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

FORM 10-K

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

For the fiscal year ended September 30, 2022
OR

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

For the transition period from_____to_____

Commission File Number: 001-37759

OUTLOOK THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**38-3982704**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
485 Route 1 South **Building F, Suite 320** **Iselin, New Jersey**	
(Address of principal executive offices)	**08852** **(Zip Code)**

(609) 619-3990
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OTLK	The Nasdaq Stock Market LLC

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of March 31, 2022 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on The Nasdaq Capital Market on that date, was approximately $221.5 million.

As of December 27, 2022, the registrant had outstanding 228,205,963 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this report incorporates information by reference from the Company's definitive proxy statement, which proxy statement is due to be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2022.

OUTLOOK THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
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In this report, unless otherwise stated or as the context otherwise requires, references to "Outlook Therapeutics," "Outlook," "the Company," "we," "us," "our" and similar references refer to Outlook Therapeutics, Inc. (formerly known as Oncobiologics, Inc.) and its consolidated subsidiaries. The Outlook logo, Oncobiologics logo, LYTENAVA and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this report are the property of Outlook Therapeutics, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

Convenience translations between Swiss Francs, or CHF, and U.S. dollars provided herein are based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York on September 30, 2022, or CHF 0.9845 = $1.00. We do not represent that CHF were, could have been, or could be, converted into U.S. dollars at such rate or at any other rate.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "estimate," "expect," "intend," "may," "might," "plan," "project," "predict," "potential," "should," "will," the negative of terms like these or other comparable terminology, in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail in Item 1A under the heading "Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

SELECTED RISKS AFFECTING OUR BUSINESS

Investing in our common stock involves numerous risks, including the risks described in "Part I, Item 1A. Risk Factors" of this Annual Report on Form 10-K, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, among others, the following:

- We have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months;
- We have never generated any revenue from product sales and may never be profitable;
- We will need to raise substantial additional funding to complete the development of ONS-5010 (LYTENAVA (bevacizumab-vikg)) and support our operations after the planned launch in late 2023 until we are able to generate sufficient revenue. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations;
- Raising additional capital may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- We are highly dependent on the success of ONS-5010, our only product candidate in active development, and if ONS-5010 does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed;
- We may not be successful in our efforts, or wish to enter into a strategic partnership for ONS-5010;
- Due to our limited resources and access to capital, we have, and will continue to need to, prioritize development of certain product candidates, and these decisions may prove to have been wrong and may harm our business;
- Clinical drug development is a lengthy and expensive process and we may encounter substantial delays in our clinical trials or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities;
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise;
- The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ONS-5010 in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all;
- Any delays in the commencement or completion, or termination or suspension, of our current, planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects;
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours. Other products may be approved and successfully commercialized before ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates;
- We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights, we may be unable to generate any revenue and will depend on the efforts of our licensing partners, if any;
- We rely on third parties to manufacture and test ONS-5010, conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed;
- We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business;
- If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts;

- We may become involved in lawsuits to protect or enforce any future patents, which could be expensive, time-consuming and unsuccessful;
- If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in the development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us;
- If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets;
- If we fail to comply with our obligations in the agreements under which we license intellectual property and other 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;
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing novel coronavirus, or COVID-19 global pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, including at our headquarters in New Jersey and at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations, or CROs, or other third parties with whom we conduct business;
- Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.;
- We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer;
- The trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses; and
- GMS Ventures and Investments, or GMS Ventures, and Tenshi Healthcare Pte. Ltd., or Tenshi, beneficially own of a significant percentage of our common stock, and GMS Ventures has the right to designate members of our board of directors and is able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions.

PART I

Item 1. Business

We are a biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the U.S. Food and Drug Administration, or the FDA, for use in retinal indications. Our goal is to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO. Our plans also include potentially securing a strategic partner for the United Kingdom, Europe, Japan and other markets. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of regulatory exclusivity in the European Union.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In March 2022, we submitted a Biologics License Application, or BLA, with the FDA for ONS-5010 (LYTENAVA (bevacizumab-vikg)), an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010 on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA has been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, in October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010 with the European Medicines Agency, or the EMA. On December 22, 2022 our MAA was validated for review by the EMA. The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use, or CHMP, is now set to begin with an estimated decision date expected in early 2024. ONS-5010 is our sole product candidate in active development.

Our BLA registration program for ONS-5010 in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant. For a discussion of NORSE TWO, please see "Our Product Candidate Portfolio—*ONS-5010 — Bevacizumab for Ophthalmic Use—Clinical Development Status*—NORSE TWO". NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010. The NORSE BLA registration program is also being used to support our MAA submission in the European Union.

For additional information on our clinical development status and product candidates, see "Our Product Candidate Portfolio—*ONS-5010 — Bevacizumab for Ophthalmic Use—Clinical Development Status*."

