology, which is intended to leverage two decades of immunotherapy research, development, and manufacturing in order to enable us to pursue multiple therapeutic targets. Our scientists and scientific advisors have accumulated over 150 years of collective experience in the field of immunotherapy, oncology, and small molecule production, contributing key insights and significant achievement in our clinical development process.

Our team

We have assembled a management team of biopharmaceutical industry veterans with extensive experience in developing novel oncology therapies from research through commercialization. Our team is led by our Chief Executive Officer, Paul Romness, M.P.H, who has over [•] years of experience, including at [•]. and [•]. Our Chief Financial Officer, Christopher Acevedo, M.B.A., C.P.A., has over [•] years of [industry] experience and was previously at [•] and [•]. Our [Chief Medical Officer], [•], has over [•] years of experience in drug development, including at [•], Inc. and [•]. Our [Chief Legal Officer], [•], J.D., has over [•] years of legal experience managing the [entire pharmaceutical lifecycle from early discovery through litigation], including at [•] and [•]. Our [Senior Vice President of Product Development & Regulatory Affairs], [•], has over [•] years of experience in global drug development in rare diseases and oncology, including at [•] and [•].

Our Strategy

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 strategies:

- Obtain marketing approval for OST31-164 (AKA: OST-HER2) in Osteosarcoma, then quickly pivot to a basket trial within other solid tumors where metastases express HER2 that could be targeted by immune cells.
- Conclude pre-clinical and toxicology trials with the lead drug candidate for OST-TDC (OST-TDC-A, Exatecan-silanol-FolateRa)), and file for IND to initiate Phase I trial in Ovarian Cancer and other folate receptor alpha overexpressing cancers like endometrial cancer and some osteosarcomas. We believe that positive results from preclinical two-week and GLP Toxicology studies may also stimulate potential out-licensing activity of SiLinker™ and Conditionally Active Payloads (CAPs™) drug products, while not limiting therapeutic development.
- Establish global commercial and medical affairs capabilities for OST31-164 (AKA: OST-HER2) based therapies, beginning with OST31-164. Both of these platforms are secured intellectual propeety.

Growth Opportunities

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

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, as well as any additional collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to and fund our operating expenses and capital expenditure requirements over the next two to three years. Moreover, we have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Summary of the Offering

Class A Common Stock offered	• shares.
Class A Common Stock to be outstanding immediately after the offering	shares (shares if the Underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares	We have granted a 45-day option to the underwriters to purchase up to an aggregate of additional shares of Class A common stock from us at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Use of proceeds	We estimate that our net proceeds from the sale of shares of our Class A common stock in this offering will be approximately $ million, or $ million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to create a public market for our Class A common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. This offering is intended to provide funding through multiple proof-of-concept readouts for our product candidates. In particular, we expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows: (i) approximately $ million to advance the clinical development of OST-HER2 for Osteosarcoma; (ii) approximately $ million to advance OST-TDC for Ovarian cancer; and (iii) OST-HER2 in other solid tumors.
Voting rights	Shares of Common Stock are entitled to one vote per share.
Risk Factors	You should carefully read the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our Class A common stock.
Proposed ticker symbol	"OSTX"

FORWARD LOOKING STATEMENTS

Information set forth in this Prospectus may contain various "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All information relative to future markets for our product candidates and trends in and anticipated levels of revenue, gross margins and expenses, as well as other statements containing words such as "believe," "project," "may," "will," "anticipate," "target," "plan," "estimate," "expect" and "intend" and other similar expressions constitute forward-looking statements. These forward-looking statements are subject to business, economic and other risks and uncertainties, both known and unknown, and actual results may differ materially from those contained in the forward-looking statements. 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," as well as any subsequent filings with the Securities and Exchange Commission.

Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should read carefully this Prospectus and any related free writing prospectuses that we have authorized for use in connection with this Offering, together with the information incorporated herein or therein by reference as described under the heading "Where You Can Find More Information," completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

RISK FACTORS

You should carefully review and consider the risk factors described below and described under the heading "Risk Factors" in the accompanying prospectus and the other information contained in this prospectus, including the financial statements and notes to the financial statements, matters addressed in the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factor Summary" included in this a prospectus. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. We may face additional risks and uncertainties that are not presently known to us, or, or that we currently deem immaterial, which may also harm our business, financial condition, results of operations and prospects.

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.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing our company, business planning, raising capital, researching and developing our drug discovery technology, developing our pipeline, building our intellectual property portfolio, undertaking preclinical and clinical studies of our core product candidates and pursuing partnerships for our non-core product candidates. We have never generated any revenue from drug sales. We have not obtained regulatory approvals required for any of our current product candidates and may not obtain regulatory approvals for our future product candidates, if any.

Typically, it takes many years to develop one new pharmaceutical drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the COVID-19 pandemic. We will need to transition from a company with a research and development focus to a company capable of supporting late stage development and commercial activities. We may not be successful in such a transition.

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

Since inception, we have focused substantially all of our efforts on the development of OST31-164 (AKA: OST-HER2)/OST-TDC/ and our other clinical developments. To date, we have financed our operations primarily with proceeds from loans, collaboration agreements, the sale of preferred stock and some consulting services. From inception through September 30, 2022, we have raised an aggregate of $8,595 million in gross proceeds from sales of our convertible notes. As of September 30, 2022, we had cash of $39,176. Due to our significant research and development expenditures, we have experienced negative cash flows from operations, even in periods of operating income. For the nine months ended September 30, 2022 we incurred a loss from operations and negative cash flows from operations. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- complete preclinical studies, initiate and complete clinical trials for product candidates;
- consult with the FDA at each stage of development to de-risk each program
- seek toxicology success of OST-TDC;
- beginning Phase III trials;

- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our core product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our drug candidates and commercialization of any of our drug candidates for which we obtain marketing approval;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel;
- take temporary precautionary measures to help minimize the risk of the coronavirus disease COVID-19 to our employees;
- secure facilities to support continued growth in our research, development and commercialization efforts; and
- incur additional costs associated with operating as a public company upon the completion of this offering.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, particularly in the ongoing evolution of the COVID-19 pandemic, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, while we have generated significant interest in various research collaboration revenue, we have not generated any commercial revenue from our current core product candidates, including our lead core product candidate, OST31-164 (AKA: OST-HER2) and our other core product candidate OST-TDC, and we do not know and do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue unless and until we complete the development of, obtain marketing approval for, and begin to sell, OST 31-164, which is being evaluated in a Phase II trial, or OST-TDC, which is still being evaluated at the preclinical stage. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, OST31-164 (AKA: OST-HER2)OST-TDC;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- our ability to establish an appropriate safety profile with IND-enabling toxicology and other preclinical studies for OST-TDC;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression, as applicable, of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;

- our ability to forecast and meet supply requirements for clinical trials and commercialized products using third-party manufacturers;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- the ability to develop and obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement, if OST31-164 (AKA: OST-HER2)/OST-TDC/ is approved;
- acceptance of our core lead product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, if OST31-164 (AKA: OST-HER2)/OST-TDC/ is approved;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection, OST31-164 (AKA: OST-HER2)/OST-TDC/ and regulatory exclusivity for OST31-164 (AKA: OST-HER2)/OST-TDC if and when approved;
- our receipt of marketing approvals for OST31-164 (AKA: OST-HER2)/OST-TDC/ from applicable regulatory authorities; and
- the continued acceptable safety profiles of our core lead products following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

Even if we consummate this offering, we will need to raise substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or commercialization efforts.

The development of pharmaceutical drugs is capital intensive. We are currently advancing OST-31-164/ through clinical development and /OST-TDC through preclinical development. The U.S. Food and Drug Administration, or FDA, approved our OST31-164-01 study in July 22, 2021, and initiated a Phase II clinical trial on October 21, 2021. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, product manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on favorable terms, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations through June 30, 2025. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future product candidates;

- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future product candidates.

Identifying potential current or future product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current or future product candidates. Disruptions in the financial markets in general and more recently due to the COVID-19 pandemic have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, 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.

If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We may be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan.

As of September 30, 2022, we had $.0 million of cash. To date, we have primarily financed our operations through proceeds from collaboration agreements and the sale of convertible notes to outside investors. We have experienced significant negative cash flows from operations during the years ended December 31, 2019 and 2020 and 2021 and nine months ended September 30, 2022. We do not expect to experience any significant positive cash flows from our existing collaboration agreements and do not expect to have any product revenue in the near term. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we continue to invest significantly in research and development of our programs. As a result, there is a significant degree of uncertainty as to how long our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date our financial statements are issued, and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included elsewhere in this prospectus.

We are seeking the anticipated proceeds from this offering to provide additional funding for our operations. Even if the offering is consummated, we may be required to obtain additional funding whether through future collaboration agreements, private or public offerings, debt or a combination thereof and such additional funding may not be available on terms we find acceptable or favorable. There is inherent uncertainty associated with these fundraising activities and they are not considered probable. If we are unable to obtain sufficient capital to continue to advance our programs, we would be forced to delay, reduce or eliminate our research and development programs and any future commercialization efforts. Accordingly, our plans do not alleviate substantial doubt of our ability to continue as a going concern for a period of at least one year after the date our financial statements are issued.

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

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future.

For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks generated in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Additionally, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, the CARES Act, which, among other things, suspends the 80% limitation on the deduction for NOLs arising in taxable years beginning before January 1, 2021, permits a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally modifies the limitation on the deduction for net interest expense to 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

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

Under Sections 382 and 383 of 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, 2021 we had federal and state NOLs of approximately $2,708,012 million and $2,708,012 million, respectively, and we had federal and state research and development tax credit or general business credit carryforwards of approximately $320,120 thousand and $0 thousand, 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 core lead product candidates, OST31-164 (AKA: OST-HER2)/OST-TDC. We may not be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

We currently have no product candidates approved for sale and may never be able to develop marketable product candidates. Our business depends heavily on the successful development, regulatory approval and commercialization of the current or future immunotherapy for Osteosarcoma product candidates, of which our lead core product candidate, OST31-164 (AKA: OST-HER2)/, is in Phase II clinical development. OST-TDC will require substantial additional clinical development, testing and regulatory approval before we are permitted to commence its commercialization. The preclinical studies and clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we raise in this offering. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Medicines Agency, or EMA. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed or commercialized.

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

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agency;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agency for marketing approval;
- the FDA or applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;

- the FDA or applicable foreign regulatory agency may require that we conduct additional preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our current or future product candidates;
- the contract research organizations, or CROs, that we retain to conduct our preclinical studies and clinical trials may take actions that materially adversely impact our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or applicable foreign regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not accept data generated at our preclinical studies and clinical trial sites;
- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or GMPs;
- the FDA or applicable foreign regulatory agency may be delayed in their review processes due to staffing or other constraints arising from the COVID-19 pandemic; or
- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

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

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

We may not be able to initiate or continue clinical trials for our current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. In particular, because we are focused on patients with rare Osteosarcoma, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point. Moreover, some of our competitors have ongoing clinical trials for current or future product candidates that treat the same patient populations as our current or future product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates.

Patient enrollment may be affected by other factors including:

- the willingness of participants to enroll in our clinical trials and available support in our countries of interest;
- 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;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (*e.g.*, outbreak of COVID-19).

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

Osteosarcoma has relatively low prevalence and it may be difficult to identify patients with the eligibility criteria we are targeting. Osteosarcoma has an incident rate of approximately 1,000 individuals affected per year.

Our inability to enroll a sufficient number of patients with the target indication for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our current or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we are unable to include patients with the target indication, this could compromise our ability to seek participation in the FDA's expedited review and approval programs, or otherwise to seek to accelerate clinical development and regulatory timelines for our other product candidates.

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

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval, if any. 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 U.S. 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 policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, premarket approval application, or PMA, application for a companion diagnostic test or equivalent application types, may cause delays in the approval or

rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our current or future product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or that it is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our current or future product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. 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 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.

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

Business interruptions resulting from the COVID-19 outbreak or similar public health crises could cause a disruption to the development of our product candidates and adversely impact our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 surfaced in Wuhan, China and has reached multiple other regions and countries, including Rockville, Maryland where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the U.S. (and outside of the U.S.), including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other

biopharmaceutical companies, we are experiencing delays in the dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, as a result of medical complications associated with Osteosarcoma, the patient populations that our lead core and other core product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the COVID-19. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative effect on the operations of our third-party manufacturers;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have took temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring employees to work remotely, suspending all non-essential travel worldwide for our employees and employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the Securities and Exchange Commission, or the SEC, or FDA or its foreign equivalent.

These and other factors arising from the coronavirus could worsen in countries that are already afflicted with the coronavirus or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

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 OST31-164 (AKA: OST-HER2), it is likely that there may be adverse side effects associated with their 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 harm our business, financial condition and prospects significantly.

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. 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. 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.

Further, clinical trials by their nature utilize a sample of the potential patient population. For example, 3945 patients in our Phase II trial of OST31-164 (AKA: 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 receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such current or future product candidates;
- 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;
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates; and
- our reputation may suffer.

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 candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our current or future product candidates will receive marketing approval.

We may seek a Breakthrough Therapy Designation for some of our 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 may not result in a faster development process, 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 may not actually lead to a faster development or 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 and may receive Fast Track Designation again in the future for certain current or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

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

We received Orphan Drug Designation for OST31-164 (AKA: OST-HER2) for Osteosarcoma in the U.S., and we may seek Orphan Drug Designation for other current or future product candidates. Regulatory authorities in some jurisdictions, including the U.S. 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 U.S.

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

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

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

Although we have obtained Rare Pediatric Disease Designation for OST31-164 (AKA: OST-HER2) for Osteosarcoma patients, we may not be eligible to receive a priority review voucher in the event that FDA approval does not occur prior to September 30, 2026.

The Rare Pediatric Disease Priority Review Voucher Program, or PRV Program, is intended to incentivize pharmaceutical sponsors to develop drugs for rare diseases. A sponsor who obtains approval of an NDA or biological license application for a rare disease may be eligible for a Priority Review Voucher, or 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 10 months. Under the 21st Century Cures Act, a drug that receives Rare Disease Designation before September 30, 2024, will continue to be eligible for a PRV if the drug is approved before September30, 2026. If we do not obtain approval of an NDA for OST31-164 (AKA: OST-HER2) in patients with Osteosarcoma, and if the PRV Program is not extended by Congressional action, we may not receive a PRV.

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

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

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

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

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

Positive results from our preclinical studies of our current or future product candidates, and any positive results we may obtain from our early clinical trials of our current or future product candidates, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our current or future product candidates according to our current development timeline, the positive results from our preclinical studies and clinical trials of our current or future product candidates may not be replicated in subsequent preclinical studies or clinical trial results. For example, our later-stage clinical trials could differ in significant ways from our ongoing Phase II clinical trial of OST31-164 (AKA: 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.

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. In order to market any product outside of the U.S., however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

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.

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 U.S., 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 U.S. to take longer and be more costly than obtaining approval in the U.S.;
- our customers' ability to obtain reimbursement for our current or future product candidates in foreign markets;
- 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;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- 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 taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political 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 are and may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are and may in the future choose to conduct one or more clinical trials outside the U.S., including in Europe. The acceptance of study data from clinical trials conducted outside the U.S. 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 U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. 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 U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to identify or discover additional product candidates or we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused on our core programs, including our lead core product candidate, OST31-164 (AKA: OST-HER2), for the treatment of Osteosarcoma and our other core product candidate, OST-TDC, for the treatment of Osteosarcoma. As a result, we may forego or delay pursuit of opportunities

with other current or future product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and current or future product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

In light of the large population of patients with Osteosarcoma who reside in foreign countries, our ability to generate meaningful revenues in those jurisdictions may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the U.S.

The prevalence of Osteosarcoma is approximately 1000 individuals in the U.S. annually and approximately 20,000 individuals globally. In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of drugs such as are product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially, based, in part, on the large population of patients with Osteosarcoma who reside in foreign countries. In parts of Africa and certain countries in the Middle East, the lack of health care infrastructure to help adequately diagnose and treat patients may limit our business potential in those otherwise viable markets.

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, patients and healthcare payors. 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;
- publicity concerning our products or competing products and treatments;
- 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 or reimbursement; 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 granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

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

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of therapies for rare diseases and cancers, including Osteosarcoma. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for rare diseases and cancers, including many major pharmaceutical and biotechnology companies. If OST31-164 (AKA: OST-HER2) receives marketing approval for the treatment of Osteosarcoma, it may face competition from other product candidates in development for these indications, including product candidates in development from AstraZeneca, Y-mAbs Therapeutics, M.D. Anderson.

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory

approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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

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

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

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of product candidates paid by consumers. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases.

Additionally, in December 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

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

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business in light of the higher proportion of Osteosarcoma patients that utilize Medicare and Medicaid programs to pay for treatments.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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. 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. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation

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

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

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

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

- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable

fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business.

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

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

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 OST31-164 (AKA: OST-HER2) and our other current and future product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer. Moreover, because the target patient populations we are seeking to treat are small, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

We focus our research and product development on treatments for Osteosarcoma. The prevalence of Osteosarcoma is approximately 1000 individuals in the U.S. annually and approximately 20,000 individuals globally. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Further, even if we obtain significant market share for OST31-164 (AKA: OST-HER2) and any of our other current or future product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our target patient populations are relatively small, and there are currently limited standard of care treatments directed at Osteosarcoma. As a result, the pricing and reimbursement of OST31-164 (AKA: OST-HER2) and any other product candidates we may develop, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell OST31-164 (AKA: OST-HER2) and any of our other current or future product candidates will be adversely affected.

Risks Related to Our Dependence on Third Parties

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

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support our clinical trials for OST31-164 (AKA: OST-HER2) and expect to rely on them when we begin clinical trials for OST-TDC and other current or future product candidates. We rely heavily on these parties for execution of clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

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

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

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

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 to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

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

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

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

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

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

Further, collaborations involving our current or future non-core product candidates, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our current or future non-core product candidates or may elect not to continue or renew development or commercialization of our current or future non-core product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future non-core product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future non-core product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future non-core product candidates;

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- collaborators may not pay in a timely manner, milestones and royalties due to us.

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

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

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. 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 environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Intellectual Property

If we 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.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U.S. and other countries for our current or future product candidates, including our lead core product candidate, OST31-164 (AKA: OST-HER2), our other core product candidate, OST-TDC/, 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, filing patent applications in the U.S. 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.

We own patent applications related to our product candidates including our lead core product candidate, OST31-164 (AKA: OST-HER2) and our other core product candidate, OST-TDC. The OST31-164 (AKA: OST-HER2)/OST-TDC/ compound is covered by granted Composition of Matter and Method of Use patents and by numerous pending patent applications (including [•] patent applications) that are expected to expire in [•] if granted, not including any patent term extension, supplementary protection certificate, or SPC, or data exclusivity.

In addition, we own patents and patent applications expected to expire between 2031 and 2037 (if granted) protecting a variety of additional novel compounds discovered by our target discovery engine for multiple therapeutic targets including ubiquitin specific protease 1, or USP1, IDH1 and others.

As of [•], our patent portfolio covering these additional novel compounds discovered by our target discovery engine included more than [•] patent families. Patent term adjustments, SPC filings, or patent term extensions could result in later expiration dates in various countries, while terminal disclaimers could result in earlier expiration dates in the U.S.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

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 our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect OST31-164 (AKA: OST-HER2)/OST-TDC or our other current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after earliest priority date of patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to a third-party submissions to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by showing an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future

product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third-party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

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

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

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, 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. Furthermore, 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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and

time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our 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.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

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 our patent applications or any patents we may own or in-license. 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 our 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 U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may

have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources to such disputes, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third-party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our current or future product candidates, including OST31-164 (AKA: OST-HER2)OST-TDC, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates, which could harm our business significantly.

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 U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we 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.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

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.

Any granted patents we may own or in-license 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. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third-party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent

proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition 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 involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S. 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 our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. 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.

We may not identify relevantthird-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

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

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

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;

- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the U.S. 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;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, 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, including any potential effects from the current global spread of COVID-19, 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 such as the COVID-19 outbreak could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, we have instituted a temporary work from home policy for non-essential office personnel and it is possible that this could have a negative impact on the execution of our business plans and operations. 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 our research facilities or 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 our facilities or 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 Dr. Robert Petit, Chief Medical & Scientific Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements 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 business strategy. Furthermore, 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 September 30, 2022, we had 3 full-time employees, and in connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development 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 development 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 development 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 business 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 development 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 shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

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. 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 ADSs. 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.

As widely reported, global credit and 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 unemployment rates and uncertainty about economic stability, including most recently in connection with the outbreak of the novel coronavirus. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

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

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

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including

financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

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

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. 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 intend to adopt, prior to the completion of this offering, 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 healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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, 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.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Risks Related to Our Common Stock and This Offering

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.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, 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 amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The [NYSE American/Nasdaq Global Market] 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, or the Dodd-Frank Act, was enacted. There are significant corporate

governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt 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 this 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 decrease our net income or 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.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of clinical trials of our current or future product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

The novel coronavirus has been spreading rapidly around the world since December 2019 and has negatively affected the stock market and investor sentiment. The price of our common stock may be disproportionately affected as investors may favor traditional profit-making industries and companies during the times of market uncertainty and instability.

An active trading market for our common stock may not develop, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we intend to apply to list our common stock on either the NYSE American or Nasdaq Global Market, an active trading market for our common stock may never develop or be sustained following this offering. The initial public offering price of our common stock was determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover of this prospectus, purchasers of common stock in this offering will experience immediate dilution of $ per share in net tangible book value of the common stock. In addition, investors purchasing common stock in this offering will contribute % of the total amount invested by stockholders since inception but will only own % of the shares of common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the section of this prospectus titled “Dilution” for a more detailed description of the dilution to new investors in the offering.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Until such time, if ever, as we can generate substantial drug revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation to become effective upon the completion of this offering. Immediately following this offering, entities affiliated with or managed by will hold an aggregate of shares of our non-voting common stock. At any time following completion of this offering, upon written notice, these entities could convert a portion of these shares of non-voting common stock into up to an aggregate of % of our shares of common stock. Upon days' prior written notice, these entities could convert all of their respective shares of non-voting common stock into shares of common stock, which would result in such entities holding approximately % of the voting power of our outstanding common stock following the completion of this offering. See "*Description of Capital Stock — Common Stock and Non-Voting Common Stock*."

Consequently, if holders of our non-voting common stock following this offering exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of our product candidates. In the past, medical, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with such events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs, divert management's attention and resources, and have a material adverse effect on our business, operating results and prospects.

We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

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

Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Immediately following the completion of this offering, and disregarding any shares of common stock that they purchase in this offering, the existing holdings of our executive officers, directors, principal stockholders and their affiliates, will represent beneficial ownership, in the aggregate, of approximately % of our outstanding common stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus. As a result, these stockholders, if they act together, 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 acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these

stockholders may have interests, with respect to their common stock, that are different from those of investors in this offering 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 of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

See the section of this prospectus titled "*Security Ownership of Certain Beneficial Owners and Management*" for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our Class A common stock in this offering will be approximately $ million, or $ million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 100,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to create a public market for our Class A common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. This offering is intended to provide funding through multiple proof-of-concept readouts for our product candidates. In particular, we expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- Clinical development of OST31-164 (AKA: OST-HER2) for Osteosarcoma;
- Development of OST-TDC for Ovarian Cancer; and
- the remainder of the net proceeds for the discovery and development of new product candidates and for working capital and other general corporate purposes.

OS Therapies TDC Pipeline

(In Prioritized Order)

1. Folate Receptor Alpha (FRa) /Exatecan-Silanol

Rationale: 78% of osteosarcomas express FRa (29% at elevated levels). Non-malignant tissues have limited folate receptor α (FRα) expression giving a good therapeutic window.

Osteosarcoma — Evaluate TDC in first-line treatment of OS and in resistant/metastatic OS.

Other Cancers — Solid Tumors that express elevated FRa

Ovarian Cancer, triple-negative breast, and lung cancer

Status:

Preclinical Synthesis — completed

Candidate selection — ongoing

Preclinical Efficacy and Pharmacodynamic data generation — pending

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Phase 1/2a P.O.C clinical trial — planned

2. Trastuzumab (HER2)/Exatecan-silanol

Rationale:

40% of osteosarcomas over-express HER2. Trastuzumab monoclonal has been well tolerated but was not effective in HER2+ osteosarcoma. HER2 TDC will target exatecan-silanol directly to the tumor cells. Capping prevents excess toxicity to improve the therapeutic window.

Osteosarcoma — Evaluate TDC in first-line treatment of HER2+ OS and in HER2+ resistant/metastatic OS

Other Cancers — Unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 based regimens. Unresectable or metastatic Her2 + Gastric and Esophageal Cancers

NOTE: AZ Paid $1.35 B and $5.5B in milestones for the Daiichi version — our SI linker technology is better and they have no competition. STRONG Out-License potential!!

Status:

Preclinical Synthesis — pending

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Phase 1/2a P.O.C, Followed by single-arm, open-label, global, multicenter, two-part trial evaluating the safety and efficacy of trastuzumab/exatecan-silanol in patients with HER2 positive unresectable and/or metastatic breast cancer previously treated with trastuzumab emtansine.

3. MAGE A3/Exatecan-Silanol or MMAE(F)-Silanol

Rationale:

100% of osteosarcoma samples express MAGE-A3. It could be a transformational treatment for *every* patient with osteosarcoma and reduce toxicity of primary therapy.

In other cancers, MAGE A3 is frequently expressed in lung cancer and melanoma, as well as in few other tumors. Its level is associated with disease burden and with prognosis, while normal tissues do not express it, except the testis and the placenta. In NSCLC MAGE-A3 expression was observed 29.5% of stage I NSCLC and 49.5% of stage II NSCLC, 70% of lymph node metastases.

Status:

Preclinical Synthesis — planned

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Osteosarcoma — Evaluate TDC in first-line treatment of OS and in resistant/metastatic OS

Other Cancers: Phase 1/2a P.O.C in Lung cancer, Melanoma, and other MAGE3 expressing cancers

4. B7H3/Exatecan-silanol

Rationale:

B7-H3 expression is expressed in 91.8% of osteosarcomas. B7-H3 expression in osteosarcoma was significantly increased compared with adjacent normal tissues suggesting a good therapeutic window. High B7H3 have a significantly shorter survival time and time to recurrence than patients with low tumor B7-H3 levels (p,0.001). Moreover, tumor B7-H3 expression is inversely correlated with the number of tumor-infiltrating CD8+ T cells (p,0.05). indicating potential resistance to immunotherapy.

In other cancers, B7H3 is expressed in 98% of clear cell kidney, 97% of colorectal, 88% of primary liver, 85% of cutaneous squamous cell carcinoma, 74% non-small cell lung, 65% of pancreatic, and 56% of breast cancers. **B7H3 ADCs are currently in Phase 1-3 clinical testing by MacroGenics. T Labs, and Daiichi-Sankyo**

Status:

Preclinical Synthesis — planned

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Osteosarcoma — Evaluate TDC in B7H3+ first-line treatment of OS and in resistant/metastatic OS

Other Cancers: Phase 1/2a P.O.C in Colorectal, prostate cancer, melanoma, HNSCC, NSCLC, urothelial cancer, neuroblastoma, rhabdomyosarcoma, osteosarcoma, Ewing sarcoma, Wilms' tumor, DSRCT or malignant solid tumors of any other histology that test positive for B7-H3

5. ROR2/ Exatecan-Silanol or MMAE(F)-Silanol

Rationale:

ROR2 is overexpressed in 73.8% of osteosarcoma and is correlated with tumor metastasis, suggesting a pivotal role in OS progression. ROR2 was found to be highly expressed in renal cell carcinomas, and has recently been found in melanoma, colon cancer, squamous cell carcinoma of the head and neck, and breast cancer.

Status:

Preclinical Synthesis — planned

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Osteosarcoma — Evaluate TDC in first-line treatment of ROR2+ OS and in resistant/metastatic OS

Other Cancers: Phase 1/2a P.O.C in ROR+ renal, colon, squamous cells and breast cancers

6. PRAME/Exatecan-Silanol

Rationale:

PRAME is expressed in more than 70% of osteosarcoma patient specimens and in osteosarcoma cell lines

In other cancers PRAME is expressed in 97% of melanomas and frequently expressed in numerous solid cancers, such as head and neck cancer, breast cancer, renal cell carcinoma and non-small-cell lung cancer (NSCLC). Notably, it has been revealed that PRAME is absent in normal hematopoietic tissues. 14 Nevertheless, some findings have uncovered that a high expression level of PRAME exists in acute and chronic leukemia as well as in Hodgkin's lymphomas.

Status:

Preclinical Synthesis — planned

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Osteosarcoma — Evaluate TDC in PRAME+ first-line treatment of OS and in resistant/metastatic OS

Other Cancers: Phase 1/2a P.O.C in PRAME+ Melanoma, other **solid tumors**, and neuroblastoma

Phase 1/2a PRAME+ in hematologic cancers including acute and chronic leukemias and lymphoma

7. Exploratory Project: WT-1 TCR mimetic antibody/Exatecan-silanol, MMAE(F)

Rationale: WT-1 is expressed in high percentages of most solid tumors and is very close to a universal cancer antigen target. It is expressed in some osteosarcoma that are very resistant to treatment and experience rapid disease progression and death. WT-1 is a nuclear antigen and not available except to the T-cell receptor. This project will utilize a unique antibody fragment that recognized WT-1 antigen and the TCR at the same time. This technology could open-up TDC/ADC to T cell targets.

Status:

Preclinical Synthesis — planned

(Significant development time and expertise will be required to work out the TCR/WT1 target antibody)

Candidate selection — planned

Preclinical Efficacy and Pharmacodynamic data generation — planned

Toxicology and IND-enabling studies — planned

Pre-IND meeting with FDA — planned

IND Submission — planned

Osteosarcoma — Evaluate TDC in WT-1+ first-line treatment of OS and in resistant/metastatic OS

Other Cancers: Phase 1/2a P.O.C in WT-1+ solid tumors

8. LHRHr/Exatecan-silanol or MMAE(F)-silanol

Rationale:

One very small study suggests that LHRHr may be elevated in ~ 60% of osteosarcomas.

In other cancers, LHRH receptors are expressed in about 80% of human endometrial and ovarian cancers, 86% of prostate cancer, and about 50% of breast cancers including triple-negative breast cancer, as well as bladder, colorectal, and pancreatic cancers, sarcomas, lymphomas, melanomas, and renal cell carcinomas. 80% of human endometrial and ovarian cancers, 80% of renal cancer, 32 – 50% of pancreatic cancers [18, 32 – 35]., Apart from the pituitary and reproductive organs, other organs and hematopoietic stem cells express LHRH receptors. This has large potential outside of osteosarcoma.

9. LMAGE-A1/Exatecan-silanol or MMAE(F)-silanol

Rationale:

MAGE-A is overexpressed in ~50-60% osteosarcoma and osteosarcoma cell lines and is associated with poor prognosis.

In other cancers, MAGE-A1 is expressed in high percentages of non-small cell lung cancers (NSCLC), bladder cancers, esophageal and head and neck cancers, and sarcomas. Also frequently expressed in triple negative breast cancers, myeloma, and Reed — Sternberg cells in Hodgkin's disease, with the highest frequency being detected in synovial sarcoma.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. We may also use a portion of the net proceeds to in-license, acquire, or invest in complementary businesses or technologies to continue to build our pipeline, research and development capabilities and our intellectual property position, although we currently have no agreements, commitments, or understandings with respect to any such transaction.

Due to the many inherent uncertainties in the development of our product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of preclinical studies, our ongoing clinical studies or clinical studies we may commence in the future, the timing of regulatory submissions, any strategic alliances that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, general business conditions, and other factors that our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and our capitalization as of [September 30, 2022]:

- on an actual basis;
- on a pro forma basis to give effect to:
  - our conversion immediately prior to the IPO, all convertible notes including accrued interest which aggregated $4.8 million into shares of Class A common stock; as of 9/30/22 the shares tally to 4,641,268 shares of Class A common stock in OS Therapies Inc.;
  - to convert warrants to Class A common stock series A, 371,081shares.
  - the automatic conversion of all outstanding shares of our Series A preferred stock into an aggregate of 1,302,082 shares of our Class A common stock (all of which shares of Class A common stock will be held by BlinkBio), immediately prior to the completion of this offering and the filing and effectiveness of our third amended and restated certificate of incorporation immediately prior to the completion of this offering;
  - the filing and effectiveness of an amendment to our amended and restated certificate of incorporation effecting, among other things, a one-for-two reverse split of our common stock, a reclassification of our then outstanding common stock to Class A common stock, and provides for Class B common stock, which became effective upon filing of such amendment prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to:
  - our issuance and sale of shares of our Class A common stock in this offering at an assumed initial public offering price of $ 5.62 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
  - our issuance and sale of shares of Series A common stock in OS Therapies Inc. for aggregate gross proceeds of $ million

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing elsewhere in this prospectus and the sections of this prospectus titled "*Selected Financial Data*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations.*" We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, general business conditions, and other factors that our board of directors may deem relevant.

(In thousands, except share and per share data)	As of September 30, 2022		
	Actual	Pro forma	Pro forma as adjusted[1]
Cash	$ [•]	$ [•]	
Convertible preferred stock (Series A), $[•] par value; [•] shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	$ [•]	$ [•]	
Stockholders' equity (deficit):			
Preferred stock, $ par value; no shares authorized, issued or outstanding, actual; shares authorized, and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	
Class A common stock, $[•] par value [•] shares authorized, [•] shares issued and outstanding, actual; [•] shares authorized, [•] shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	[•]	[•]	

(In thousands, except share and per share data)	As of September 30, 2022		
	Actual	Pro forma	Pro forma as adjusted
Class B common stock, $[•] par value; no shares authorized, issued or outstanding, actual; shares authorized, pro forma and pro forma as adjusted; [•] shares issued and outstanding, pro forma; [•] shares issued and outstanding, pro forma as adjusted	[•]	[•]	
Additional paid-in capital	[•]	[•]	
Accumulated deficit	[•]	[•]	
Promissory note from related party stockholder[2]	[•]	[•]	
Total stockholders' equity (deficit)	[•]	[•]	
Total capitalization	$ [•]	$ [•]	

(1) Assumes that all shares of common stock offered hereby are issued in the form of Class A common stock. Shares of Class B common stock may be issued in this offering solely to the extent shares of common stock offered hereby are purchased by [•], [•], or any of their respective affiliates, and such purchasers elect to receive such shares of common stock in the form of Class B common stock that will be convertible into an equivalent number of shares of our Class A common stock.

(2) See "Certain relationships and related party transactions — Agreements with our stockholders — Agreements with our scientific founder — Promissory notes."

DILUTION

If you invest in our Class A common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our Class A common stock and the pro forma as adjusted net tangible book value per share of our Class A common stock immediately after this offering.

Our historical net tangible book value (deficit) as of September 30, 2022 was $(16,941,941) million, or $(1.92) per share of our Class A and Class B common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and Series A convertible preferred stock, which is not included within our stockholders' (deficit). Historical net tangible book value per share represents historical net tangible book (deficit) divided by the shares of our common stock outstanding as of September 30, 2022.

Our pro forma net tangible book value, as of September 30, 2022, was $ million, or $ per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to conversion of preferred stock into 1,302,082 shares of Class A common stock, with no proceeds to us, and the conversion of all convertible notes with accrued interest into 4,641,268 shares of our Series A and Series B common stock into an aggregate of 4,641,268 shares of our Class A common stock. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding, as of September 30, 2022, after giving effect to the pro forma adjustments described above.

Unless otherwise noted, all per share amounts include both Class A and Class B common stock. After giving further effect to our issuance and sale of shares of our Class A common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2022 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $ to existing stockholders and immediate dilution of $ per share in pro forma as adjusted net tangible book value per share to investors purchasing Class A common stock in this offering. Dilution per share to investors purchasing Class A common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors purchasing Class A common stock in this offering. The following table illustrates this dilution on a per share basis (without giving effect to any exercise by the underwriters of their option to purchase up to additional shares of Class A common stock in this offering):

Assumed initial public offering price per share of Class A common stock		$
Historical net tangible book value (deficit) per share as of September 30, 2022	$	
Increase per share attributable to the pro forma adjustments described above	$	
Pro forma net tangible book value per share as of September 30, 2022		$
Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing Class A common stock in this offering	$	
Pro forma as adjusted net tangible book value per share after this offering		$
Dilution per share to investors purchasing Class A common stock in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $ and dilution per share to investors purchasing Class A common stock in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

An increase of 100,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by $ and decrease the dilution per share to investors purchasing Class A common stock in this offering by $,

assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. A decrease of 100,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution per share to investors purchasing Class A common stock in this offering by $, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters fully exercise their option to purchase additional shares of Class A common stock in this offering, our pro forma as adjusted net tangible book value per share after this offering would be $ and the dilution in pro forma as adjusted net tangible book value per share to investors purchasing Class A common stock in this offering would be $, assuming no change in the initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2022, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid, or to be paid, and the average price per share paid or to be paid by existing stockholders and by investors in this offering at an assumed initial public offering price of $ per share of Class A common stock, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, investors purchasing Class A common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percentage	
Existing stockholders	15,149,431	%	15 380 296	%	
Investors in this offering		%		%	
Total		100.0%		100.0%	

The table above is based on 8,835,000 shares of common stock outstanding as of September 30, 2022 and gives effect to (i) our conversion of convertible preferred A stock into Common A Stock, (ii) the automatic conversion of all outstanding shares of our Series A and Series B convertible common stock into an aggregate of 8,835,000 shares of our Class A common stock and immediately prior to the completion of this offering a conversion of convertible debt with accrued interest into Common A stock and (iii) the filing and effectiveness of an amendment to our amended and restated certificate of incorporation effecting, a reclassification of our then outstanding common A & B stock to Class A common stock, and provides for a new Class of B common stock, which became effective upon fling of such amendment prior to the completion of this offering.

[The table above does not include:

- 1,000,000 shares of Class A common stock reserved for future issuance under a pending 2023 Employee Stock Purchase Plan (the “ESPP”), which will become effective in late 2023 upon effectiveness of the registration statement of which this prospectus is a part.

If additional shares are issued in connection with the exercise of outstanding options, if new stock options are issued under our 2022 Omnibus Plan, or if we issue additional shares of common stock in the future, there will be further dilution to investors purchasing Class A common stock in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2021 and 2020 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations data for the nine months ended September 30, 2022 and 2021 and the balance sheet data as of September 30, 2022 have been derived from our unaudited financial statements appearing elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

Statement of Operations Data:

	Year ended December 31		Nine months ended September 30	
	2021	**2020**	**2022**	**2021**
Operating Expenses				
Research & Development	$ 2,174	$ 602	$ 2,194	$ 1,482
Licensing	$ 1,231	$ 795	$ 511	$ 948
General & Administrative	$ 1,160	$ 4,250	$ 1	$ 1,141
Total Operating Expenses	$ 4,565	$ 5,648	$ 2,706	$ 3,571
Loss from Operations	$ (4,565)	$ (5,647)	$ (2,706)	$ (3,571)
Other Income (expenses)				
Other income (expense) Net	$ (2,160)	$ (381)	$ (997)	$ (1,489)
Total other income (expense), net	$ (2,160)	$ (381)	$ (997)	$ (1,489)
Net income (loss) and comprehensive income (loss)	$ (6,725)	$ (6,028)	$ (3,703)	$ (5,060)
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.76)	$ (0.68)	$ (0.42)	$ (0.57)
Diluted	$ (0.45)	$ (0.44)	$ (0.24)	$ (0.34)
Weighted average shares of common stock outstanding				
Basic	$ 8,835,000	8,422,082	$ 8,835,000	8,835,000
Diluted	$ 15,059,955	13,618,324	$ 15,149,431	14,988,799

Balance Sheet Data:

	As of September 30, 2022		
(*in thousands*)	**Actual**	**Pro Forma[2]**	**Pro Forma as adjusted[3]**
Balance Sheet Data:			
Cash & Other Assets	$ 102	$	$
Working capital[1]	$		$
Total assets	$ 102		$
Convertible preferred stock & Other Liabilities	(14,544)		$
Total shareholders' equity (deficit)			$

(1) We define working capital as current IPO cash infused.

(2) The pro forma balance sheet data give effect to (i) our sale of shares of Class A common stock] in OS Therapies, Inc. for gross proceeds of $10,000,000 million and (ii) the automatic conversion of all outstanding shares of our [Series A and Series B convertible preferred stock] into an aggregate of 1,302,082 shares of our Class A common stock. We also converted convertible notes and accrued interest into 4,641,268 shares of our Class A common stock held by Notes holders immediately prior to the completion of this offering.

(3) The pro forma as adjusted balance sheet data reflect the adjustments described in footnote (2) and give further effect to our issuance and sale of shares of our Class A common stock offered in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. Similarly, an increase (decrease) of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

OUR BUSINESS

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our Common Stock. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

Overview

OS Therapies, Inc. is a clinical and development stage therapeutic company focused on the identification, development and commercialization of treatments for Osteosarcoma (OS) and other solid tumors. OS Therapies Inc. is a Delaware corporation incorporated on June 24, 2019. We are based in Rockville, Maryland.

OS Therapies was founded on the vision of a single indication bio-pharmaceutical company focused on immunotherapy for Osteosarcoma with the mission of addressing the significant need for new treatments in cancers of the bone in kids and adults. Osteosarcoma is an extremely challenging and often aggressive cancer that has particular treatment challenges due to location, changing genotypes, and high recurrence rates. At OST, we are trying to answer the calls for new treatments, considering there have been no new treatments for OS in over 30 years. We intend to expand our pipeline beyond OS with OST31-164 (AKA: OST-HER2) into other solid tumors with the same recurrence mechanism of action, including breast, esophageal and lung cancer. With the addition of OST-TDC, which we consider a next generation Antibody Drug Conjugate (ADC) platform technology, we will be targeting ovarian, lung and pancreatic cancer. We also intend to investigate clinical indications of OST-TDC in OS, furthering our founding mission.

Our Business

We are striving to be a leader in the field of Osteosarcoma and Tunable Drug Conjugates because of our technology. With OST31-164 (AKA: OST-HER2), there have not been any new treatment in Osteosarcoma in over 40 years — and initial results from multiple canine trials have shown significant improvement in overall survival and disease progression. Canine and human osteosarcoma are almost genetically identical. Osteosarcoma is an extremely rare cancer that primarily affects children and young adults. We believe that our most advanced product, OST31-164, will be the first adjuvant therapy for Osteosarcoma to be tested in children. This disease is difficult to diagnose, and even more difficult to treat. The standard of care following first line therapies is simply to screen and wait for possible recurrence/metastasis, which happens in approximately half of patients within 12-18 months of initial remittance. For those patients that do recur, metastasis is typically to the lungs and brain, with survival rates of ~14% over the next year. With OST31-164 we seek to transform this reactive process into a proactive treatment regimen.

Pipeline of Product Candidates

We have built a pipeline of product candidates targeting multiple indications for other solid cancers. Our pipeline includes two platform technologies: OST31-164 (AKA: OST-HER2) — an off-the-shelf Immunotherapy of a genetically modified strain of Listeria monocytogenes fused to a HER2 vector, and OST-TDC — a next generation Tunable Antibody Drug Conjugate (ADC) that can carry additional payloads, and has pH sensitive silicone linkers (SiLinkers™) that can transport antibodies, cytotoxins and potentially mRNA treatments.