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. In addition to our BLA submission in the United States, we have submitted an MAA for approval in Europe and plan to submit for regulatory approval in multiple other markets, including the UK. Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of unapproved bevacizumab. Off-label use of unapproved bevacizumab is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States**.**

Our Strategy

Our goal is to launch ONS-5010 as the first, and only, approved bevacizumab for ophthalmic use in the United States, United Kingdom, Europe and other markets. We plan to do this directly in the United States and either directly or through a strategic partner outside of the United States. In order to achieve this goal, we have adopted a streamlined clinical and regulatory strategy, the key elements of which include:

- ***Leveraging the ophthalmic drug development and commercialization expertise of our leadership team.*** Members of our executive team have extensive expertise in developing and commercializing treatments for retinal diseases, such as wet AMD, DME and BRVO. We intend to leverage their collective experience to further the development of, and execute an optimal commercial strategy for, ONS-5010, including potentially licensing rights to ONS-5010 to a strategic partner outside the United States.

- ***Engaging with regulatory agencies to establish clear guidelines for potential approval.*** We have continued our approach to work closely with regulatory authorities to develop and conduct clinical trials that we believe will appropriately support approval of our product candidates if our clinical trials are successful. As an ophthalmic formulation of bevacizumab, we believe ONS-5010 has a well-defined regulatory pathway.

- ***Leveraging the expertise of large partners in the biopharma industry to support launch of ONS-5010, if approved.*** We have entered into a strategic commercialization agreement for the future distribution of ONS-5010, which is intended to provide us with the leverage and capabilities of a large biopharmaceutical company, if approved. We use the same approach for leveraging the expertise of experienced third party biologic manufacturers for the production of our drug substance and finished product.

- ***Reducing and managing costs to minimize additional investment to complete our development programs and plan for a potential commercial launch.*** We have made the strategic decision to outsource the commercial manufacturing and future clinical trial supply manufacturing for our product candidates. We believe this will significantly reduce future overhead costs not directly related to our ONS-5010 program.

Our Product Candidate Portfolio

We are actively developing ONS-5010 (LYTENAVA (bevacizumab-vikg)) for use in the treatment of retina diseases such as wet AMD, DME and BRVO. We continue to hold the developed market commercialization rights for two legacy biosimilar product candidates, but currently have no plans to further develop these assets.

ONS-5010 — Bevacizumab for Ophthalmic Use

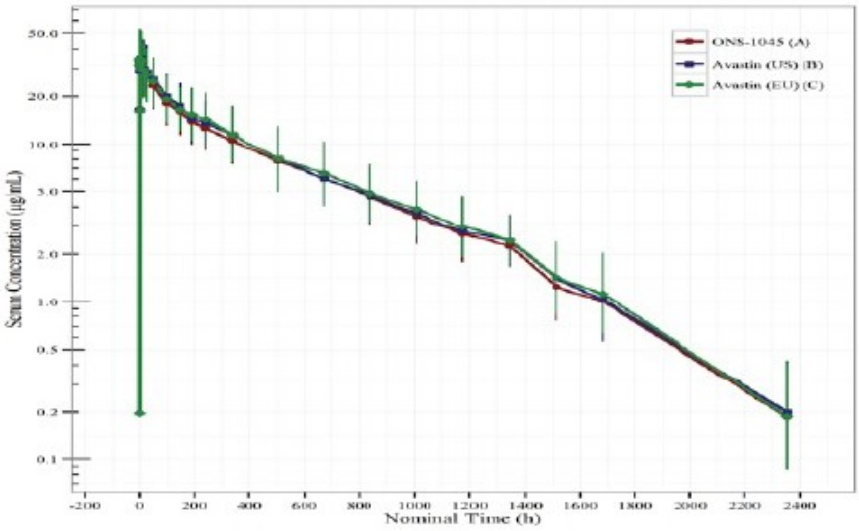
ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. We currently intend to commercialize in both vials and pre-filled syringes, if approved.

Bevacizumab is a full-length, humanized anti-VEGF recombinant mAb that inhibits VEGF and associated angiogenic (the growth of new blood vessels) activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard of care treatment option within the retina community, globally.

Previously, we were developing ONS-5010 as a biosimilar of the cancer drug Avastin for use in oncology indications (ONS-1045). In the ONS-1045 program, our bevacizumab met the primary and secondary endpoints in a three-arm single-dose pharmacokinetic, or PK, Phase 1 clinical trial. All the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125% when compared to both U.S.- and E.U.-sourced Avastin reference products. We are developing ONS-5010 as an ophthalmic formulation of bevacizumab for a BLA submission and not using the biosimilar drug development pathway. The following figure demonstrates the concentration-time profile of ONS-

1045, U.S.-licensed Avastin, and E.U.-licensed Avastin as the mean. The vertical line at time zero denotes dosing. These results suggest a high degree of similarity among the three products.

Comparative Potency of ONS-1045 versus Avastin (U.S. and E.U.)