OST31-164 (AKA: OST-HER2): Our most advanced product candidate, OST31-164 (AKA: 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 form the bacteria. This drug product is in Phase II Clinical Trials. OST31-164 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 ~1,000 individuals affected per year. 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, and other solid tumors.

OST-TDC: Tunable Drug Conjugate platform is currently in preclinical development. Each tunable drug conjugate contains four main components: ligand, payload cassette adaptor, linker, and payload. In addition, TDCs contain units to optimize physicochemical properties. The ligands are selected to bind to receptors overexpressed on cancer cells. Upon binding the TDC construct gets internalized into the cancer cell, where the payload is released, causing cell death. The payload cassette adaptors enable the stoichiometrical attachments of linkers and payloads. The SiLinkers represent a novel are 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. The lead program targets Folate Receptor alpha, which 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 as payloads. The discovery work is being carried out at Syngene.

From time to time, we may evaluate collaboration opportunities for our product candidates, we also expect to work opportunistically with pharmaceutical and biotechnology companies, as we have with Blinkbio Inc., 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.

Technology

We are in the process of building a fully integrated platform to accelerate the development of product candidates across multiple therapeutic areas. Our platform technology, which is intended to leverage two decades of immunotherapy research, development, and manufacturing in order to enable us to pursue multiple therapeutic targets. Our scientists and scientific advisors have accumulated over 150 years of collective experience in the field of immunotherapy, oncology, and small molecule production, contributing key insights and significant achievement in our clinical development process.

Our team

We have assembled a management team of biopharmaceutical industry veterans with extensive experience in developing novel oncology therapies from research through commercialization. Our team is led by our Chief Executive Officer, Paul Romness, M.P.H, who has over [•] years of experience, including at [•]. and [•]. Our Chief Financial Officer, Christopher Acevedo, M.B.A., C.P.A., has over [•] years of [industry] experience and was previously at [•] and [•]. Our [Chief Medical Officer], [•], has over [•] years of experience in drug development, including at [•], Inc. and [•]. Our [Chief Legal Officer], [•], J.D., has over [•] years of legal experience managing the [entire pharmaceutical lifecycle from early discovery through litigation], including at [•] and [•]. Our [Senior Vice President of Product Development & Regulatory Affairs], [•], has over [•] years of experience in global drug development in rare diseases and oncology, including at [•] and [•].

Our Values

Our three core values are:

- ***Patient Impact.*** We care deeply about what we are building to change the future for patients.
- ***Empowerment.*** We are all responsible for delivering on our mission to develop new medicines for patients: listen, speak up, engage.
- ***Collaboration.*** We know that we are better together and thrive when we challenge each other to find a better way for patients.

Our Strategy

Our goal is to enrich and lengthen the lives of patients by being the 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 strategies:

- Obtain marketing approval for OST31-164 (AKA: OST-HER2) in Osteosarcoma, then quickly pivot to a basket trial of other solid tumors that metastasize through the HER2 mechanism of vascularization.
- Conclude pre-clinical and toxicology trials in OST-TDC, and file for IND to initiate PhI trial in Ovarian Cancer. Two-week and GLP Toxicology success would also stimulate out-licensing activity of SiLinker™ and Conditionally Active Payloads (CAPs™), while not limiting therapeutic development.
- Establish global commercial and medical affairs capabilities for OST31-164 (AKA: OST-HER2) based therapies, beginning with OST31-164.

Growth Opportunities

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

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, as well as any additional collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from any offering.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to and fund our operating expenses and capital expenditure requirements over the next five to seven years. Moreover, we have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Background

Our scientific collaborators and our scientific advisory board

To help advance our programs, we are collaborating with experts and physicians 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 proprietary technology developed at [ ] under the guidance of scientific founder and head scientific advisor [ ], [Title]. Our approach of partnering with physician-scientists to understand the limitations of existing therapies helps lead to product candidates that address the dual needs of treatment resistance and kinase selectivity.

Further, we have built a scientific advisory board with experts 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 currently includes:

- [ ]
- [ ]
- [ ]
- [ ]

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.

Revenue Sharing Agreements

Revenue Sharing Agreement with [ ]

We are party to an Amended and Restated Revenue Sharing Agreement with Deerfield pursuant to which we are obligated to pay Deerfield a low single digit percentage of net sales of any commercial products discovered, identified or generated by the Company during the period commencing on [ ] and ending on the date that is the earlier of (i) five years after Deerfield's last investment in our capital stock and (ii) the fifth anniversary of the closing of the offering contemplated hereby. Any payments in respect of such products would be through the later of twelve years from the first commercial sale in a country or the expiration of the last-to-expire patent in that country. To date, we have not made any payments under this agreement and there are no upfront fees or milestone payments required to be paid by us under this agreement. We have not yet obtained or exclusively in-licensed any issued patents, and all of the patent applications that we own are at a very early stage of prosecution. Any U.S. and foreign patents that may issue based on our pending PCT applications for our ROS1 and ALK programs are expected to expire in 2041, without giving effect to any patent term adjustments, patent term extensions that may be awarded or additional patents that may be filed. We also have no products approved for commercial sale and have not generated any revenue.

Revenue Sharing Agreements with our scientific founder

We are party to an Amended and Restated Revenue Sharing Agreement with our scientific founder, [ ], pursuant to which we are obligated to pay [ ] a low single digit percentage of net sales of certain commercial products that either have a mechanism of action of (i) [ ] inhibition and contain [ ] or a backup compound substituted therefor in the event of a product development failure or (ii) [ ] inhibition and contain [ ] or a backup compound substituted therefor in the event of a product development failure, in each case through the later of twelve years from the first commercial sale in a country or the expiration of the last-to-expire patent in that country.

To date, we have not made any payments under this agreement and there are no upfront fees or milestone payments required to be paid by us under this agreement. We have not yet obtained or exclusively in-licensed any issued patents, and all of the patent applications that we own are at a very early stage of prosecution. Any U.S. and foreign patents that may issue based on our pending PCT applications for our [ ] and [ ] programs are expected to expire in [ ], without giving effect to any patent term adjustments or patent term extensions that may be awarded or additional patents that may be filed. We also have no products approved for commercial sale and have not generated any revenue.

Intellectual property

Our commercial success depends in part on our ability (i) to obtain and maintain patent and other proprietary and/or intellectual property rights and protection for our technology, inventions, and improvements; (ii) to protect and preserve the confidentiality of our trade secrets; (iii) to defend and enforce our proprietary and intellectual property rights, including any patents that we may own or license in the future; and (iv) to operate without infringing the valid and enforceable patents and other proprietary and/or intellectual property rights of third parties.

We own PCT and provisional patent applications relating to our lead and planned product candidates. We strive to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. 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.

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

We have filed certain patent applications directed generally to compositions of matter, pharmaceutical formulations and therapeutic methods of using the foregoing related to our ROS1, ALK, and ErbB programs, as summarized below. We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology. In addition, we own certain pending U.S. trademark applications.

With respect to our ROS1 program, we own a pending Patent Cooperation Treaty (PCT) patent application directed to our ROS1 inhibitory compounds (e.g., NVL-520) and methods of use of such compounds. Any U.S. and foreign patents that may issue based on the PCT application are expected to expire in 2041, ignoring any patent term adjustments or patent term extensions that may be awarded. With respect to our ALK program, we own a pending PCT application directed to our ALK inhibitory compounds (e.g., NVL-655) and methods of use of such compounds. Any U.S. and foreign patents that may issue based on this PCT application are expected to expire in 2041, without giving effect to any patent term adjustments or patent term extensions that may be awarded. With respect to our ErbB program, we filed a U.S. provisional patent application and a PCT patent application related to our ErbB program. Any U.S. or foreign patents that may issue based on these applications are expected to expire no earlier than 2041. In addition, we expect to file additional patent applications related to each of these programs.

Our pending and planned applications may not result in issued patents and we cannot provide any assurance that any patents that might issue in the future will protect our future products or provide us with any competitive advantage. Moreover, U.S. provisional patent applications are not eligible to become issued patents until, among

other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to our provisional patent application, if we do not timely file a non-provisional patent applications, we may lose our priority date with respect to our provisional patent application and therefore any patent protection on the inventions disclosed in our provisional patent application. While we intend to timely file one or more non-provisional patent applications relating to our provisional patent application, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. For more information regarding the risks related to our intellectual property, please see "Risk Factors — Risks Related to Our Intellectual Property."

Commercialization

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing, or commercial product distribution capabilities. 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.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products if marketing approval is obtained.

We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

All of our product candidates are small molecules 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 [ ] active pharmaceutical ingredients ("API") (*i.e.*, clinical drug substance) is manufactured in accordance with [ ].

The drug product formulation is being developed with the goal of producing tablets with consistent and immediate release dissolution profiles that can be reproducibly manufactured using automated equipment. All manufacturing activities for the [ ] drug product are performed in accordance with [ ]. 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 [ ] 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 [ ] 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 we may develop.

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 the "Selected Financial Data" section of this prospectus and our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 prospectus, 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 creating precisely targeted therapies for patients with cancer. We focus our discovery efforts on Osteosarcoma and Tunable Drug Conjugates because of our technology. We were founded in 2018 as a limited liability company and incorporated on June 24, 2019 as a Delaware corporation. We are headquartered in Rockville, Maryland.

Since commencing significant operations in 2018 we have focused substantially all of our efforts and financial resources on research and development activities for our programs, including OST31-164 and OST-TDC, establishing and maintaining our intellectual property portfolio, organizing and staffing our company, business planning, raising capital, and providing general and administrative support for these operations.

Our Business

We are striving to be a leader in the field of Osteosarcoma and Tunable Drug Conjugates because of our technology. With OST31-164 (AKA: OST-HER2), there have been no new treatments in Osteosarcoma in over 40 years — and results from initial canine trials have shown significant improvement in overall survival and disease progression. Canine and human osteosarcoma are almost genetically identical. In Humans, Osteosarcoma is an extremely rare cancer that primarily affects children and young adults. Our most advanced product, OST31-164, will be the first adjuvant therapy for Osteosarcoma to be tested in children. This disease is difficult to diagnose, the standard of care following first line therapies is simply to screen and wait for possible recurrence/metastasis, which happens in approximately half of patients within 12-18 months of initial remittance. For those patients that do recur, metastasis is typically to the lungs and brain, with survival rates of ~14% over the next year. We hope that OST31-164 can delay or prevent recurrence of osteosarcoma in some patients.

We do not have any products approved for sale and have not generated revenue from product sales or any other source. To date, we have funded our operations primarily with proceeds from the sales of convertible notes and debt financing from stockholders.

Pipeline of Product Candidates

We have built a pipeline of product candidates targeting multiple indications for other solid cancers. Our pipeline includes two drug technologies: OST31-164 (AKA: OST-HER2), an off-the-shelf Immunotherapy comprised of a genetically weakened and modified strain of Listeria monocytogenes vector that secretes a fusion peptide of bacteria and HER-2 peptides, and OST-TDC — a next generation Tunable Antibody Drug Conjugate (ADC) plug-and-play platform that can carry various types of payloads, and features tuneable pH sensitive silicone linkers (SiLinkers™) that can payloads including antibodies, chemotherapeutics, cytotoxins, and potentially mRNA treatments directly into and in the vicinity of solid tumors.

OST31-164 (AKA: OST-HER2): Our most advanced product candidate, OST31-164 (AKA: 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 form the bacteria. This drug product is in Phase 2B clinical trials. OST31-164 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 ~1,000 individuals affected per year. 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, and other solid tumors.

OST-TDC: Our Tunable Drug Conjugate platform is currently in preclinical development. Each tunable drug conjugate contains four main components: ligand, payload cassette adaptor, linker, and payload. In addition, TDCs contain units to optimize physicochemical properties. The ligands are selected to bind to receptors overexpressed on cancer cells. Upon binding the TDC construct gets internalized into the cancer cell, where the payload is released, causing cell death. The payload cassette adaptors enable the stoichiometrical attachments of linkers and payloads. The SiLinkers represent a novel are 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. The lead program targets Folate Receptor alpha, which 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 as payloads. The discovery work is being carried out at Syngene, a clinical research organization ("CRO") what we have engaged.

From time to time, we may evaluate collaboration opportunities for our product candidates. We also expect to work opportunistically with pharmaceutical and biotechnology companies, as we have with BlinkBio Inc., seeking to utilize our technology and know-how for developing additional oncologic drug products.

Technology

We are building a fully integrated platform to accelerate the development of product candidates across multiple therapeutic areas. Our platform technology, which leverages two decades of immunotherapy research, development, and manufacturing enables us to pursue multiple therapeutic targets. Our scientists and scientific advisors have accumulated over 150 years of collective experience in the field of immunotherapy, oncology, and small molecule production, contributing key insights and significant achievement in our clinical development process.

Our strategy

Our goal is to enrich and lengthen the lives of patients by being the 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 strategies:

- Obtain marketing approval for OST-HER2 in Osteosarcoma, then quickly pivot to a basket trial of other solid tumors that metastasize through the HER2 mechanism of vascularization.
- Conclude pre-clinical and toxicology trials in OST-TDC, and file for IND to initiate Phase I trial in Ovarian Cancer. Two-week and GLP Toxicology success would also stimulate out-licensing activity of SiLinker™ and Conditionally Active Payloads (CAPs™), while not limiting therapeutic development.
- Establish global commercial and medical affairs capabilities for OST-HER2 based therapies, beginning with OST31-164.

Funding and Operations

Since 2018, we have raised approximately $10,000,000 in the form of convertible notes under the exemptions set forth in Regulation D of the Securities Act. We continue to raise funding under convertible note offerings. See discussion of funding below for the terms of the various group of notes payable that executed since 2018.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidates. We reported net losses of $6.8 million and $6.0 million for the years ended December 31, 2021 and 2020, respectively. We reported a net loss of $3.7 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $17.0 million. We expect to incur significant expenses at an increasing rate and increasing operating losses for the foreseeable future. We expect our expenses and capital requirements will increase substantially in connection with ongoing activities, particularly if and as we:

- advance our OST31-164 program through our Phase 2B clinical trial, which commenced in 2022 and is expected to be completed June 2024 with expected feedback from the U.S. F.D.A. later in 2024;
- advance our OST-TDC program through September 2023, at which time we should have our FDA required testing completed on our Anti-body and Linker and be able to potentially out-license this groundbreaking technology to major pharmaceutical companies:
- expand our pipeline of product candidates through our own product discovery and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- implement operational, financial and management systems;
- attract, hire and retain additional clinical, scientific, management and administrative personnel;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies; and
- operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Further, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts.

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

As of September 30, 2022, we had cash of $39,000. We received gross proceeds of $1.9 million from the sale of our convertible notes during the nine months ended September 30, 2022. We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements through December 2023. Our goal for our TDC product is to have licensing agreements in place that will self-fund our continued need for cash to finish out our OST 164 trial. See "— Liquidity and Capital Resources."

Impact of the COVID-19 Pandemic on Our Business

The global COVID-19 pandemic continues to rapidly evolve. The extent of the impact of the COVID-19 on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our development activities, planned clinical trial enrollment, future trial sites, CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with our employees working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

Recent Developments

From October 1 to November 15, 2022, we issued approximately $5.5 million in the form of Group C convertible notes (see principal terms below). In addition, we intend to raise an additional $1.5 million in the form a bridge financing.

Components of our Results of Operations

Revenue

We did not recognize revenues for years ended December 31, 2021 and 2020 or the nine months ended September 30, 2022.

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 OST31-164 and OST-TDC into clinical development and expand our discovery, research and preclinical activities in the near term and in the future. Although we anticipate completion and FDA approval of our Phase 2 trial in June 2024 and finishing up required testing of our TDC programs in the first half of 2023, at this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any product candidates we may develop. A change in the outcome of any number of variables with respect to product candidates we may develop could significantly change the costs and timing associated with the development of that product candidate. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of development activities relating to OST31-164 and OST-TDC, and any future product candidates from our other discovery programs, including any additional costs that may result from delays in enrollment or other factors;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the number of trials required for regulatory approval;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects and initial clinical trials;
- the number of subjects that participate in the trials and per subject trial costs;
- potential additional safety monitoring requested by regulatory authorities;
- the duration of subject participation in the trials and follow-up;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to applicable regulatory authorities;
- the receipt of regulatory approval from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships or other strategic arrangements with third parties, if any, and the performance of any such third party;
- Establishing commercial manufacturing capabilities or making arrangements with CMOs;
- Development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch; and
- Obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those

that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

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

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

Licensing Costs

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

Interest Expense

We account for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, *Derivative and Hedging*, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts, and requires recognition of all derivatives on the balance sheet at fair value. Our derivative financial instrument consists of an embedded feature contained in our convertible debt that we call the "redemption premium."

The initial fair value of the redemption feature relating to the convertible debt instruments is treated as a debt discount and amortized over the term of the related debt using the straight-line method, which approximates the interest method. If a loan is paid in full, any unamortized financing costs will be removed from the related accounts and charged to operations. Amortization of debt discount is recorded as a component of interest expense. In accordance with Accounting Standards Update ("ASU") 2015-03, *Interest — Imputation of Interest*, the unamortized debt discount is presented in the accompanying balance sheet as a direct deduction from the carrying amount of the related debt.

The redemption liability includes a provision that provides the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for us. The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, determined based upon a Probability-Weighted Expected Returns Method ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since we have not entered into a priced equity round through September 30, 2022. The significant assumptions utilized in these calculations are the possible exit scenarios (either a conversion of the principal and accrued interest of the Notes in the event of a Next Equity Financing, a repayment of the Notes and accrued interest in the event of a Corporate Transaction (as defined in the Notes) or a repayment of the Notes and accrued interest at maturity), the pre-money valuation of our common stock, the probabilities of such exit events occurring and discounts/premiums available to the noteholders at such measurement dates. At December 31, 2021, the Company assumed a 25% probability of a Next Equity Financing event occurring at IPO pricing and a 5% probability of a Corporate Transaction. The calculation of the redemption liability at December 31, 2021 is based upon the actual incremental value derived by the noteholders at the IPO date. At September 30 2022, the Company assumed a 49% probability of a Next Equity Financing event occurring at IPO pricing and a 3% probability of a Corporate Transaction. The calculation of the redemption liability at September 30 2022 is based upon the actual incremental value derived by the noteholders at the IPO date.

Other Income

Other income (expense), net, consists of interest income from our loan receivable from our Chairman and Chief Executive Officer, and other income (expense) unrelated to our core operations.

Cumulative Series A preferred stock dividend

The Series A preferred stock dividend requirement represents the coupon dividends on our preferred stock and is identified as a separate component of our statement of operations to compute net income (loss) available to common shareholders. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly. The cumulative accrued dividend at September 30, 2022 is $187,500.

Income taxes

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

As of December 31, 2021, we had U.S. federal net operating loss carryforwards of $2.7 million, which may be available to offset future taxable income. The federal net operating loss carryforward indefinitely but may only be used to offset 80% of annual taxable income. As of December 31, 2021, we also had federal and state general business tax credit carryforwards of $.03 million and $0 million, respectively, which may be available to offset future tax liabilities and expire at various dates beginning in January 1, 2022. As of December 31, 2021, we also had federal and state research and development tax credit carryforwards of $0.3 million and $0 million, respectively, which may be available to offset future tax liabilities and expire at various dates beginning January 1, 2022.

Deferred Offering Costs

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

Results of operations

Comparison of the nine months ended September 30, 2022, and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine months ended			
	September 30, 2022	**September 30, 2021**	**Change**	**Percentage Change**
EXPENSES				
Research & Development Expenses	2,193,614	1,481,210	712,403	48%
General & Administrative	511,048	948,261	–437,212	–46%
Licensing	1,210	1,141,165	–1,139,955	–100%
Total Operating Expenses	2,705,872	3,570,637	–864,764	–24%
Loss from Operations	–2,705,872	–3,570,637	864,765	–24%
OTHER INCOME/EXPENSE				
Interest Income	1	—	0.56	100%
Interest Expense	(996,701)	(1,489,055)	492,354	–33%
Total other income	*(996,700)*	*(1,489,055)*	*492,355*	–33%
NET LOSS	$ –3,702,574	$ –5,059,691	1,357,118	0%
Cumulative Series A Preferred Stock Dividend Requirement	–93,750	–93,750	—	–26%

Research and development expenses

Research and development expenses were $2.2 million for the nine months ended September 30, 2022, compared to $1.5 million for the nine months ended September 30, 2021. The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,		
(In millions)	**2022**	**2021**	**Change**
Direct research and development expenses by program:			
OST 164	$ 1.5	$ .8	$ 0.7
OST TDC	0.4	0.4	—
Unallocated research and development expenses:			
Personnel-related	0.3	0.3	0
Total research and development expenses	$ 2.2	$ 1.5	$ 0.7

The increase in direct research and development expenses related to OST 164 was primarily lab fees of $0.7 million and was primarily due to increased Phase 2B trial preparation and CRO costs as we completed IND-enabling studies. We have also incurred expenses for our planned Phase 2B clinical trial for 2022. There was no significant increase in direct research and development expenses related to OST — TDC for the nine months ended September 30, 2022, compared to $1.5 million for the nine months ended September 30, 2021

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2022 were $0.5 million compared to $0.9 million for the nine months ended September 30, 2021. The decrease in general and administrative expenses was primarily due reduced legal expenses in 2022 along with a 1-time payment to a consultant in the 2021 period.

Licensing costs

Licensing costs for the nine months ended September 30, 2022 were minimal compared to $1.1 million for the nine months ended September 30, 2021. The decrease in licensing costs was primarily due to making an early milestone payment to Advaxis in 2021 of $1.1 million, that was due upon having secured at least 8.0 million US Dollars, in the aggregate of capital raise.

Interest expense

Interest expense for the nine months ended September 30, 2022 was $1.0 million compared to $1.5 million for the nine months ended September 30, 2021. The decrease in interest expenses was primarily due to a decrease in the amount of debt discount being amortized in 2022 as compared to the corresponding 2021 period, partially offset by an increase in the total amount of convertible notes.

Cumulative Series A preferred stock dividend

The Series A preferred stock coupon dividend requirement was $93,750 for both the nine months ended September 30, 2022 and 2021, as there were no changes in the coupon dividend rate or preferred shares outstanding in such periods.

Comparison of the years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Twelve months ended			
	December 31, 2021	**December 31, 2020**	**Change**	**Percentage Change**
EXPENSES				
Research & Development Expenses	2,174,179	601,777	1,572,402	261%
General & Administrative	1,231,052	795,424	435,628	55%
Licensing	1,159,642	4,250,000	–3,090,358	–73%
Total Operating Expenses	4,564,873	5,647,201	–1,082,327	–19%
Loss from Operations	–4,564,873	–5,647,201	1,082,328	–19%
OTHER INCOME/EXPENSE				
Interest Income	—	61,285	–61285	–100%
Consulting Income	—	20,000		0%
Interest Expense	(2,160,177)	(461,785)	(1,698,392)	368%
Total other income	*(2,160,177)*	*(380,500)*	*(1,779,677)*	468%
NET LOSS	$ –6,725,050	$ –6,027,701	–697,349	12%
Cumulative Series A Preferred Stock Dividend Requirement	–93,750	0	(93,750.00)	100%
			—	
NET LOSS available to stockholders	–6,818,800	–6,027,701	(791,098.61)	13%

Research and development expenses

Research and development expenses were $2.2 million for the year ended December 31, 2021, compared to $0.6 million for the year ended December 31, 2020. The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020:

	Year ended December 31,		
(In thousands)	**2021**	**2020**	**Change**
Direct research and development expenses by program:			
OST 164	$ 1.0	$ 0.4	$ 0.6
OST TDC	0.8	0.0	0.8
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	0.4	0.2	0.2
Other			
Total research and development expenses	$ 2.2	$ 0.6	$ 1.6

The increase in direct research and development expenses related to OST-164 of $0.6 million was primarily due to increased preclinical and lab costs as we progressed from preliminary stage to drug enabling studies and corresponding lab work. The increase in direct research and development expenses related to OST TDC of $0.8 million was primarily due to increased lab costs as we progressed the drugs from a preliminary stage idea to molecular testing. The increase/increase in personnel-related expenses of $0.2 million was primarily due to an increase in employee headcount commencing mid-2020.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2021 were $1.2 million compared to $0.8 million for the year ended December 31, 2020. The increase in general and administrative expenses was primarily due to an increase in personnel-related costs of $.07 million driven by compensation increases for general and administrative employees during the year ended December 31, 2021. Professional and consultant fees also increased by $.4 million as we incurred costs for an annual audit, more legal expenses and increased operational costs in this category.

Licensing costs

Licensing costs for the year ended December 31, 2021 were $1.2 million compared to $2.4 million for the year ended December 31, 2020. The decrease in licensing costs was primarily due to varying milestone payments: $2.4 million in 2020 to Blinkbio vs. $1.2 million to Advaxis in 2021 as specified milestones were met.

Interest expense

Interest expense for the year ended December 31, 2021 was $2.1 million compared to $0.5 million for the year ended December 31, 2020. The increase in interest expenses was primarily due to increased balances in outstanding Convertible Notes, of which a majority of the 2020 raise of $3.3 million was executed late in the fourth quarter of 2020. During 2021, we raised $3.6 million in Convertible Notes.

Series A preferred stock dividend

Series A preferred stock coupon dividend requirement was $93,750 for the year ended December 31, 2021 compared to $0 for the year ended December 31, 2020, as the preferred shares were issued in March 2021.

Liquidity and capital resources

The accompanying financial statements have been prepared on the basis that we are a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for the foreseeable future, if at all. To date, we have funded substantially all our operations with proceeds from the sales of convertible debt and debt financing from stockholders. Through September 30, 2022, we had received gross proceeds of approximately $10.0 million from sales of our convertible notes. As of September 30, 2022, we had cash of $39,000.

Cash flows

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

	Year ended December 31,		Nine months ended September 31,	
(In thousands)	**2021**	**2020**	**2022**	**2021**
Cash used in operating activities	$ (4,403)	$ (2,413)	$ (2,269)	$ (3,721)
Cash used in investing activities	201	158	231	208
Cash provided by financing activities	3,050	3,478	1,997	2,445
Net increase (decrease) in cash and cash equivalents	$ (1,152)	$ 1,223	$ (41)	$ (1,069)

Operating activities

During the nine months ended September 30, 2022, operating activities used $2.2 million of cash, resulting from our net loss of $3.7 million, partially offset by net non-cash charges of $0.5 million and net cash provided by changes in our operating assets and liabilities of $1.0 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2022 consisted of an increase in accounts payable and accrued expenses and other current liabilities of $0.3 million and an increase in accrued interest of $0.4 million.

During the nine months ended September 30, 2021, operating activities used $3.7 million of cash, primarily resulting from our net loss of $5.1 million, partially offset by net non-cash income of $1.3 million and net cash provided by changes in our operating assets and liabilities of $0.1 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2021 consisted of an decrease in officer loans of $0.2 million.

During the year ended December 31, 2021, operating activities used $4.4 million of cash, resulting from our net loss of $6.7 million and net non-cash income of $ 1.7 million, partially offset by net cash provided by changes in our operating assets and liabilities of $0.2 million from the repayment of Shareholder loan.

During the year ended December 31, 2020, operating activities used $2.4 million of cash, resulting from our net loss of $6.0 million, partially offset by net non-cash charges of $2.6 million and net cash provided by changes in our operating assets and liabilities of $1.0 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of a increase in accrued expenses $.6 million, $.2 million increase in accrued interest and $.2 million increase in accrued payroll.

Non-cash charges in all periods were primarily the result of the amortization of debt discount on our convertible debt, and for the year ended December 31, 2020 the fair value of a licensed asset classified as acquired in-process research and development costs. Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses and other current assets in all periods were generally due to growth in our business, the advancement of our research programs and the timing of vendor invoicing and payments.

Investing activities

During the nine months ended September 30, 2022 and 2021, net cash provided by investing activities was $0.2 million, consisting primarily of proceeds from shareholder loans of $0.2 million in both periods.

During the year ended December 31, 2021 and 2020, net cash provided by investing activities was $0.2 million, consisting primarily of proceeds from shareholder loans of $0.2 million in both periods.

A shareholder has loaned, and been loaned, funds periodically since the inception of the Company. At September 30, 2022, the Company owed the shareholder $115,000.

Financing activities

During the nine months ended September 30, 2022 and 2021, net cash provided by financing activities was $2.0 million and $2.4 million, consisting primarily of proceeds from the sale of convertible debt of $1.9 million, and $2.4 million, respectively.

During the year ended December 31, 2021, net cash provided by financing activities was $3.0 million, consisting primarily of proceeds from the sale of convertible debt of $3.0 million. During the year ended December 31, 2020, net cash provided by financing activities was $3.5 million, consisting primarily of proceeds from the sale of convertible debt of $3.6 million.

Convertible Debt

The Convertible Notes are separated into four groups — A, B, C and BlinkBio — per the table below.

Group	Dates of issuance	Rate	Maturity	Collateral	Conversion Rate	September 30, 2022 Carrying Amount	September 30, 2022 Face amount
A	Pre – 2020	10%	3/31/2024, as extended	None	87.5% – 100%	$ 1,130,284	$ 1,154,000
B	2020 – 2021	6%	3/31/2024, as extended	None	80%	$ 5,154,000	$ 5,154,000
C	2021 – 2022	6%	3/31/2024	None	80%	$ 3,111,285	$ 3,695,020
Blink Bio	2020	10%	3/15/2022	None	100%	$ 0	$ 0

The total accrued interest on such notes was $1.0 million at September 30, 2022. The carrying amount and face amount of the convertible notes differ because of the unamortized debt issuance costs and the debt discount (which are amortized over the original term of the instrument) — see accounting policy discussion below. Major terms of each group of notes is contained below:

Group A

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 shall 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). In general, the stated Maturity Date varies from the date of issuance of 2-4 years, and were extended in April, 2022, under the same terms until March 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 87.5-100% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $3,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes) or $5,000,000, depending upon the signed agreement terms. In the event that the Company raises aggregate additional cash proceeds of at least $3,000,000 or $5,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due shall 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 and 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.

Group B

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 shall 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). In general, the stated Maturity Date varies from the date of issuance of 2-4 years, and were extended in April, 2022, under the same terms until March 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. No such Next Equity Financing has occurred through September 30, 2022. 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 shall 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 and 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.

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 shall 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). In general, the stated Maturity Date is March 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. No such Next Equity Financing has occurred through September 30, 2022. 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 shall 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 and 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.

Blink Bio

On August 19, 2020, the Company gave a convertible note, initially valued at $2,400,000, to Blink Bio in exchange for a license of an asset. The Note bears simple interest at the rate of 10% per annum and is set to convert within 120 days of the signing date, to Preferred Stock at conversion price per share equal to the Capped Conversion Price (1.92 per share), unless agreed by mutual consent to extend, which it was in December 2020 to March 2021. The principal and then total interest of $100,000 converted into 1,302,082 shares of Preferred Stock on March 15, 2021.

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 shall 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 shall become due to TEDCO immediately; however the discount for meeting the obligation shall still apply.

Preferred Stock

In 2021, 5,000,000 shares of Preferred Stock were authorized, 1,400,000 was designated as Series A Preferred Stock, with 1,302,082 shares issued of Series A Preferred Stock. Preferred Stock has 5% cumulative coupon and liquidation priority above all Common Shares. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly. The cumulative accrued dividend at September 30, 2022 is $187,500. The preferred stock can be converted to common shares at a 1:1 ratio.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical and clinical activities and clinical trials for our product candidates in development. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results and clinical trials for our discovery programs and product candidates, including the planned advancement of OST-164 and OST- TDC into clinical development;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we discover and develop through our product discovery and research efforts;
- the terms of any collaboration agreements we may choose to pursue;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

As of September 30, 2022, we had cash of $39,176. For the nine months ended September 30, 2022, we received gross proceeds of $1.9 million from the convertible note offering. We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through . We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including those listed above.

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

Contractual obligations and other commitments

We lease certain office space in Rockville, Maryland pursuant to a month-to-month lease. 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 cancelable by us. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

License Obligation and Manufacturing Agreements

Advaxis

The Company entered into an exclusive license agreement with Advaxis Inc in September 2018, as amended, pursuant to which it acquired the right to develop and commercialize Advaxis HER2 Construct, the Company's product candidate and the use of Advaxis HER2 Construct patents. Per the agreement, monthly payments began April 30, 2020, and a total of $2,975,000 has been paid to ADVAXIS towards the License Commencement Payment by December 31, 2021, the grand total of which is comprised of the $1,550,000 and the $1,375,000 (Milestone 2 was paid early, in return Milestone 3 was delayed. These payments have been recorded as licensing expenses in the accompanying statement of operations. Of note: Milestone 3 due date was updated to item (A) receipt of Regulatory Approval from the FDA for the First Indication of the first Licensed Product for $5,000,000 and that expected date is June 2024. A payment schedule is set for future milestones, as follows:

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

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

On an aggregate basis across all Licensed Products under the licensing agreement and during the Royalty term, OST shall pay quarterly to Advaxis royalties on Net Sales of Licensed Products at a rate of Ten Percent (10%) with respect to all Net Sales in a given Calendar Quarter. No royalties were payable in 2020 or 2021 or through September 30, 2022.

BlinkBio

In July 2020, the Company entered into a Licensing Agreement with BlinkBio, to utilize their proprietary technology. On 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 accompany statement of operation. A payment schedule is set for future milestones, is summarized below:

Milestone Bearing Event	Milestone Payment
1. License Fee to utilize proprietary technology (paid)	$300,000 + $2.4MM 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 shall make the cash payments set forth in the table above by wire transfer of immediately available funds, to BlinkBio within thirty (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 shall apply with respect to The Company's first product candidate. During the Royalty Term, the Company will pay BlinkBio a royalty of six percent (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 shall be reduced to three percent (3%).

For the avoidance of doubt, each Milestone payment shall be payable only once, and the aggregate amount of Milestone payments payable hereunder shall not exceed Twenty-Two Million Three Hundred Seventy-Five US Dollars ($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 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"*. The study has seventeen patients and is expected to last for 28 months, or through September 2022. The Agreement budget totals $2,423,928. The total research and development expense recorded in the statement of operations for the year ended December 31, 2021 was $556,000 and $244,000 for the year ended December 31, 2020. The remainder is set up to be paid according to the service fee schedule below:

George Clinical Payment Schedule	Payment Amount
1. Service Fee Advance (paid 6/8/2020)	$49,989
2. Float – Service Fee Advance of 20% of $372145.28 and PTC Advance Fee of 20% of $313,254 (Paid 11/4/2020)	$162,346
3. Statistics Fees – 10% on Commencement of Study	$13,640
4. Statistics Fees – 50% on Development of SAP tables	$68,200
5. Statistics Fees – 40% on Final Analysis	$54,560
6. Service Fees – Remainder Due	Split Monthly Over Course of Study

George Clinical will track and invoice the Company for the number of task units completed and passthrough costs will be invoiced each month in arrears based on actual costs without mark-up. The PTC Advance Fee will be used to offset final pass-through fees payable.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. However, our exposure to market risk for changes in interest rates as our outstanding interest-bearing debt instruments have a fixed rate, and we do not hold any interest-generating securities. See "Liquidity and Capital Resources" above.

Critical accounting policies and significant judgments and estimates

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

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

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of services performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some may require advance payments. As of September 30, 2022, no prepayments exist. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with the preclinical development activities;
- CROs in connection with preclinical and clinical studies and testing; and
- CDMOs in connection with the process development and scale up activities and the production of materials.

We base the expense recorded related to contract research and manufacturing on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs and CDMOs that conduct services and supply materials. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses. While the majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual

milestones are met some require advance payments. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. We record these as prepaid expenses on our balance sheet.

Debt Discount and Derivative Instruments

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

The initial fair value of the redemption value relating to the convertible debt instruments are capitalized and amortized over the term of the related debt using the straight-line method, which approximates the interest method. If a loan is paid in full, any unamortized financing costs will be removed from the related accounts and charged to operations. Amortization of debt discount is recorded as a component of interest expense. In accordance with ASU 2015-03, *Interest — Imputation of Interest*, the unamortized debt discount is presented in the accompanying balance sheet as a direct deduction from the carrying amount of the related debt.

The Company accounts for derivative instruments in accordance with ASC 815,*Derivative and Hedging*, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. The Company's derivative financial instrument consists of an embedded option in the Company's convertible debt. The embedded derivative includes provisions that provide the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for the Company.

The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, is determined based upon a Probability-Weighted of Expected Returns Model ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since the Company has not entered into a priced equity round through September 30, 2022. The fair value of the redemption liability is calculated using the initial value of the convertible note less the debt discount rate of 12.5% in Group A and 20% in Groups B and C. The redemption liability is then amortized over the remaining life of the note, utilizing the interest rates of 10% and 6% respectively for the groups. The life of each note in Group A is for a set period of 3 years, and is variable in Groups B and C, with a range of 15 months to 3 years. The Company retains the option to negotiate an extended maturity date for Groups B and C.

The fees associated with the convertible debt raise are legal and investment fees associated with the issuance of the convertible notes for Groups A, B, & C. The fees are amortized over the life of the convertible note utilizing an interest rate of 10% for Group A and 6% for Groups B and C.

Licensing costs

We have acquired, and may in the future acquire, rights to develop and commercialize new product candidates and/or other in-process research and development assets. In accordance with Financial Accounting Standards Board's ASC 730-10-25-1, *Research and Development*, the up-front acquisition or licensing payments are expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing, and, absent obtaining such approval, have no alternative future use.

Determination of fair value of common stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed

from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

Our common stock valuations were prepared using either an option pricing method ("OPM") or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a hybrid of the probability-weighted expected return method, or PWERM, and OPM, estimating the probability-weighted value across multiple scenarios, but using the OPM to estimate the allocation of value within one or more of the scenarios. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of $1.90 per share as of 12/31/2020, $2.00 per share as of 9/30/21, $5.00 per share as of 12/31/2021 and $5.50 per share as of 9/30/2022. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold our convertible notes (a primary indicator to management);
- the progress of our research and development programs, including the status and results of preclinical and clinical studies in our programs;
- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering ("IPO"), or sale of our company in light of prevailing market conditions;
- the hiring of key personnel and the experience of management; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

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 Securities and Exchange Commission.

Recently issued and adopted 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 our financial statements appearing elsewhere in this prospectus

Emerging growth company and smaller reporting company status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of 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 prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

MANAGEMENT

Directors and Executive Officers

The following table sets forth the name, age and position of each of our executive officers and directors as of September 30, 2022.

Name	Age	Position
Executive Officers:		
Paul Romness	56	Chief Executive Officer and President
Christopher Acevedo	59	Chief Financial Officer
Jutta Wanner	54	Chief Technology Officer
Robert G. Petit	63	Chief Scientific Officer and Chief Medical Officer
Directors:		
Colin Goddard[(1)(2)(3)]	63	Executive Chairman
Theodore F. Search[(2)(3)]	41	Director
John Ciccio[(1)(2)]	42	Director
Paul Romness	56	Director
Joacim Borg[(1)(3)]	31	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

Executive Officers

Paul Romness, M.P.H. Mr. Romness currently serves as the President and Chief Executive Officer of OS Therapies, Inc. and serves as a Class [•] member of our Board. Paul Romness is the founder of OS Therapies and has served as the President and Chief Executive Officer since its inception. 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-TDC, a next generation tunable drug conjugate delivery system. Prior to founding OS Therapies, Mr. Romness served as the Director of State Government Affairs at Amgen from March 2005 to March 2008 and the Vice President of Government Affairs and Public Policy at Boehringer Ingelheim from 2008 to 2014. Mr. Romness holds a M.P.H. in health policy from George Washington University Medical Center and a B.S. in finance from American University. The Company believes that Mr. Romness is qualified to serve on the Company's Board because of his extensive business leadership and experience in the field of biotechnology, as well as his role as the President and Chief Executive Officer of the Company.

Christopher Acevedo. Mr. Acevedo currently serves as Interim Chief Financial Officer of OS Therapies, Inc. on a part-time basis since June 2020. Currently he also runs a DE and MD CPA practice, serving a wide range of small to medium business, mainly in the service sector. He holds CPA certificates in MD, DE and PA and graduated with an MBA in Administration and BS in Accounting, minoring in finance from the University of Delaware. Prior position, Mr. Acevedo's professional career spans nearly 30 years and includes CFO positions in a variety of DE service business.

Jutta Wanner, Ph.D, PMP. Dr. Wanner currently serves as the Chief Technology Officer of OS Therapies, Inc. Dr. Wanner has served as Chief Technology Officer since September 2020. Prior to joining OS Therapies, Dr. Wanner served as Director of the Arizona Center for Drug Discovery from August 2019 to August 2020 where she provided strategic leadership for a wide portfolio across biological targets, therapeutic areas and therapeutic modalities in drug discovery from early state research to clinical trials. Prior to that Dr. Wanner served as a Chief Scientific Officer and Vice President of Research at BlinkBio Inc. from August 2013 to July 2019. While at BlinkBio, Dr. Wanner developed BlinkBio's lead Tunable Drug Conjugate program. Dr. Wanner holds more than 20 publications and more than 10 patents. Dr. Wanner holds a Vordiplom in Chemistry from Universität Erlangen-Nürnberg and a Ph.D. from the University of Kansas.

Robert G. Petit, Ph.D. (Md*). Dr. Petit currently serves as the Chief Scientific Officer and Chief Medical Officer of OS Therapies, Inc. Prior to joining OS Therapies, Dr. Petit served, and continues to serve, as a Principal for RGP Biotech, LLC where he advises clients on non-clinical and clinical development programs. Prior to that, Dr. Petit served as the Chief Scientific Officer and Executive Vice President of Advaxis, Inc. from March 2013 to June 2019. Dr. Petit holds a Ph.D. from the Ohio State University College of Medicine and a B.S. from Indiana State University. The Company believes that that Mr. Petit is qualified to serve on the Company's Board because [•].

Directors

Colin Goddard, Ph.D. Dr. Goddard currently serves as a member of our Board. Prior to joining the Board of OS Therapies, Dr. Goddard has served, and currently serves, on the board of cancer research focused companies such as Mission Therapeutics, FoRx Thereapeutics, OS Therapies, HiberCell and Ryvu Therapeutics from July 2010. Prior to serving as a director for cancer research companies, Dr. Goddard served as Chief Executive Officer and Director of OSI Pharmaceuticals, Inc. from January 1989 to July 2010. Dr. Goddard has more than 10 publications and was an inductee of the Long Island Technology Hall of Fame in 2013. Dr. Goddard has a Ph.D. in Cancer Pharmacology from the University of Aston and a BSc in Biochemistry from the University of York. The Company believes that that Mr. Goddard is qualified to serve on the Company's Board because of his extensive experience in the biotechnology and pharmaceutical industry.

Theodore F. Search, Pharm.D., R.Ph. Dr. Search currently serves as a member of our Board. Dr. Search is the Founder and Chief Executive Officer of Skipta, an Informa Pharma Intelligence Company. Dr. Search served as the Chief Executive Officer and Executive Chairman of Skipta from 2009 to 2017. Dr. Search is has been invited to speak at various conferences around the globe and named amongst the Top 100 Most Inspiring People in the Life Sciences Industry in 2015 and amongst 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. The Company believes that that Mr. Search is qualified to serve on the Company's Board because of his extensive experience in the pharmaceutical industry, and early stage companies.

John Ciccio. Mr. Ciccio currently serves as a member of our Board. Since 2019, Mr. Ciccio has served as the President and Chief Executive Officer of Adheris Health. Prior to joining Adheris Health, Mr. Ciccio was the President and a member of the Board of Managers of Skipta LLC from 2014 to 2018 which he lead to eventual sale to Informa PLLC. 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. in Government from Harvard University. The Company believes that that Mr. Ciccio is qualified to serve on the Company's Board because of his extensive experience in the biotechnology and pharmaceutical industry, and growth stage companies.

Paul Romness, M.P.H. Mr. Romness currently serves as a member of the Board and as the Chief Executive Officer and President of OS Therapies, Inc. Biographical information for Mr. Romness is set forth under "*Management — Executive Officers.*"

Joacim Borg. Mr. Borg currently serves as a member of Our Board. Since 2013, Mr. Borg has worked at Index Investment Group where he currently serves as the Chief Marketing Officer where he strategizes and spearheads the North American companies marketing and branding, their development projects and subsidiary investments across the three pillars of the company. Additionally, Mr. Borg is the Founder and Chief Executive Officer of Wavelength, a commercial marketing and media company. Mr. Borg holds a B.S. in Managerial Economics and Liberal Studies in Global Perspectives from Bentley University. The Company believes that that Mr. Borg is qualified to serve on the Company's Board because of his extensive experience in marketing, promotion and social media.

Composition of our Board of Directors

Our board consists of five members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our Nominating and Corporate Governance Committee and our Board of Directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our Nominating and Corporate Governance Committee's and our Board of

Directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our third amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our Board of Directors, including a vacancy resulting from an enlargement of our Board of Directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

Our Board of Directors has determined that all members of the Board of Directors, except Paul Romness, are independent directors, including for purposes of the rules of the [NYSE American/Nasdaq Capital Market] 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 common stock. Upon the completion of this offering, we expect that the composition and functioning of our Board of Directors and each of our committees will comply with all applicable requirements of either the NYSE American exchange or Nasdaq Capital Market, as applicable 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 the Company.

Board leadership structure and board's role in risk oversight

Currently, the role of chairman of the Board of Directors is separated from the role of Chief Executive Officer. Our Chief Executive Officer is responsible for recommending strategic decisions and capital allocation to the Board of Directors and to ensure the execution of the recommended plans. The chairman of the Board of Directors is responsible for leading the Board of Directors in its fundamental role of providing advice to and independent oversight of management. Our Board of Directors recognizes the time, effort, and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the Board of Directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines will not require that our chairman and Chief Executive Officer positions be separate, our Board of Directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including the four risks more fully discussed in the section entitled "Business" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our Board of Directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our Board of Directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the Board of Directors in overseeing the management of our risks is conducted primarily through committees of the Board of Directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full Board of Directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full Board of Directors during the committee reports portion of the next board meeting. This enables the Board of Directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.]

Committees of our Board of Directors

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each of which will operate pursuant to a charter to be adopted by our Board of Directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The Board of Directors may also establish other committees from time to time to assist the Company and the Board of Directors. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, [NYSE American/Nasdaq] and SEC rules and regulations, if applicable. Upon our listing on Nasdaq, each committee's charter will be available on our website at *www.ostherapies.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

Audit Committee

Colin Goddard, Theodore Search and John Ciccio serve on the Audit Committee, which is chaired by [•]. 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/Nasdaq], and that each has sufficient knowledge in financial and auditing matters to serve on the Audit Committee. Our Board of Directors has designated John Ciccio as an "Audit Committee financial expert," as defined under the applicable rules of the SEC. Under Rule 10A-3 under the Exchange Act, we are permitted to phase in our compliance with the independent Audit Committee requirements set forth in [NYSE American/Nasdaq] Rule 5605(c) and Rule 10A-3 under the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our Board of Directors intends to cause our Audit Committee to comply with the transition rules within the applicable time periods.

The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the Audit Committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall 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.

Compensation Committee

Colin Goddard, Theodore Search and John Ciccio serve on the Compensation Committee, which is chaired by Colin Goddard. Our Board has determined that each member of the Compensation Committee is "independent" as defined in the applicable [NYSE American/Nasdaq]rules. We are permitted to phase in our compliance with the independent Compensation Committee requirements set forth by [NYSE American/Nasdaq]listing standards as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our Board of Directors intends to cause our Compensation Committee to comply with the transition rules within the applicable time periods. The Compensation Committee's responsibilities include:

- reviewing and approving the corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other Section 16 officers;
- evaluating the performance of our Chief Executive Officer and other Section 16 officers in light of such corporate goals and objectives and based on such evaluation, recommending to the Board of Directors the compensation of our Chief Executive Officer and other Section 16 officers;
- reviewing and approving the compensation of our other officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable [NYSE American/Nasdaq] rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and recommending to the Board of Directors the policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the Board of Directors the compensation of our directors; and
- preparing the Compensation Committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

Nominating and Corporate Governance Committee

Joacim Borg, John Ciccio and Theodore Search serve on the Nominating and Corporate Governance Committee, which is chaired by Theodore Search. Our Board of Directors has determined that each member of the Nominating and Corporate Governance Committee is "independent" as defined in the applicable [NYSE American/Nasdaq] rules. We are permitted to phase in our compliance with the independent Compensation Committee requirements set forth by [NYSE American/Nasdaq] listing standards as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our Board of Directors intends to cause our Nominating and Corporate Governance Committee to comply with the transition rules within the applicable time periods. The Nominating and Corporate Governance Committee's responsibilities include:

- developing and recommending to the Board of Directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the Board of Directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the Board of Directors;

- recommending to the Board of Directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the Board of Directors appropriate corporate governance guidelines; and
- overseeing the evaluation of our Board of Directors.

Compensation Committee interlocks and insider participation

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

Corporate governance

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 to accounting officer, or controller, or persons performing similar functions. Following the effectiveness of the Registration Statement of which this prospectus is a part, a current copy of this code will be posted on the Corporate Governance section of our website, which is located at [•]. The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. 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.]

EXECUTIVE COMPENSATION

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act.

The compensation provided to our named executive officers for the fiscal years ended December 31, 2020, and 2021 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers for the fiscal year ended December 31, 2021, are:

- Paul Romness, our Chief Executive Officer & President;
- Christopher Acevedo, our Chief Financial Officer; and
- Robert Petit, our Chief Medical & Scientific Officer.

To date, the compensation of our named executive officers has consisted of a combination of base salary, cash bonuses and long-term incentive compensation in the form of stock options and restricted stock awards. Our named executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

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 fiscal years ended December 31, 2021, and 2020.

Name and principal position	Year	Salary ($)	Option awards ($)[1]	Non-Equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Paul Romness	2021	360,000	0	0	0	360,000
Chief Executive Officer and President	2020	360.000	0	0	0	360,000
Christopher Acevedo	2021	36,000	0	0	0	36,000
Chief Financial Officer	2020	14,000	0	0	0	14,000

(1) [These amounts represent the aggregate grant date fair value of stock option awards granted to our named executive officers during our fiscal year ended December 31, 2021, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 8 to our financial statements for the year ended December 31, 2021, included elsewhere in this prospectus. This amount does not correspond to the actual value that may be recognized by the named executive officer upon exercise of the applicable award or sale of the underlying shares of stock.]

Narrative disclosure to summary compensation table

2021 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 fiscal year ended December 31, 2021, the annual base salary for Mr. Romness was $360,000.

Each of our named executive officer's cash bonus is determined by reference to the achievement of predetermined corporate performance goals related to our research and development programs and corporate development. [Following review and determinations of corporate performance for 2020, the Board of Directors determined that the corporate performance goals were achieved at [•]% of target. The annual cash bonus paid to Mr. Romness for the fiscal year ended December 31, 2021, is set forth in the "*Non-Equity Incentive Plan Compensation*" column of the "*Summary Compensation Table*" above.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our Board of Directors during the year ended December 31, 2021. 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-employee members of our Board of Directors in 2021.

Name	Fees earned or paid in cash ($)	Option awards ($)	All other compensation ($)	Total ($)
Paul Romness	0	0	0	0
Colin Goddard Chairman of Board	10,000	0	40]	10,040
Joacim Borg	0]	0	40]	40
John Ciccio	0	0	40]	40
Theordore Search	0]	0	40]	40

_____

(2) [•].

Non-Employee Director Compensation Policy

Our Board of Directors has adopted a non-employee director compensation policy that will become effective upon the completion of this offering and is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	Annual retainer
Board of Directors:	
Members	$ 0
Additional retainer for Audit Committee chair	$ 0
Additional retainer for Compensation Committee chair	$ 0
Additional retainer for Nominating and Corporate Governance Committee chair	$ 0

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

Beneficial ownership is determined in accordance with the applicable rules and regulations of the SEC and includes voting or investment power with respect to our capital stock. Unless otherwise indicated, we believe that all persons named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them.

The percentage ownership of common stock of OST is based on [•] shares of common stock of OST outstanding, consisting of [•] shares of Class A common stock and [•] shares of Class B common stock issued and outstanding as of [•].

Beneficial Owner	Number of Shares of Common Stock	Total Number of Shares Beneficially Owned	Percentage of Common Stock Outstanding
Paul Romness			
Christopher Acevedo			
Jutta Wanner			
Robert G. Petit			
Colin Goddard			
Theodore F. Search			
John Ciccio			
All Directors and Executive Officers as a group, 7 persons			

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our tenth amended and restated certificate of incorporation, which will be effective upon the closing of this offering and amended and restated bylaws, which will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering.

General

Upon completion of this offering, our authorized capital stock will consist of [•] shares of common stock, par value $[0.00001] per share, and [•] shares of preferred stock, par value $[0.00001] per share, all of which shares of preferred stock will be undesignated.

As of September 30, 2022, [•] shares of our common stock were outstanding and held by [•] stockholders of record. This amount assumes the conversion of all outstanding shares of our preferred stock into common stock, which will occur immediately prior to the closing of this offering.

Class A and Class B common stock

The holders of our Class A common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights.

Holders of our Class B common stock have identical rights to holders of our Class A common stock, other than as follows: (i) except as otherwise expressly provided in our third amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, while holders of our Class A common stock are entitled to one vote per share of Class A common stock, holders of our Class B common stock are not entitled to any votes per share of Class B common stock, including for the election of directors, and (ii) while holders of our Class A common stock have no conversion rights, holders of our Class B common stock shall have the right to convert each share of our Class B common stock into one share of Class A common stock at such holder's election subject to the ownership limitations provided for in our third amended and restated certificate of incorporation that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder and any other persons with whom such holder's beneficial ownership would be aggregated for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of [•] % or [•] %, as applicable, based on the holder's election, of any class of our securities registered under the Exchange Act. Accordingly, the holders of a majority of the outstanding shares of Class A common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect.

Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares of Class A common stock to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred stock

Immediately prior to the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our Class A common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to [•] shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of Class A common stock. The issuance of our preferred stock could adversely affect

the voting power of holders of Class A common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration rights

Upon the completion of this offering, the holders of [•] shares of our Class A common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of our Investor Rights Agreement between us and the holders of our preferred stock. The Investor Rights Agreement includes demand registration rights, short-form registration rights, and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Beginning [•] months after the completion of this offering, the holders of [•] shares of our Class A common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, will be entitled to demand registration rights. Under the terms of the Investor Rights Agreement, we will be required, upon the written request of a majority of holders of the registrable securities then outstanding that would result in an aggregate offering price of at least $[•] million, to file a registration statement and to use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale.

Short-form registration rights

Upon the completion of this offering, the holders of [•] shares of our Class A common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are also entitled to short-form registration rights. Pursuant to the Investor Rights Agreement, if we are eligible to file a registration statement on Form S-3, upon the written request from any such holder to sell registrable securities at an aggregate price of at least $[•] million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any twelve-month period pursuant to this provision of the investor rights agreement.

Piggyback registration rights

Upon the completion of this offering, the holders of [•] shares of our Class A common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the Investor Rights Agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

The Investor Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short-form registration rights granted under the Investor Rights Agreement will terminate on the [•] anniversary of the completion of this offering.

Anti-takeover effects of our certificate of incorporation and bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock

Upon the completion of this offering, our certificate of incorporation will provide for [•] authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exclusive Forum

Our amended and restated bylaws to be adopted upon the completion of this offering will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or by-laws (including the interpretation, validity or enforceability thereof); or (4) any action asserting a claim that is governed by the internal affairs doctrine; provided, however, that this provision shall not apply to any causes of action arising under the Securities Act or the Exchange Act. In addition, our amended and restated bylaws will provide that, unless we consent to an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action under the Securities Act (the Federal Forum Provision). Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these forum provisions. These forum provisions may impose additional costs on stockholders and may limit our stockholders' ability to bring a claim in a forum they find favorable, and the designated courts may reach different judgements or results than other courts. In addition, there is uncertainty as to whether our Federal Forum Provision will be enforced, which may impose additional costs on us and our stockholders.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

NYSE American/Nasdaq Global Market listing

We intend to apply to list our Class A common stock on either the NYSE American or the Nasdaq Global Market under the trading symbol “OSTX”.

Transfer agent and registrar

The transfer agent and registrar for our common stock will be [•]. The transfer agent and registrar’s address is [•], and its telephone number is [•].

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2019, 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 five percent 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 prospectus under "Executive Compensation" and "Management — Director Compensation."

Shareholder Loan

Our founder, Paul Romness, took advances for compensation in 2020 and 2019 for living expenses. An agreement was made where the CEO would pay back these advances, with appropriate interest. The Board of Directors was notified of this agreement and approved it on December 15, 2020. The agreement was later modified as the Board determined the CEO was due market rate compensation for two years, spanning service dates of July 1, 2018, through June 30, 2020. As of January 1, 2021, all advances have been repaid, with interest. The balance as of December 31, 2020, was $200,272.65, which was fully repaid upon the execution of his backpay in 2021.

The awarded backpay for July 2018 through June 2019 was $120,000 and $240,000 for July 2019 to June 2020. In July 2020, normal payroll commenced for all employees. As of December 31, 2020, the back pay was paid in full.

Employee Advances

Employee advances were made upon hire. Repayment of the advances for employees are fully paid as of April 1, 2021.

[2021 & 2022 RELATED PARTY TRANSACTIONS TO BE ADDED]

MARKET PRICE AND DIVIDENDS ON REGISTRANT'S COMMON EQUITY

Market Information

There is no established public trading market in our common stock. Our securities are not listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

Securities Authorized for Issuance under Equity Compensation Plans

[As of December 31, 20__, the Company issued _____ unrestricted shares of common stock to employees and consultants pursuant to written individual compensation agreements, which agreements were not approved by our security holders.

Holders

As of _____, 20___, there were _____ shares of common stock outstanding, which were held by approximately ___ record holders. In addition, there were _____ shares of our Series A preferred stock outstanding, which were held by one record holder and there were _____ shares of our Series B preferred stock outstanding, which were held by one record holder. As of _____, 20__, each share of Series A preferred stock was convertible into common stock on a one for one basis and each share of Series B preferred stock was convertible into common stock into what would equal ten percent of the outstanding common stock of the Company. For more information, please see "Item 11. Description of Registrant's Securities to be Registered — Series A and Series B Preferred Stock."

As of the date of this Registration Statement, we have no present commitments to issue shares of our capital stock to any 5% holder, director or nominee.]

Dividends

We have never paid cash dividends on any of our capital stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

SHARES ELIGIBLE FOR FUTURE SALE

Before our initial public offering, there has not been a public market for shares of our Common Stock. Future sales of substantial amounts of shares of our Common Stock in the public market after our initial public offering, or the possibility of these sales occurring, could cause the prevailing market price for our Common Stock to fall or impair our ability to raise equity capital in the future.

After our initial public offering, we will have outstanding shares of our Common Stock, based on the number of shares outstanding as of December 31, 20__. This includes shares that we intend to sell in our initial public offering, which shares may be resold in the public market immediately following our initial public offering.

The shares of Common Stock that were not offered and sold in our initial public offering will be upon issuance, "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below.

[As a result of the lock-up agreements and market standoff provisions described below and subject to the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

- on the date of this prospectus, none of these restricted securities will be available for sale in the public market;
- [•] days after the date of this prospectus, shares; and
- [•] days after the date of this prospectus, shares held by the selling stockholders.

Rule 144

For a person who has not been deemed to have been one of our affiliates at any time during the 90 days preceding a sale, sales of our shares of common stock held longer than six months, but less than one year, will be subject only to the current public information requirement and can be sold under Rule 144 beginning 90 days after the effectiveness of this Registration Statement without restriction. A person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell his or her shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

Beginning 90 days after the effectiveness of this Registration Statement, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, will generally be entitled to sell within any three-month period a number of shares that does not exceed one percent of the number of shares of our common stock then outstanding. Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Persons who may be deemed to be our affiliates generally include individuals or entities that control, or are controlled by, or are under common control with, us and may include our directors and officers, as well as our significant stockholders.

Approximately [ ] shares of our Common Stock will be eligible for sale under Rule 144 90 days following the effective date of this Registration Statement. In _____ 20__, _____ additional shares will become eligible for sale under Rule 144, subject to applicable volume limitations. We cannot estimate the number of shares of our Common Stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

Rule 701 under the Securities Act permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement and the volume and public information requirements. Any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effective date of this Registration Statement before selling their shares under Rule 701. None of our currently outstanding shares, other than the [ ] shares that will otherwise become eligible for resale under Rule 144, will become eligible for sale pursuant to Rule 701 90 days following the effective date of this Registration Statement.

Lock-Up Agreements and Market Standoff Provisions

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of [•]. See the section entitled "Underwriting" appearing elsewhere in this prospectus for more information.

See "*Underwriting*" for a more complete description of the lock-up agreements our directors, and executive officers have entered into with the underwriters.

[Registration Rights

Upon the closing of our initial public offering, certain holders of shares of our Common Stock will be entitled to rights with respect to the registration of the sale of these shares under the Securities Act. Registration of the sale of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See "*Description of Capital Stock — Registration Rights*" for additional information.]

Registration Statement

[We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock reserved for future issuance under our stock plans. We expect to file this registration statement as soon as practicable after our initial public offering. However, none of the shares registered on Form S-8 will be eligible for resale until the expiration of the lock-up agreements to which they are subject.]

UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following discussion is a summary of certain material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a "non-U.S. holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a nonresident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. We have not sought any ruling from the Internal Revenue Service, which we refer to as the IRS, with respect to the statements made and the conclusions reached in this summary, and there can be no assurance that the IRS will not challenge one or more of the tax consequences described herein. We assume in this discussion that each non-U.S. holder holds shares of our common stock as a "capital asset" within the meaning of Section 1221 of the Code, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, any tax treaties or any U.S. federal tax other than the income tax (including, for example, the estate tax). This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and partners and investors therein);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;

- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who have elected to mark securities to market;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- investors in pass-through entities (or entities that are treated as disregarded entities for U.S. federal income tax purposes); and
- U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock, including the consequences of any proposed changes in applicable laws.

Distributions on our common stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale or other taxable disposition of our common stock." Any such distributions will also be subject to the discussion below under the section titled "Withholding and information reporting requirements — FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we are unable to determine, at a time reasonably close to the date of payment of a distribution on our common stock, what portion, if any, of the distribution will constitute a dividend, then we may withhold U.S. federal income tax on the basis of assuming that the full amount of the distribution will be a dividend. If we or another withholding agent apply over-withholding, a non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To obtain this exemption, a non-U.S. holder must generally provide us with a properly executed original IRS Form W-8ECI properly certifying such exemption. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to "United States persons" (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. The certification requirements described above may require a non-U.S. holder to provide its U.S. taxpayer identification number. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on sale or other taxable disposition of our common stock

Subject to the discussion below under "Backup withholding and information reporting" and "Withholding and information reporting requirements — FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to "United States persons" (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on our common stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market, within the meaning of the relevant provisions of the Code, and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to "United States persons" (as defined in the Code), except that the branch profits tax generally will not apply. If we are a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, a non-U.S. holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its "U.S. real property interests" (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation for U.S. federal income tax purposes, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Non-U.S. holders should consult their tax advisors with respect to the application of the foregoing rules to their ownership and disposition of our common stock.

Backup withholding and information reporting

We (or the applicable paying agent) must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a "United States person" (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on our common stock," generally will be exempt from U.S. backup withholding if the non-U.S. holders establish an exemption by properly certifying their non-U.S. status on an IRS Form W-8BEN or W-8BEN-E (or other applicable or successor form).

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and information reporting requirements — FATCA

Legislation commonly referred to as the Foreign Account Tax Compliance Act ("FATCA") generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of proceeds of sales or other dispositions of our common stock, although under proposed U.S. Treasury Regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization), no withholding will apply to payments of gross proceeds. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock, but will only apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

In connection with this offering, we expect to enter an underwriting agreement with Boustead Securities, LLC, as the representative of the underwriters named in this prospectus, with respect to the Class A common stock in this offering. Under the terms and subject to the conditions contained in the underwriting agreement, the representative will agree to purchase from us on a firm commitment basis the respective number of shares of Class A common stock at the public price less the underwriting discounts set forth on the cover page of this prospectus, and each of the underwriters has severally and not jointly agreed to purchase, and we have agreed to sell to the underwriters, at the public offering price per shares less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of Class A common stock listed next to its name in the following table:

Underwriter	Number of Shares
Boustead Securities, LLC	0
Total	**0**

The shares of Class A common stock sold by the underwriters to the public will initially be offered at the initial public offering price range set forth on the cover page of this prospectus. Any shares of Class A common stock sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed $ per share. If all of the shares are not sold at the initial offering price, the representative may change the offering price and the other selling terms. The representative has advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more shares of Class A common stock than the total number set forth in the table above, we have granted to the representative an option, exercisable for 45 days from the date of this prospectus, to purchase up to additional shares of Class A common stock at the public offering price less the underwriting discount, constituting 15% of the total number of shares of Class A common stock to be offered in this offering (excluding shares subject to this option). The representative may exercise this option solely for the purpose of covering over-allotments in connection with this offering. This offering is being conducted on a firm commitment basis. Any shares of Class A common stock issued or sold under the option will be issued and sold on the same terms and conditions as the other shares of Class A common stock that are the subject of this offering.

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in compliance with Regulation M under the Exchange Act, as described below:

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing securities in the open market.
- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared to the price at which they may purchase securities through the over-allotment option. A naked short position occurs if the underwriters sell more securities than could be covered by the over-allotment option. This position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in this offering.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of the securities. As a result, the price of our shares of Class A common stock may be higher than the price that might otherwise exist in the open market. These transactions may be discontinued at any time.

Discounts and Expenses

The following table shows the underwriting discounts payable to the underwriters by us in connection with this offering (assuming both the exercise and non-exercise of the over-allotment option that we have granted to the representative), based on the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus:

	Per Share	Total Without Over-Allotment Option	Total With Entire Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions (%)	$	$	$
Non-accountable expense allowance (%)	$	$	$
Proceeds, before expenses, to us	$	$	$

We have agreed to pay a non-accountable expense allowance to the representative equal to % of the gross proceeds received at the closing of the offering.

We have agreed to pay the representative the reasonable out-of-pocket expenses incurred by the representative in connection with this offering up to $258,000. The representative's reimbursable out-of-pocket expenses include but are not limited to: (i) reasonable fees of representative's legal counsel up to $100,000, (ii) due diligence and other expenses incurred prior to completion of this offering up to $75,000, (iii) road show, travel, platform on-boarding fees, and other reasonable out-of-pocket accountable expenses up to $75,000, and (iv) $8,000 for background check on our officers, directors and major shareholders. As of the date of this prospectus, we have paid the representative advances of $ for its anticipated out-of-pocket costs. Such advance payments will be returned to us to the extent such out-of-pocket expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

Representative's Warrants

We have agreed to issue warrants to the representative to purchase a number of shares of Class A common stock equal to 7% of the total number of shares sold in this offering at an exercise price equal to 100% of the public offering price of the shares sold in this offering. The underwriters' warrants will be exercisable upon issuance, will have a cashless exercise provision and will terminate on the fifth anniversary of the commencement date of sales in this offering. The underwriters' warrants are not exercisable or convertible for more than five years from the commencement date of sales in this offering. The underwriters' warrants also provide for customary anti-dilution provisions and immediate "piggyback" registration rights with respect to the registration of the shares of Class A common stock underlying the warrants for a period not to exceed five years from the commencement of sales in the offering. We have registered the underwriters' warrants and the shares underlying the underwriters' warrants in this offering.

The underwriters' warrant and the underlying shares may be deemed to be compensation by FINRA, and therefore will be subject to FINRA Rule 5110(e)(1). In accordance with FINRA Rule 5110(e)(1), neither the underwriters' warrant nor any of our shares of Class A common stock issued upon exercise of the underwriters' warrants may be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities by any person, for a period of 180 days immediately following the commencement date of sales in this offering, subject to certain exceptions. The underwriters' warrant to be received by the representative and related persons in connection with this offering: (i) fully comply with lock-up restrictions pursuant to FINRA Rule 5110(e)(1); and (ii) fully comply with transfer restrictions pursuant to FINRA Rule 5110(e)(2).

Determination of Offering Price

In determining the initial public offering price, we and the representative have considered a number of factors, including:

- the information set forth in this prospectus and otherwise available to the representative;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future revenue and earnings;
- the recent prices of, and demand for, shares sold by us prior to this offering;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded securities of generally comparable companies; and
- other factors deemed relevant by the representative and us.

The estimated initial public offering price set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the representative can assure investors that an active trading market will develop for our shares of Class A common stock, or that the shares will trade in the public market at or above the initial public offering price.

We have agreed to indemnify the representative and the other underwriters against certain liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments that the representative and the other underwriters may be required to make for these liabilities.

Right of First Refusal

We have agreed to provide the representative the right of first refusal for twelve months following the consummation of this offering, to act as sole investment banker, sole book-runner, and/or sole placement agent, at the representative's sole discretion, for each and every equity or debt transaction, including future public and private equity and/or debt offerings, including all equity linked financings, whether in conjunction with another advisor, or broker-dealer, or on our own volition. In the event that we engage the representative to provide such services, the representative will be compensated consistent with our engagement agreement with the representative, unless we mutually agree otherwise.

Tail Rights

Following the termination or expiration of our engagement agreement with the representative, the representative shall be entitled to success fees in accordance with our engagement agreement if we complete a transaction with a party who became aware of us or who became known to us prior to such termination or expiration of the engagement agreement.

Company Lock-Up

We will not, without the prior written consent of the representative, from the date of execution of the Underwriting Agreement and continuing for a period of months from the date on which the trading of our common stock commences (the "Lock-Up Period"), (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, change the terms of (including to re-price) or grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, or file with the Commission a registration statement under the Securities Act relating to, our common stock or any securities convertible into or exercisable or exchangeable for our common stock, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or any

such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise. We will agree not to accelerate the vesting of any option or warrant or allow the lapse of any repurchase right prior to the expiration of the Lock-Up Period.

Our officers, directors and holders of approximately % of our outstanding common stock have agreed to be locked up for a period of months from the date on which the trading of our Class A common stock commences. During the lock-up period, without the prior written consent of the representative, they shall not, directly or indirectly, (i) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, lend, grant, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any shares of Class A common stock or any securities convertible into or exercisable or exchangeable for Class A common stock, owned either of record or beneficially, by any signatory of the lock-up agreement on the date of the prospectus or thereafter acquired; (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Class A common stock or any securities convertible into or exercisable or exchangeable for Class A common stock, whether any such transaction described in clauses (i) or (ii) above is to be settled by delivery of Class A common stock or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing; and (iii) make any demand for or exercise any right with respect to, the registration of any shares of Class A common stock or any security convertible into or exercisable or exchangeable for Class A common stock.

Electronic Offer, Sale and Distribution of Shares of Common Stock

A prospectus in electronic format may be made available on the websites maintained by the representative. In addition, shares of Class A common stock may be sold by the representative to securities dealers who resell shares of Class A common stock to online brokerage account holders. Other than the prospectus in electronic format, the information on the representative's website and any information contained in any other website maintained by the representative is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the representative in its capacity as representative and should not be relied upon by investors.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the shares of Class A Common Stock offered by this prospectus will be passed upon for us by Greenberg Traurig, P.A. Certain legal matters related to this offering will be passed upon for the underwriters by Arent Fox Schiff LLP, Washington, DC.

EXPERTS

The financial statements of OS Therapies, Inc. as of December 31, 2020 and 2021, and for each of the years then ended, have been included herein in reliance upon the report of MaloneBailey, LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC the Registration Statement on Form S-1 (File Number) under the Securities Act with respect to the Class A common stock we are offering by this prospectus. For further information pertaining to us and our Class A common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at *www.sec.gov*. We also maintain a website at *www.ostherapies.com*. Upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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FINANCIAL STATEMENTS

The financial statements of OS Therapies, Inc. for the years ended December 31, 2020, and December 31, 2021, and related notes, included in this prospectus have been audited by Malone and Bailey, LLP anour independent registered public accounting firm independent accountants, and have been so included in reliance upon the opinion of such accountants given upon their authority as an expert in auditing and accounting. The financial statements as of [September 30, 2022__ and for the nine months ended September 30, 2021 and 2022], have been prepared by management without audit.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
OS Therapies, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of OS Therapies, Inc. (the "Company") as of December31, 2021 and 2020, and the related statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the 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.

Critical Audit Matters

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

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2020.
Houston, Texas
October 11, 2022

OS Therapies, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	Dec. 31, 2021	Dec. 31, 2020
ASSETS		
Current Assets		
Cash	$ 80,788	$ 1,232,776
Employee Advances	956	12,800
Shareholder Loan Receivable	229,925	430,488
Total Current Assets	**311,669**	**1,676,064**
Long Term Assets		
Fixed Assets (Net)	13,076	1,947
TOTAL ASSETS	**$ 324,745**	**$ 1,678,011**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	$ 856,521	$ 40
Accrued Expenses	—	595,000
Accrued Interest on Convertible Notes	601,410	214,029
Accrued Payroll and Payroll Taxes	367,020	422,810
Redemption Premium	1,612,054	871,250
Preferred Dividends Payable	93,750	—
Total Current Liabilities	**3,530,755**	**2,103,129**
Long Term Liabilities		
Convertible Notes – A (net Debt Discount and Debt Issuance Cost)	999,613	771,632
Convertible Notes – A Related Party (net Debt Discount and Debt Issuance Cost)	97,497	92,501
Convertible Notes – B (net Debt Discount and Debt Issuance Cost)	4,906,862	2,637,566
Convertible Notes – C (net Debt Discount)	1,335,635	—
Convertible Note – Blink Bio	—	2,400,000
TEDCO Grant	100,000	—
Total Long Term Liabilities	**7,439,607**	**5,901,699**
TOTAL LIABILITIES	**10,970,362**	**8,004,828**
STOCKHOLDERS' DEFICIT		
Common A Stock, par value $0.001, 50,000,000 shares authorized, 8,221,000 shares issued (2021) and 8,835,000 shares issued(2020)	8,221	8,221
Common B Stock, par value $0.001, 20,000,000 shares authorized, 614,000 shares issued(2021)	614	614
Preferred A Stock, par value $0.001, 5,000,000 shares authorized, 1,302,820 Preferred A Shares issued(2021)	1,302	—
Additional Paid In Capital	2,498,698	—
Accumulated deficit	(13,154,453)	(6,335,652)
Total Stockholders' Deficit	**(10,645,618)**	**(6,326,817)**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 324,745**	**$ 1,678,011**

OS Therapies, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended	
	December 31, 2021	**December 31, 2020**
OPERATING EXPENSES		
Research & Development Expenses	$ 2,174,179	601,777
General & Administrative	1,231,052	795,424
Licensing costs	1,159,642	4,250,000
Total Operating Expenses	**4,564,873**	**5,647,201**
Loss from Operations	**(4,564,873)**	**(5,647,201)**
OTHER INCOME/EXPENSE		
Interest Income – related party (See Note 3)	—	61,285
Consulting Income	—	20,000
Interest Expense	(2,160,177)	(461,785)
Total Other Income/Expense	**(2,160,177)**	**(380,500)**
NET LOSS	**$ (6,725,050)**	**$ (6,027,701)**
Cumulative Series A Preferred Stock Dividend Requirement	(93,750)	—
NET LOSS available to common stockholders	**(6,818,800)**	**(6,027,701)**
Basic & Diluted Loss per Common Share Class A	$ (0.77)	$ (0.71)
Basic & Diluted Loss per Common Share Class B	$ (0.77)	$ (0.58)
Weighted Average Shares Outstanding Class A	8,221,000	7,808,082
Weighted Average Shares Outstanding Class B	614,000	614,000

OS Therapies, Inc.
Statement of Stockholders' Deficit
For the Years Ended December 2021 and 2020

	Common Stock				Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	CS A Shares	CS A Amount	CS B Shares	CS B Amount	Shares	Amount			
Balances, December 31, 2019	**6,122,000**	**6,122**	**614,000**	**614**	**—**	**—**	**—**	**(307,951)**	**(301,215)**
Stock Sold	2,099,000	2,099	—	—	—	—	—	—	2,099
Net Loss 2020	—	—	—	—	—	—	—	(6,027,701)	(6,027,701)
Balances, December 31, 2020	**8,221,000**	**8,221**	**614,000**	**614**	**—**	**—**	**—**	**(6,335,652)**	**(6,326,817)**
Conversion of Debt and interest to Preferred Shares	—	—	—	—	1,302,082	1,302	2,498,698	—	2,500,000
Preferred Dividends	—	—	—	—	—	—	—	(93,750)	(93,750)
Net loss	—	—	—	—	—	—	—	(6,725,050)	(6,725,050)
Balances, December 31, 2021	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(13,154,452)**	**(10,645,617)**

OS Therapies, Inc.
Statements of Cash Flows
For the Years Ended December 2021 and 2020

	Twelve months ended	
	December 31, 2021	**December 31, 2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (6,725,050)	$ (6,027,701)
Depreciation Expense	805	67
Amortization of Debt Discounts – Redemption Liability	1,628,362	273,400
Preferred Stock issued for interest	100,000	—
Convertible Debt for License – Blink Bio	—	2,400,000
Shareholder Loan Interest	—	(61,285)
Shareholder Loan Repayment through payroll	—	38,000
Adjustments to reconcile net loss to net cash used in operating activities:		
Accounts Payable	856,481	9
Accrued Expenses	(595,000)	595,000
Accrued Interest on Convertible Notes	387,381	190,053
Accrued Payroll and payroll taxes	(55,790)	179,330
Net cash used in operating activities	(4,402,811)	(2,413,127)
CASH FLOWS FROM INVESTING ACTIVITIES		
Employee Advances	11,844	(12,800)
Purchases of Equipment	(11,934)	(2,014)
Increase/Decrease in Shareholder Loan	563	(276,899)
Shareholder Loan Repayment	200,000	450,000
Net cash provided by investing activities	200,473	158,287
CASH FLOWS FROM FINANCING ACTIVITIES		
TEDCO Grant	100,000	—
Repayment of debt	—	(120,000)
Sale of Common Stock	—	2,099
Net Proceeds from Convertible Debt – A, B, & C	2,950,350	3,595,577
Net cash provided by financing activities	3,050,350	3,477,676
Net change in cash and cash equivalents	(1,151,988)	1,222,836
Cash and cash equivalents – beginning of period	1,232,776	9,940
Cash and cash equivalents – end of period	$ 80,788	$ 1,232,776
Cash paid during the year for Interest	$ 10,000	$ 10,000
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Redemption Premium – Discount	740,804	805,125
Conversion of Convertible Note and accrued interest to preferred stock	2,400,000	—
Preferred Dividends Payable	93,750	—

OS Therapies, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	$ 39,176	$ 80,788
Employee Advances	—	956
Deferred Offering Costs	50,000	—
Shareholder Loan Receivable	—	229,925
Total Current Assets	**89,176**	**311,669**
Long Term Assets		
Fixed Assets (Net)	13,076	13,076
TOTAL ASSETS	**$ 102,252**	**$ 324,745**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	$ 1,152,608	$ 856,521
Accrued Interest on Convertible Notes	1,072,151	601,410
Accrued Payroll and Payroll Taxes	508,311	367,020
Redemption Premium	2,014,054	1,612,054
Preferred Dividends Payable	187,500	93,750
Shareholder Loan Payable	115,000	—
Total Current Liabilities	**$ 5,048,624**	**3,530,755**
Long Term Liabilities		
Convertible Notes – A (net Debt Discount and Debt Issuance Cost)	1,030,284	999,613
Convertible Notes – A Related Party (net Debt Discount and Debt Issuance Cost)	100,000	97,497
Convertible Notes – B (net Debt Discount and Debt Issuance Cost)	5,154,000	4,906,862
Convertible Notes – C (net Debt Discount)	3,111,285	1,335,635
TEDCO Grant	100,000	100,000
Total Long Term Liabilities	**9,495,567**	**7,439,607**
TOTAL LIABILITIES	**$ 14,544,191**	**10,970,362**
STOCKHOLDERS' DEFICIT		
Preferred A Stock, par value $0.001, 5,000,000 shares authorized, 1,302,820 Preferred A Shares issued (2021)	1,302	1,302
Common A Stock, par value $0.001, 50,000,000 shares authorized, 8,221,000 shares issued (2021) and 8,835,000 shares issued (2020)	8,221	8,221
Common B Stock, par value $0.001, 20,000,000 shares authorized, 614,000 shares issued (2021)	614	614
Additional Paid In Capital	2,498,698	2,498,698
Accumulated deficit	(16,950,776)	(13,154,453)
Total Stockholders' Deficit	**(14,441,941)**	**(10,645,618)**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 102,252**	**$ 324,745**

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

OS Therapies, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
OPERATING EXPENSES		
Research & Development Expenses	$ 2,193,614	$ 1,481,210
General & Administrative	511,048	948,261
Licensing costs	1,210	1,141,165
Total Operating Expenses	**2,705,872**	**3,570,637**
Loss from Operations	**(2,705,872)**	**(3,570,637)**
OTHER INCOME/EXPENSE		
Interest Expense	(996,700)	(1,489,055)
Total Other Income/Expense	**(996,700)**	**(1,489,055)**
NET LOSS	**(3,702,572)**	**(5,059,691)**
Cumulative Series A Preferred Stock Dividend Requirement	(93,750)	(93,750)
NET LOSS available to common stockholders	**$ (3,796,322)**	**$ (5,153,441)**
Basic & Diluted Loss per Common Share Class A	$ (0.42)	$ (0.57)
Basic & Diluted Loss per Common Share Class B	$ (0.42)	$ (0.57)
Weighted Average Shares Outstanding Class A	8,221,000	8,221,000
Weighted Average Shares Outstanding Class B	614,000	614,000

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

OS Therapies, Inc.
Statement of Stockholders' Deficit
For the Years Ended December 2021 and 2020

	Common Stock				Preferred Stock		Additional		Total
	CS A Shares	CS A Amount	CS B Shares	CS B Amount	Shares	Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
Balances, December 30, 2020	**8,221,000**	**8,221**	**614,000**	**614**	**—**	**—**	**—**	**(6,335,652)**	**(6,326,817)**
Conversion of Debt and interest to Preferred Shares	—	—	—	—	1,302,082	1,302	2,498,698	—	2,500,000
Preferred Dividends	—	—	—	—	—	—	—	(62,500)	(62,500)
Net Loss	—	—	—	—	—	—	—	(5,059,691)	(5,059,691)
Balances, September 30, 2021	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(11,457,843)**	**(8,949,007)**
Balances, December 30, 2021	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(13,154,453)**	**(10,645,618)**
Preferred Dividends	—	—	—	—	—	—	—	(93,750)	(93,750)
Net loss	—	—	—	—	—	—	—	(3,702,574)	(3,702,574)
Balances, September 30, 2022	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(16,950,774)**	**(14,441,941)**

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

OS Therapies, Inc.
Statements of Cash Flows

	September 30, 2022	September 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (3,702,574)	$ (5,059,691)
Amortization of Debt Discounts – Redemption Liability	525,961	1,184,510
Preferred Stock issued for interest	—	100,000
Adjustments to reconcile net loss to net cash used in operating activities:		
Accounts Payable	295,086	551,174
Accrued Expenses	—	(595,000)
Accrued Interest on Convertible Notes	470,741	160,111
Accrued Payroll and payroll taxes	141,291	(62,295)
Net cash used in operating activities	**(2,269,493)**	**(3,721,191)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Employee Advances	956	11,844
Purchases of Equipment	—	(4,831)
Increase/Decrease in Shareholder Loan Receivable	—	564
Shareholder Loan Repayment	229,925	200,000
Net cash provided by investing activities	**230,881**	**207,577**
CASH FLOWS FROM FINANCING ACTIVITIES		
TEDCO Grant	—	50,000
Deferred Offering Costs	(50,000)	—
Increase/Decrease in Shareholder Loan Payable	115,000	—
Net Proceeds from Convertible Debt – A, B, & C	1,932,000	2,394,715
Net cash provided by financing activities	**1,997,000**	**2,444,715**
Net change in cash and cash equivalents	(41,612)	(1,068,900)
Cash and cash equivalents – beginning of period	80,788	1,232,776
Cash and cash equivalents – end of period	$ 39,176	$ 163,877
Cash paid during the year for Interest	$ —	$ —
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Redemption Premium – Discount	$ 402,000	$ 624,377
Conversion of Convertible Note and accrued interest to preferred stock	—	2,400,000
Preferred Dividends Payable	93,750	62,500

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

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

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

OS Therapies Inc. ("we," "us," "our," the "Company") is a Delaware corporation incorporated on June 24, 2019. It is based in Cambridge, 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 2021, there is one ongoing clinical trial for osteosarcoma therapy.

Liquidity

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

As of December 31, 2021, the Company had cash of $80,788. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital. The company is currently seeking to raise additional capital through a public or private financing of equity, although there are no assurances, we will be successful in such a campaign.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Use of Estimates

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

Cash

Cash and cash equivalents consist 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. At December 31, 2021, there were no accounts in excess of the FDIC limits.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Fixed Asset Policy

A capital asset is defined as a unit of property that has an economic useful life that extends beyond 12 months. Any items costing below the threshold or not fitting the definition of a capital asset will be expensed in the financial statements. All capital assets are recorded at historical cost as of the date acquired. Computer assets will be capitalized and Straight-Line depreciated over 5-years for financial statement purposes.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded as of December 31, 2021 & 2020.

Debt Discount and Derivative Instruments

The initial fair value of the redemption value relating to the convertible debt instruments are capitalized and amortized over the term of the related debt using the straight-line method, which approximates the interest method. If a loan is paid in full, any unamortized financing costs will be removed from the related accounts and charged to operations. Amortization of debt discount is recorded as a component of interest expense. In accordance with ASU 2015-03, Interest — Imputation of Interest, the unamortized debt discount is presented in the accompanying balance sheet as a direct deduction from the carrying amount of the related debt.

The Company accounts for derivative instruments in accordance with Accounting Standards Codification ("ASC") ASC 815, Derivative and Hedging ("ASC 815"), which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value.

The Company's derivative financial instrument consists of an embedded option in the Company's convertible debt. The embedded derivative includes provisions that provide the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for the Company.

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

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

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.

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 bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of a change in tax rate is recognized in the period that includes the enactment date. A valuation allowance is recorded if it is "more likely than not" that some portion or all of the deferred tax assets will not be realized in future periods.

The Company follows the guidance in ASC Topic 740-10 in assessing uncertain tax positions. The standard applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely- than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to be recognized. Tax positions that meet the more-likely than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more likely than not to be sustained by the relevant taxing authority.

The Company will recognize interest and penalties related to tax positions in income tax expense. As of December 31, 2021 and 2020, the Company had no unrecognized uncertain income tax positions.

Basic and Diluted Loss per Share

The Company computes loss per share in accordance with ASC 260, Earnings per Share ("ASC 260"). ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the statements of operations. Basic EPS is computed by dividing 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 dilutive potential shares if their effect is antidilutive.

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

	Total Number of Shares	
Common Stock Equivalents	**12/31/2021**	**12/31/2020**
Convertible Debt	11,968,285*	3,045,040*
Common Stock	8,835,000	8,835,000
Preferred Stock	1,302,082	—
Total	**22,105,367**	**11,880,040**

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Basic and Diluted Loss per Share

	Twelve Months Ended			
	December 31, 2021		December 31, 2020	
	Class A	Class B	Class A	Class B
Numerator:				
Allocation of net loss, as adjusted	$ (6,344,918)	(473,882)	(5,506,975)	(358,156)
Basic & Diluted Weighted Average shares outstanding	8,221,000	614,000	7,808,082	614,000
Denominator:				
Basic & Diluted net loss per ordinary Share	$ (0.77)	(0.77)	(0.71)	(0.58)

The number of shares issuable upon the conversion of convertible debt and accrued interest cannot be determined at this time, since the number of shares exercisable into is based on a number of possible outcomes.

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 prepaid expenses, accounts payable and accrued expenses 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).

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.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

Recent Accounting Pronouncements

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

Accounting policies being evaluated:

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) which replaces the existing guidance in ASC 840 — Leases. This ASU requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. This ASU is effective for fiscal years beginning after December 15, 2021, and for interim periods within those fiscal years. The Company is currently evaluating the impact of this adoption on its financial statements

Accounting principles adopted:

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*. This amendment modifies the disclosure requirements for fair value measurements. The guidance is effective for all entities for fiscal years ending after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted. The guidance was adopted as of January 1, 2020. The impact on the Company's financial position, results of operations and cash flows was negligible.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting.* ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The Company adopted this standard effective January 1, 2019. Effective January 1, 2019, the date of adoption, the Company changed its expense recognition for share-based payments to non-employees to an amount determined at the grant or modification date instead of a variable amount to be re-measured each reporting period. The Company calculated the fair value of its non-employee grants as of the adoption date and determined that there was no impact to the Company's accumulated deficit or other components of equity upon adoption of ASU 2018-07. The unamortized expense for non-employee grants will be recognized on a straight-line basis over the remaining contractual term of the respective non-employee option agreements. The adoption of ASU 2018-07 did not have a material impact on the Company's financial statements.

In January 2021, the Company early adopted ASU 2020-06 *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40).* ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and limiting the number of embedded conversion features separately recognized from the primary contract. The guidance also includes targeted improvements to the disclosures for convertible instruments and earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020.

NOTE 3 — RELATED PARTY TRANSACTIONS

Shareholder Loan

The Company founder, Paul Romness, took advances from the company of $0 and $338,184 in 2021 and 2020, respectively. On December 15, 2020, The Board of Directors approved an agreement whereby the CEO would pay back these advances, with appropriate interest. The agreement was later modified as the Board determined the CEO was due market rate compensation for two years (July 2018 through June 2020 was $120,000, and $240,000 for July 2020 to June 2021).

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 3 — RELATED PARTY TRANSACTIONS (cont.)

In the fourth quarter of 2022, a $360,000 bonus check will be issued to Paul Romness, CEO. The payroll taxes will be paid, and the net paycheck will be applied to the Paul Romness loan receivable, fully satisfying the debt. The $360,000 is comprised of backpay (see paragraph above).

The following summarizes activity under the related party loan:

Balance December 31, 2019	**$**	**580,304**
Borrowings during 2020		276,899
Interest income during 2020		61,285
Repayment from salary during 2020		(38,000)
Repayment		(450,000)
Balance December 31, 2020		**430,488**
Contributions during 2021		(564)
Repayment		(200,000)
Balance December 31, 2021	**$**	**229,925**

The Company had $240,000 of payroll due to the CEO, and related payroll taxes of $3,480 at December 31, 2019. During 2020, the CEO earned $120,000 of compensation. As such, at December 31, 2020, the Company had a payroll payable to the CEO of $360,000 and related income taxes payable of $5,220. In 2021, The Company and the CEO agreed to no imputed interest for the CEO as the debt owed to and from the CEO net a difference of the payroll taxes due.

In 2021, the CEO made personal payments towards business expenses in the amount of $563.65 which were credited against his Shareholder loan.

Employee Advances

In 2019, there were two short term advances given to the Company in the amounts of $10,000 and $100,000 from Jeffrey Stewart, Interim COO, and Mac Tichenor, Investor, respectively. The advancements were repaid in full by July 2020, with no interest accrued or expected.

Director was paid $12,500 in June 2021 as a subcontractor. After the payment was issued, he requested to be paid as a W-2. The $956.25 represents the advanced payroll taxes to be repaid on the 2022 wages.

Accrued Expenses

In November 2020, compensation in the amount of $250,000 was accrued for an exit package for former COO, Jeffrey Stewart. The payment was made in March 2021.

Related Parties — Convertible Debt

Of the total outstanding notes at December 31, 2021, 10.4% of Group A and 0% of Group B are held by related parties. Ted Search and John Ciccio, collectively known as Mill Partners LLC, are members of the Board and hold convertible notes with face amounts of $97,497 as of December 31, 2021 and $92,501 as of December 31, 2020.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 4 — CONVERTIBLE DEBT

Convertible Debt

The Convertible Notes are separated into four groups — A, B,C and BlinkBio — per the table below.

Group	Rate	Maturity	Collateral	Conversion Rate	2021 Carrying Amount	2020 Carrying Amount
A	10%	Varies	None	87.5% – 100%	$ 1,097,110	$ 864,133
B	6%	3/31/2022	None	80%	$ 4,906,863	$ 2,637,567
C	6%	3/31/2024	None	80%	$ 1,335,635	$ 0
Blink Bio	10%	3/15/2022	None	100%	$ 0	$ 2,400,000

Group A

Commencing in September 2018 through 2020, 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 shall 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). In general, the stated Maturity Date varies from the date of issuance.

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 87.5 – 100% 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 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 shall 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 and 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.

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $144,250 and $119,250, for the years 2021 and 2020, respectively. Accrued interest expense associated with the Notes at December 31, 2021 and 2020 amounted to $113,460 and $112,162, respectively.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 4 — CONVERTIBLE DEBT (cont.)

The accrued convertible debt balance at December 31, 2021 and 2020 is summarized as follows:

	December 31,	
	2021	**2020**
Principal amount outstanding	$ 1,154,000	$ 954,000
Less: debt issuance costs	(37,528)	(37,528)
Amortization of debt issuance	27,509	14,244
Less: redemption premium	(144,250)	(119,250)
Amortization of redemption premium (debt discount)	97,378	52,6677
Carrying value	$ 1,097,110	$ 864,133

The following table breaks out Group A and Group A-Related Party totals per year:

	2021			2020		
	Group A	**Group A Related Party**	**2021 Total**	**Group A**	**Group A Related Party**	**2020 Total**
Principal amount outstanding	$ 971,632	$ 92,501	$ 1,064,113	$ 790,511	$ 97,335	$ 887,846
Less: Debt issuance costs,	—	—	—	(16,528)	—	(16,528)
Amortization of debt issuance (legal fees)	13,265	—	13,265	9,543	—	9,543
Debt Issuance Total	*13,265*	—	*13,265*	*(6,985)*	—	*(6,985)*
Less: Redemption premium (RP)	(25,000)	—	(25,000)	(43,750)	(9,375)	(53,125)
Amortization of RP (debt discount)	39,716	4,995	44,711	31,856	4,541	36,397
Debt Discount Total	*14,716*	*4,995*	*19,711*	*(11,894)*	*(4,834)*	*(16,728)*
Carrying value	$ 999,613	$ 97,496	$ 1,097,110	$ 771,632	$ 92,501	$ 864,133

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 shall 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). In general, the stated Maturity Dates are March 31, 2022. Negotiations are currently underway to extend these notes to March 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. No such Next Equity Financing has occurred through December 31, 2021. 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

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 4 — CONVERTIBLE DEBT (cont.)

the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due shall 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 and 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.

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $1,130,800 and $752,000, for the years 2021 and 2020, respectively. Accrued interest expense associated with the Notes at December 31, 2021, and 2020 amounted to approximately $308,338 and $57,762, respectively.

The accrued convertible debt balance at December 31, 2021 and 2020 is summarized as follows:

	December 31,	
	2021	**2020**
Principal amount outstanding	$ 5,154,000	$ 3,760,000
Less: debt issuance costs	(851,314)	(597,894)
Amortization of debt issuance	741,928	112,543
Less: redemption premium	(1,130,800)	(752,000)
Amortization of redemption premium (debt discount)	993,049	114,918
Carrying value	$ 4,906,863	$ 2,637,566

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 shall 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). In general, the stated Maturity Date is March 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. No such Next Equity Financing has occurred through December 31, 2021. 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

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 4 — CONVERTIBLE DEBT (cont.)

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 shall 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 and 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.

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $337,004. Accrued interest expense associated with the Notes at December 31, 2021 amounted to approximately $22,348.

The accrued convertible debt balance at December 31, 2021 and 2020 is summarized as follows:

	December 31,	
	2021	**2020**
Principal amount outstanding	$ 1,685,020	$ —
Less: debt issuance costs	(75,250)	—
Amortization of debt issuance	9,973	—
Less: redemption premium	(337,004)	—
Amortization of redemption premium (debt discount)	52,896	—
Carrying value	$ 1,335,635	$ —

Blink Bio

Note payable

On August 19, 2020, the Company gave a convertible note, initially valued at $2,400,000, to Blink Bio (see Note 6 for license agreement). The Note bears simple interest at the rate of 10% per annum and is set to convert within 120 days of the signing date, to Preferred Stock at conversion price per share equal to the Capped Conversion Price (1.92 per share), unless agreed by mutual consent to extend, which it was in December 2021 to March 2021.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 4 — CONVERTIBLE DEBT (cont.)

Principal and accrued interest were due in a balloon payment on March 15, 2021. Interest expense through March 15, 2021 was $55,804 and the year ended December 31, 2020, was $44,196. The principal and then total interest of $100,000 converted into 1,302,082 shares of Preferred Stock on March 15, 2021.

Redemption Liability

The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, is determined based upon a Probability-Weighted of Expected Returns Model ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since the Company has not entered into a priced equity round through December 31, 2021. The fair value of the redemption liability is calculated using the initial value of the convertible note less the debt discount rate of 12.5% in Group A and 20% in Groups B and C. The redemption liability is then amortized over the remaining life of the note, utilizing the interest rates of 10% and 6% respectively for the groups. The life of each note in Group A is for a set period of 3 years, and is variable in Groups B and C, with a range of 15 months to 3 years. The Company retains the option to negotiate an extended maturity date for Groups B and C. The new embedded redemption values were $740,804 and 805,125 for the years ending December 31, 2021 and December 31, 2020, respectively. The redemption liability is re-measured at each period end and is summarized as follows:

	December 31,	
	2021	**2020**
Beginning Balance	**$ 871,250**	**$ 66,125**
New Embedded Redemption Value – Group A	25,000	43,750
New Embedded Redemption Value – Group A Related Parties	—	9,375
New Embedded Redemption Value – Group B	378,800	752,000
New Embedded Redemption Value – Group C	337,004	—
Ending Balance	**$ 1,612,054**	**$ 871,250**

Fees Associated with Convertible Debt Raise

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

	2021	**2020**
Debt Issuance		
Group A	$ —	$ 16,528
Group A – Related Party	—	—
Group B	253,420	582,895
Group C	75,250	—
Total Net Debt Issuance	$ 328,670	$ 599,423

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

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 shall 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 shall become due to TEDCO immediately; however the discount for meeting the obligation shall still apply.

NOTE 6 — INCOME TAXES

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

	December 31,	
	2021	**2020**
Deferred tax assets:		
Net operating loss carryforwards	$ 3,263,790	$ 1,772,957
General Business Credit Carryover	34,602	—
R&D Credit (available for payroll tax offset)	285,518	35,518
Subtotal	3,583,910	1,808,475
Valuation allowance	(3,583,910)	(1,808,475)
Total deferred tax assets	$ —	$ —

The federal income tax rate used for 2021 and 2020 was 21%. The Maryland rate is 8.25%. At December 31, 2021 and 2020, the Company had federal net operating loss ("NOL") of $3,196,769 and $6,061,393, respectively. The 2019 NOL carryforward of $306,595 will expire in tax years up through 2037. The NOLs generated in tax years 2020 and beyond will carry forward indefinitely, but the deductibility of such federal net operating losses is limited. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

The Company's issuances of common stock may have likely resulted in ownership changes as defined by Section 382 of the Code; however, the Company has not conducted a Section 382 study to date. It is possible that a future analysis may result in the conclusion that a substantial portion, or perhaps substantially all of the Company's NOL carryforwards and R&D tax credit carryforwards will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of the carryforwards may be limited, and a portion of the carryforwards may expire unused. The Company is subject to U.S. federal tax examinations by tax authorities for the years 2021 and 2020 due to the fact that NOL carryforwards exist going back to 2019 that may be utilized on a current or future year tax return.

NOTE 7 — COMMITMENTS AND CONTINGENCIES

Rental Agreement

The Company has a rental agreement with Dorchester County Council, beginning in February 2019 and ending in February 2021. The payment term of the license agreement is $250 per month. Rent expense for the year ended December 31, 2021, was $3305 and $2,500 for the year ended December 31, 2020.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 7 — COMMITMENTS AND CONTINGENCIES (cont.)

Employee Commitments

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

License Obligation and Manufacturing Agreements Advaxis

The Company entered into an exclusive license agreement with Advaxis Inc in September 2018, as amended, pursuant to which it acquired the right to develop and commercialize Advaxis HER2 Construct, the Company's product candidate and the use of Advaxis HER2 Construct patents. Per the agreement, monthly payments began April 30, 2020, and a total of $1,205,000 has been paid to ADVAXIS towards the License Commencement Payment by December 31, 2020, the grand total of which is $1,550,000. These payments have been recorded as licensing expenses in the accompanying statement of operations. Milestone 3 was updated to a $5,000,000 payment on April 23, 2021. A payment schedule is set for future milestones, as follows:

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

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

On an aggregate basis across all Licensed Products under the licensing agreement and during the Royalty term, OST shall pay quarterly to Advaxis royalties on Net Sales of Licensed Products at a rate of Ten Percent (10%) with respect to all Net Sales in a given Calendar Quarter. No royalties were payable in 2020 or 2021.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 7 — COMMITMENTS AND CONTINGENCIES (cont.)

BlinkBio

In July 2020, the Company entered into a Licensing Agreement with BlinkBio, 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 accompany statement of operation. A payment schedule is set for future milestones, is summarized below:

Milestone Bearing Event	Milestone Payment
1. License Fee to utilize proprietary technology (paid)	$300,000 + $2.4MM 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 shall make the cash payments set forth in the table above by wire transfer of immediately available funds, to BlinkBio within thirty (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 shall apply with respect to The Company’s first product candidate. During the Royalty Term, the Company will pay BlinkBio a royalty of six percent (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 shall be reduced to three percent (3%).

For the avoidance of doubt, each Milestone payment shall be payable only once, and the aggregate amount of Milestone payments payable hereunder shall not exceed Twenty-Two Million Three Hundred Seventy-Five US Dollars ($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 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”. The study has seventeen patients and is expected to last for 28 months, or through September 2022. The Agreement budget totals $2,423,928. The total research and

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 7 — COMMITMENTS AND CONTINGENCIES (cont.)

development expense recorded in the statement of operations for the year ended December 31, 2021 was $555,724 and $243,659 for the year ended December 31, 2020. The remainder is set up to be paid according to the service fee schedule below:

George Clinical Payment Schedule		Payment Amount
1.	Service Fee Advance (paid 6/8/2020)	$49,989
2.	Float – Service Fee Advance of 20% of $372145.28 and PTC Advance Fee of 20% of $313,254 (Paid 11/4/2020)	$162,346
3.	Statistics Fees – 10% on Commencement of Study	$13,640
4.	Statistics Fees – 50% on Development of SAP tables	$68,200
5.	Statistics Fees – 40% on Final Analysis	$54,560
6.	Service Fees – Remainder Due	Split Monthly Over Course of Study

George Clinical will track and invoice the Company for the number of task units completed and pass through costs will be invoiced each month in arrears based on actual costs without mark-up. The PTC Advance Fee will be used to offset final pass through fees payable.

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 our results of operations or financial position.

NOTE 8 — EQUITY

Common Stock

As of December 31, 2020, the Company had issued 8,335,000 shares of common stock. During 2020, investors were sold 1,075,000 shares of common stock and employees, directors, and advisors were sold 1,024,000 shares of common stock at $0.001 per share, for both parties.

In 2021, the Company split Common Stock into two classes with fifty million shares of Class A Common Stock, $0.001 par value per share ("Class A Common Stock") designated and twenty million shares of Class B Common Stock, $0.001 par value per share ("Class B Common Stock"). As of December 31, 2021, the Company has 8,221,000 shares of Class A Common Stock and 614,000 shares of Class B Common Stock, with 70,000,000 (seventy million) total common stock shares authorized. Common Stock A has voting rights and Class B Common Stock has no voting rights.

OS Therapies, Inc.
Notes to the Financial Statements
For the Twelve Months Ended December 31, 2021 & 2020

NOTE 8 — EQUITY (cont.)

This accounting change has been applied by retrospective application to the financial statements of all prior periods represented. No material change to the financial statements has occurred.

	Total, as of 12/31/2021	Total, as of 12/31/2020
Shares Issued to Investors	1,100,000	1,100,000
Shares Issued to Employees, Directors, & Advisors	7,735,000	7,735,000
Total Shares Issued	8,835,000	8,835,000

Preferred Stock

In 2021, 5,000,000 shares of Preferred Stock were authorized, 1,400,000 was designated as Series A Preferred Stock, with 1,302,082 shares issued of Series A Preferred Stock. Preferred Stock has 5% cumulative coupon and liquidation priority above all Common Shares. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly. The accrued dividend for and as of December 31, 2021 was $93,750. The stock can be converted to common shares at a 1:1 ratio with a $0.001 par value.

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] [66%] 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.

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.

The remaining 3,600,000 shares of Preferred Stock were designated for Series B with none issued. All rights and privileges of Series B are the same as Series A Preferred Stock with the exception being Series B does not have voting rights.

	Total, as of 12/31/2021	Total, as of 12/31/2020
Shares Issued to Investors	1,302,082	—
Total Shares Issued	1,302,082	—

NOTE 9 — SUBSEQUENT EVENTS

a. The Company is continuing the A-2 Round and, as of August 31, 2022, has received $1.91 million new notes.

b. The Company has negotiated the extension of the maturity dates for all Group B Convertible Notes and Group A notes that would have come due in 2021 to at least March 31, 2024.

OS Therapies, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	$ 39,176	$ 80,788
Employee Advances	—	956
Deferred Offering Costs	50,000	—
Shareholder Loan Receivable	—	229,925
Total Current Assets	**89,176**	**311,669**
Long Term Assets		
Fixed Assets (Net)	13,076	13,076
TOTAL ASSETS	**$ 102,252**	**$ 324,745**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts Payable	$ 1,152,608	$ 856,521
Accrued Interest on Convertible Notes	1,072,151	601,410
Accrued Payroll and Payroll Taxes	508,311	367,020
Redemption Premium	2,014,054	1,612,054
Preferred Dividends Payable	187,500	93,750
Shareholder Loan Payable	115,000	—
Total Current Liabilities	**$ 5,048,624**	**3,530,755**
Long Term Liabilities		
Convertible Notes – A (net Debt Discount and Debt Issuance Cost)	1,030,282	999,613
Convertible Notes – A Related Party (net Debt Discount and Debt Issuance Cost)	100,000	97,497
Convertible Notes – B (net Debt Discount and Debt Issuance Cost)	5,154,000	4,906,862
Convertible Notes – C (net Debt Discount)	3,111,285	1,335,635
TEDCO Grant	100,000	100,000
Total Long Term Liabilities	**9,495,567**	**7,439,607**
TOTAL LIABILITIES	**$ 14,544,191**	**10,970,362**
STOCKHOLDERS' DEFICIT		
Preferred A Stock, par value $0.001, 5,000,000 shares authorized, 1,302,820 Preferred A Shares issued (2021)	1,302	1,302
Common A Stock, par value $0.001, 50,000,000 shares authorized, 8,221,000 shares issued (2021) and 8,835,000 shares issued (2020)	8,221	8,221
Common B Stock, par value $0.001, 20,000,000 shares authorized, 614,000 shares issued (2021)	614	614
Additional Paid In Capital	2,498,698	2,498,698
Accumulated deficit	(16,950,774)	(13,154,452)
Total Stockholders' Deficit	**(14,441,939)**	**(10,645,617)**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 102,252**	**$ 324,745**

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

OS Therapies, Inc.
Statements of Operations
For the Nine Months Ended September 2022 and 2021
(Unaudited)

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
OPERATING EXPENSES		
Research & Development Expenses	$ 2,193,614	$ 1,481,210
General & Administrative	511,048	948,261
Licensing costs	1,210	1,141,165
Total Operating Expenses	**2,705,872**	**3,570,637**
Loss from Operations	**(2,705,872)**	**(3,570,637)**
OTHER INCOME/EXPENSE		
Interest Expense	(996,700)	(1,489,055)
Total Other Income/Expense	**(996,700)**	**(1,489,055)**
NET LOSS	**(3,702,572)**	**(5,059,691)**
Cumulative Series A Preferred Stock Dividend Requirement	(93,750)	(93,750)
NET LOSS available to common stockholders	**$ (3,796,322)**	**$ (5,153,441)**
Basic & Diluted Loss per Common Share Class A	$ (0.42)	$ (0.57)
Basic & Diluted Loss per Common Share Class B	$ (0.42)	$ (0.57)
Weighted Average Shares Outstanding Class A	8,221,000	8,221,000
Weighted Average Shares Outstanding Class B	614,000	614,000

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

OS Therapies, Inc.
Statement of Stockholders' Deficit
For the Nine Months Ended September 30, 2022 and 2021
(Unaudited)

	Common Stock				Preferred Stock		Additional		Total
	Class A Shares	Class A Amount	Class B Shares	Class B Amount	Shares	Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
Balances, December 30, 2020	**8,221,000**	**8,221**	**614,000**	**614**	**—**	**—**	**—**	**(6,335,652)**	**(6,326,817)**
Conversion of Debt and interest to Preferred Shares	—	—	—	—	1,302,082	1,302	2,498,698	—	2,500,000
Preferred Dividends	—	—	—	—	—	—	—	(93,750)	(93,750)
Net Loss	—	—	—	—	—	—	—	(6,724,585)	(6,724,585)
Balances, December 30, 2021	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(13,154,452)**	**(10,645,617)**
Preferred Dividends	—	—	—	—	—	—	—	(93,750)	(93,750)
Net loss	—	—	—	—	—	—	—	(3,702,574)	(3,702,574)
Balances, September 30, 2022	**8,221,000**	**8,221**	**614,000**	**614**	**1,302,082**	**1,302**	**2,498,698**	**(16,950,774)**	**(14,441,939)**

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

OS Therapies, Inc.
Statements of Cash Flows
For the Nine Months Ended September 30, 2022 and 2021
(Unaudited)

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (3,702,572)	$ (5,059,691)
Depreciation Expense	—	1,184,510
Amortization of Debt Discounts – Redemption Liability	525,960	100,000
Preferred Stock issued for interest	—	
Adjustments to reconcile net loss to net cash used in operating activities:		
Accounts Payable	295,086	551,174
Accrued Expenses	—	(595,000)
Accrued Interest on Convertible Notes	470,741	160,111
Accrued Payroll and payroll taxes	141,291	(62,295)
Net cash used in operating activities	**(2,269,493)**	**(3,721,191)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Employee Advances	956	11,844
Purchases of Equipment	—	(4,831)
Increase/Decrease in Shareholder Loan Receivable	—	564
Shareholder Loan Repayment	229,925	200,000
Net cash provided by investing activities	**230,881**	**207,577**
CASH FLOWS FROM FINANCING ACTIVITIES		
TEDCO Grant	—	50,000
Deferred Offering Costs	(50,000)	—
Increase/Decrease in Shareholder Loan Payable	115,000	—
Net Proceeds from Convertible Debt – A, B, & C	1,932,000	2,394,715
Net cash provided by financing activities	**1,997,000**	**2,444,715**
Net change in cash and cash equivalents	(41,612)	(1,068,900)
Cash and cash equivalents – beginning of period	80,788	1,232,776
Cash and cash equivalents – end of period	$ 39,176	$ 163,877
		(5,059,691)
Cash paid during the year for Interest	$ —	$ —
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Redemption Premium – Discount	$ 402,000	$ 624,377
Conversion of Convertible Note and accrued interest to preferred stock	—	2,400,000
Preferred Dividends Payable	93,750	62,500

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

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

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

OS Therapies Inc. ("we," "us," "our," the "Company") is a Delaware corporation incorporated on June 24, 2019. It is based in Cambridge, 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 2021, there is one ongoing clinical trial for osteosarcoma therapy.

Liquidity

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

As of September 30, 2022, the Company had cash of $39,176. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital. The company is currently seeking to raise additional capital through a public or private financing of equity, although there are no assurances, we will be successful in such a campaign.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The interim unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States and should be read in conjunction with the audited financial statements and notes thereto for the years ended December 31, 2021, and 2020. In the opinion of management, all adjustments which include normal recurring adjustments, necessary to present fairly the financial position, results of operations, and cash flows for the periods shown have been reflected herein. The results of operations for the nine months ended September 30, 2022 are not necessarily indicative of the operating results for the full year. Certain information and footnote disclosures which would substantially duplicate the disclosures contained in the audited financial statements for the years ended December 31, 2021, and 2020 have been omitted.

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 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 dilutive potential shares if their effect is antidilutive.

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (cont.)

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

	Total Number of Shares	
Common Stock Equivalents	**9/30/2022**	**12/31/2021**
Convertible Debt	4,740,952*	4,504,890*
Common Stock	8,835,000	8,835,000
Preferred Stock	1,302,082	1,302,082
Total	**14,878,034**	**14,641,972**

Basic and Diluted Loss per Share

	September 30, 2022		December 31, 2021	
	Class A	**Class B**	**Class A**	**Class B**
Numerator:				
Allocation of net loss, as adjusted	$ (3,443,393)	(259,180)	(6,253,864)	(470,721)
Denominator:				
Basic & Diluted Weighted Average shares outstanding	8,221,000	614,000	8,221,000	614,000
Basic & Diluted net loss per ordinary Share	$ (0.42)	(0.42)	(0.77)	(0.77)

The number of shares issuable upon the conversion of convertible debt and accrued interest cannot be determined at this time, since the number of shares exercisable into is based on a number of possible outcomes.

Accounting policies being evaluated:

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which replaces the existing guidance in ASC 840 — Leases. This ASU requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. This ASU is effective for fiscal years beginning after December 15, 2021, and for interim periods within those fiscal years. The Company evaluated the impact of this adoption on its financial statements in 2021. On January 1, 2022 the Company adopted ASU No. 2016-02.

In January 2022, the Company adopted ASU 2020-06 *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40).* ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and limiting the number of embedded conversion features separately recognized from the primary contract. The guidance also includes targeted improvements to the disclosures for convertible instruments and earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020.

NOTE 3 — RELATED PARTY TRANSACTIONS

Shareholder Loan

The following summarizes activity under the related party loan receivable:

Balance December 31, 2020	**$ 430,489**
Contributions during 2022	(564)
Repayment	(200,000)
Balance December 31, 2021	**$ 229,925**
Repayment	(229,925)
Balance September 30, 2022	**$ —**

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 3 — RELATED PARTY TRANSACTIONS (cont.)

In 2022, the CEO paid his advances in full and lent the Company a total of $150,000, of which $35,000 has been repaid. The balance of the loan payable is $115,000 as of September 30, 2022.

Accrued Payroll

As of December 31, 2021, the Company had a payroll payable to the CEO of $360,000 and related income taxes payable of $5,220. As of September 30, 2022, the CEO and the CFO had an additional accrued payroll totaling $129,000 with associated accrued payroll taxes totaling $4,102.50. These are expected to be paid when funds become available to do so. In early 2021, The Company and the CEO agreed to no imputed interest for the CEO as the debt owed to and from the CEO net a difference of the payroll taxes due. As of September 30, 2022 there is also $9,989 due for current payroll taxes.

Employee Advances

Director was paid $12,500 in June 2021 as a subcontractor. After the payment was issued, he requested to be paid as a W-2. The $956.25 represents the advanced payroll taxes that were repaid on the 2022 wages.

Accrued Expenses

In November 2020, compensation in the amount of $250,000 was accrued for an exit package for former COO, Jeffrey Stewart. The payment was made in March 2021.

Related Parties — Convertible Debt

Of the total outstanding notes at September 30, 2022, 10.4% of Group A and 0% of Group B are held by related parties.

Ted Search and John Ciccio, collectively known as Mill Partners LLC, are members of the Board and hold convertible notes with face amounts of $100,000 as of September 30, 2022 and $97,497 as of December 31, 2021.

NOTE 4 — CONVERTIBLE DEBT

Convertible Debt

The Convertible Notes are separated into four groups — A, B,C and BlinkBio — per the table below.

Group	Rate	Maturity	Collateral	Conversion Rate	2022 Carrying Amount	2021 Carrying Amount
A	10%	Varies	None	87.5% – 100%	$ 1,130,284	$ 1,097,110
B	6%	3/31/2022	None	80%	$ 5,154,000	$ 4,906,863
C	6%	3/31/2024	None	80%	$ 3,111,285	$ 1,335,635
Blink Bio	10%	3/15/2022	None	100%	$ 0	$ 0

Group A

Commencing in September 2018 through 2020, 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

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
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NOTE 4 — CONVERTIBLE DEBT (cont.)

Securities, the principal and accrued interest shall 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). In general, the stated Maturity Date varies from the date of issuance.

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 87.5 – 100% of the price paid per share for Equity Securities by the investors in the Next Equity Financing. Equity Securities refers to Company's common stock or preferred stock and Next Equity Financing refers to the next sale (or series of related sales) by the Company of its equity securities from which the Company receives gross proceeds of not less than $3,000,000 (including the aggregate amount of debt securities converted into Equity Securities upon conversion or cancellation of promissory notes) or $5,000,000, depending upon the signed agreement terms. In the event that the Company raises aggregate additional cash proceeds of at least $3,000,000 or $5,000,000 through the sale of the Company's equity securities, excluding the sales or conversions of Notes under the Agreement, the outstanding principal amount due shall 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 and 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.

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $147,696 and $144,250, for the nine months ended September 30, 2022 and the twelve months ended December 31, 2021, respectively. Accrued interest expense associated with the Notes at September 30, 2022 amounted to $94,212 and $138,398 as of December 31, 2021.

The accrued convertible debt balance at September 30, 2022 and December 31, 2021 is summarized as follows:

	September 30, 2022	December 31, 2021
Principal amount outstanding	$ 1,154,000	$ 1,064,133
Less: debt issuance costs	(37,528)	(37,528)
Amortization of debt issuance	34,200	27,509
Less: redemption premium	(147,696)	(144,250)
Amortization of redemption premium (debt discount)	127,307	97,378
Carrying value	$ 1,130,284	$ 1,097,110

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 4 — CONVERTIBLE DEBT (cont.)

The following table breaks out Group A and Group A-Related Party totals per year:

	September 30, 2022			December 31, 2021		
	Group A	Group A Related Party	2022 Total	Group A	Group A Related Party	2021 Total
Principal amount outstanding	$ 999,611	97,497	**1,097,108**	971,632	92,502	**1,064,134**
Less: Debt issuance costs	—	—	**—**	—	—	**—**
Amortization of debt issuance (legal fees)	6,691	—	**6,691**	13,265	—	**13,265**
Debt Issuance Total	*6,691*	—	***6,691***	*13,265*	—	***13,265***
Less: Redemption premium (RP)	—	—	**—**	(25,000)	—	**(25,000)**
Amortization of RP (debt discount)	23,980	2,503	**26,483**	39,716	4,995	**44,711**
Debt Discount Total	*23,980*	*2,503*	***26,483***	*14,716*	*4,995*	***19,711***
Carrying value	$ 1,030,282	100,000	**1,130,282**	999,613	97,497	**1,097,110**

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 shall 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). In general, the stated Maturity Dates are March 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. No such Next Equity Financing has occurred through September 30, 2022. 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 shall 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 and 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.

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 4 — CONVERTIBLE DEBT (cont.)

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

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $0 and $378,800, for the nine months ended September 30, 2022 and twelve months ended December 31, 2021, respectively. Accrued interest expense associated with the Notes at September 30, 2022, amounted to approximately $243,573 and $283,399 for the twelve months ended December 31, 2021.

The accrued convertible debt balance at September 30, 2022 and December 31, 2021 is summarized as follows:

	September 30, 2022	December 31, 2021
Principal amount outstanding	$ 5,154,000	$ 5,154,000
Less: debt issuance costs	(849,646)	(851,314)
Amortization of debt issuance	849,646	741,928
Less: redemption premium	(1,130,800)	(1,130,800)
Amortization of redemption premium (debt discount)	1,130,800	993,049
Carrying value	$ 5,154,000	$ 4,906,863

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 shall 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). In general, the stated Maturity Date is March 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. No such Next Equity Financing has occurred through September 30, 2022. 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 shall 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.

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 4 — CONVERTIBLE DEBT (cont.)

The Company, at its option, may pay and 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. As of September 30, 2022 there were $2,010,000 in new notes for the 2022 Fiscal Year.

The various conversion and redemption features contained in the Subordinated Convertible Note are embedded derivative instruments, which were recorded as a debt discount and redemption liability at the issuance date at their estimated fair value of $402,000 and $337,004, for the nine months ended September 30, 2022 and December 31, 2021, respectively. Accrued interest expense associated with the Notes at September 30, 2022, and December 31, 2021 amounted to approximately $132,956 and $22,348, respectively.

The accrued convertible debt balance at September 30, 2022 and December 31, 2021 is summarized as follows:

	September 30, 2022	December 31, 2021
Principal amount outstanding	$ 3,695,020	$ 1,685,020
Less: debt issuance costs	(153,250)	(75,250)
Amortization of debt issuance	59,611	9,973
Less: redemption premium	(739,004)	(337,004)
Amortization of redemption premium (debt discount)	248,909	52,896
Carrying value	$ 3,111,285	$ 1,335,635

Blink Bio

Note payable

On August 19, 2020, the Company gave a convertible note, initially valued at $2,400,000, to Blink Bio (see Note 6 for license agreement). The Note bears simple interest at the rate of 10% per annum and is set to convert within 120 days of the signing date, to Preferred Stock at conversion price per share equal to the Capped Conversion Price (1.92 per share), unless agreed by mutual consent to extend, which it was in December 2020 to March 2021.

Principal and accrued interest were due in a balloon payment on March 15, 2021. Interest expense through March 15, 2021 was $55,804 and the year ended December, 2020, was $44,196. The principal and then total interest of $100,000 converted into 1,302,082 shares of Preferred Stock on March 15, 2021.

Redemption Liability

The fair value of the redemption liability is calculated under Level 3 of the fair value hierarchy, is determined based upon a Probability-Weighted of Expected Returns Model ("PWERM"). This PWERM was determined to be the most appropriate method of estimating the value of possible redemption or conversion outcomes over time, since the Company has not entered into a priced equity round through September 30, 2022. The fair value of the redemption liability is calculated using the initial value of the convertible note less the debt discount rate of 12.5% in Group A and 20% in Groups B and C. The redemption liability is then amortized over the remaining life of the note, utilizing the interest rates of 10% and 6% respectively for the groups. The life of each note in Group A is for a set period of

OS Therapies, Inc.
Notes to Financial Statements
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NOTE 4 — CONVERTIBLE DEBT (cont.)

3 years, and is variable in Groups B and C, with a range of 15 months to 3 years. The Company retains the option to negotiate an extended maturity date for Groups B and C. The new embedded redemption values were $402,000 and $740,804 for the nine months ending September 30, 2022 and twelve months ending December 31, 2021, respectively.

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

	September 30, 2022	December 31, 2021
Beginning Balance	**$ 1,612,054**	**$ 871,250**
New Embedded Redemption Value – Group A	—	25,000
New Embedded Redemption Value – Group A Related Parties	—	—
New Embedded Redemption Value – Group B	—	378,800
New Embedded Redemption Value – Group C	402,000	337,004
Ending Balance	**$ 2,014,054**	**$ 1,612,054**

Fees Associated with Convertible Debt Raise

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

Debt Issuance	9/30/2022	12/31/2021
Group A	$ —	—
Group A – Related Party	$ —	—
Group B	$ —	253,420
Group C	$ 78,000	75,250
Total Net Debt Issuance	78,000	328,670

NOTE 5 — EQUITY

Preferred Stock

In 2021, 5,000,000 shares of Preferred Stock were authorized, 1,400,000 was designated as Series A Preferred Stock, with 1,302,082 shares issued of Series A Preferred Stock. Preferred Stock has 5% cumulative coupon and liquidation priority above all Common Shares. The coupon dividends are computed at 5% of the principal per annum and are recorded monthly. The accrued dividend for the nine months ended September 30, 2022 is $187,500 and as of December 31, 2021 was $93,750. The stock can be converted to common shares at a 1:1 ratio with a $0.001 par value.

NOTE 6 — COMMITMENTS AND CONTINGENCIES

Rental Agreement

The Company has a rental agreement with Dorchester County Council, beginning in February 2019 and ending in March 2022. The payment term of the license agreement is $250 per month. In April 2022, the Company entered into a one year rental agreement with Boston Properties in Rockville, MD, for $1000 per month. Rent expense for the year ended December 31, 2021 was $3,305 and the rent expense for the nine months ended September 30, 2022, was $7,259.

OS Therapies, Inc.
Notes to Financial Statements
(Unaudited)
For the Nine Months Ended September 30, 2022 & 2021

NOTE 7 — SUBSEQUENT EVENTS

The Company is continuing the A-2 Round and, since September 30, 2022, has received $125,000 in new notes.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company" (as defined by §229.10(f)(1)), the Company is not required to provide the information required by this Item.

CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Exchange Act) that is designed to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of the end of the period covered by this report, we have carried out an evaluation of the effectiveness of the design and operation of our company's disclosure controls and procedures.

Annual Report of Management on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company's principal executive officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

1. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

2. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

3. Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

As a smaller reporting company, the Company is not required to include in this Quarterly Report a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

We have had no changes in or disagreements with our independent registered public accountant.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the Registration Statement filed with the Securities and Exchange Commission becomes effective. [This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS
SUBJECT TO COMPLETION
DATED , 2022

OS THERAPIES

OS THERAPIES, INC.

SHARES OF CLASS A COMMON STOCK

Preliminary prospectus

Until , 2022, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

, 2022

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the Class A common stock hereunder. All amounts are estimates except the SEC registration fee.

Item	Amount to be Paid*
SEC registration fee	$
FINRA filing fee	
NYSE American/Nasdaq listing fee	*
Printing and mailing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

[Section 145 of the Delaware General Corporation Law (the "DGCL"), authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation to be in effect upon the closing of this offering and bylaws to be in effect upon the effectiveness of this registration statement that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with our executive officers. These agreements provide that we will indemnify each of our directors, our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended (the "Securities Act").

The underwriting agreement to be filed as an exhibit to this registration statement is expected to provide for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934]

Delaware Law

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Amended and Restated Certificate of Incorporation

[Our certificate of incorporation provides that we are authorized to provide indemnification and advancement of expenses to our directors, officers and certain other covered persons to the fullest extent permitted by the DGCL. Our certificate of incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the DGCL and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors for:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

In addition, our certificate of incorporation also provide that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, other than an action by or in the right of us, by reason of the fact that such person is or was a director or officer of the Company or is or was serving at the request of the Company as a director, officer, employee, general partner, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), against all expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.]

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We intend to apply for a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on their acts or omissions committed in their capacities as directors or officers.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of capital stock

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

In 2020, we issued and sold an aggregate of 8,835,000 shares of our Class A common stock at a purchase price of $.17 per share for an aggregate purchase price of approximately $1.5 million.

In 2021, we issued 1,302,082 shares of Class A common stock with our vendor and Convertible Note Holder, BlinkBio.

We have not sold any shares of Class A common stock so far in 2022.

No underwriters were involved in the foregoing sales of securities. Unless otherwise stated, the sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits

Exhibit number	Description
1.1*	Form of Underwriting Agreement.
3.1*	Certificate of Incorporation of OS Therapies, Inc.
3.2*	Form of Amended and Restated Certificate of Incorporation of OS Therapies, Inc, to be in effect prior to completion of this offering.
3.3*	Bylaws of OS Therapies, Inc.
3.4**	Form of Amended and Restated Bylaws of OS Therapies, Inc, to be in effect upon the effectiveness of this registration statement.
4.1*	Specimen Class A Common Stock Certificate.
5.1*	Opinion of Greenberg Traurig, P.A.
10.2*#	[2022 Stock Incentive Plan and form of award agreements thereunder.]
10.3*#	[2022 Employee Stock Purchase Plan.]
10.4*#	Form of Indemnification Agreement between OS Therapies, Inc. and each of its directors.
10.5*#	[Form of Indemnification Agreement between OS Therapies, Inc. and each of its executive officers.]
23.1*	Consent of Malone and Bailey, independent registered public accounting firm.
23.2*	Consent of Greenberg Traurig, P.A. (included in Exhibit 5.1).
24*	Power of Attorney (included on signature page).

* To be filed by amendment.
† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with Item 601(b)(10) of Regulation S-K.
# Indicates a management contract or any compensatory plan, contract or arrangement.

(b) Financial statements schedules

The financial statements filed as part of this registration statement are listed in the index to the financial statements immediately preceding such financial statements, which index to the financial statements is incorporated herein by reference.

ITEM 17. UNDERTAKINGS

[The undersigned registrant hereby undertakes:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events which, individually or together represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to

Rule 424(b) (Section 230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) For determining liability under the Securities Act, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities as at that time to be the initial bona fide offering thereof.

(3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

(4) (i) For the purpose of determining liability under the Securities Act to any purchaser: Each prospectus filed pursuant to Rule 424(b) under the Securities Act as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(v) Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the small business issuer in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the small business issuer will, unless in the opinion of its counsel that matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(6) The undersigned registrant hereby undertakes that it will:

(i) For purposes of determining any liability under the Securities Act that the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be a part of this registration statement as of the time the Commission declared it effective.

(ii) For the purpose of determining any liability under the Securities Act, that each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.]

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Rockville Maryland, on the day of , 2022.

	OS Therapies, Inc.
	By:
	Name: Paul Romness
	Title: Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Paul Romness and Christopher Acevedo, and each of them, his or her true and lawful attorney in fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, to this registration statement and any registration statement relating to the offering covered by this registration statement and filed pursuant to Rule 462(b) under the Securities Act of 1933 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 Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities indicated on the [Filing Date].

Name	Position	Date
Paul Romness	President, Chief Executive Officer and Chairman (Principal Executive Officer)	
Christopher Acevedo	Chief Financial Officer (Principal Financial Officer)	
John Ciccio	Director	
Colin Goddard	Director	
Dr. Theodore Search	Director	
Joacim Borg	Director	