Market Opportunity

Age-related macular degeneration, or AMD, is a common eye condition and a leading cause of vision loss among people age 50 and older. Wet AMD is a form of "late stage" AMD and is also called neovascular AMD. In wet AMD, abnormal blood vessels grow underneath the retina. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula causing vision loss. With wet AMD, abnormally high levels of VEGF are secreted in the eyes. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard of care treatment option within the retina community, globally. Wet AMD is a significant disease worldwide, with an estimated prevalence of over 2.9 million patients diagnosed in the United States, European countries and Japan alone in 2020 (GlobalData). Although bevacizumab is not currently FDA-approved for use in treating wet AMD, it is believed that bevacizumab currently accounts for approximately 50% of all wet AMD intravitreal injections in the United States, where Avastin is repackaged through compounding pharmacies and prescribed off-label. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label repackaging of bevacizumab including, but not limited to, variability in potency, safety and sterility adverse events and syringe-related adverse events.

DME is caused by a complication of diabetes called diabetic retinopathy. Diabetic retinopathy is the most common diabetic eye disease and the leading cause of irreversible blindness in working age Americans. Diabetic retinopathy usually affects both eyes and is caused by ongoing damage to the small blood vessels of the retina. The leakage of fluid into the retina may lead to swelling of the surrounding tissue, including the macula. DME is the most common cause of vision loss in people with diabetic retinopathy. DME can occur at any stage of diabetic retinopathy, although it is more likely to occur in later stages of the disease. There were approximately 8.6 million patients with DME in the United States, European countries and Japan alone in 2020 (GlobalData).

In BRVO, retinal vein occlusions occur when there is a blockage of veins carrying blood with needed oxygen and nutrients away from the nerve cells in the retina. A blockage in the main vein of the retina is referred to as a central retinal vein occlusion, or CRVO, while a blockage in a smaller vein is called BRVO. Per the American Academy of Ophthalmology, retinal vein occlusions are the second most common retinal vascular disorder after diabetic retinopathy. There were an

estimated 0.3 million patients with BRVO in the United States, European countries and Japan alone in 2020 (Triangulation of Global Data, Market Scope and Investor Forecasts (2020)).

Annual revenue (worldwide) for anti-VEGF therapies was estimated to be $13.1 billion in 2020 (GlobalData).

Clinical Development Status

The study design for our Phase 3 clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed with the FDA at an end of Phase 2 meeting in April 2018, and we filed our IND with the FDA in the first quarter of calendar 2019. Our registration plans for wet AMD, the initial indication planned for ONS-5010, consists of three clinical trials which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. All three clinical trials have been completed. We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 to ranibizumab (LUCENTIS) that reported highly statistically significant topline results in August 2021. NORSE THREE is an open-label safety study conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA.

We have also received agreements from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010 to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010 to treat DME. We intend to initiate these studies following the anticipated FDA approval of our BLA for wet AMD.

In November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes. This study supports a planned supplemental BLA, or sBLA, we expect to submit subsequent to our current BLA receiving approval for wet AMD.

NORSE ONE

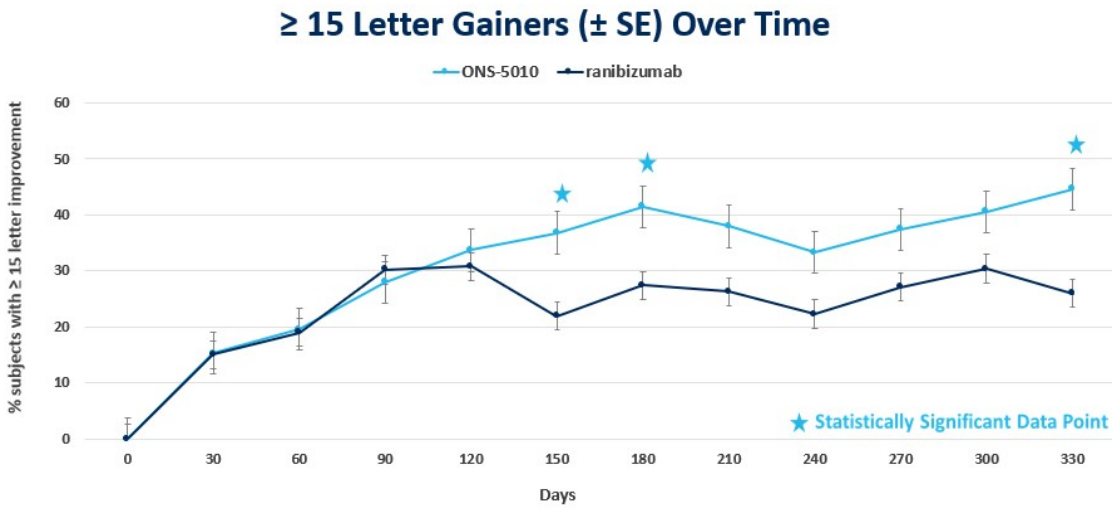
NORSE ONE was designed as a randomized, masked clinical experience trial and served as the first of our two required registration clinical trials to support our BLA submission with the FDA for ONS-5010 for the treatment of wet AMD. A total of 61 treatment naïve and previously treated patients were enrolled in the study at nine sites in Australia and randomized onto treatment arms of ONS-5010 or ranibizumab. The primary endpoint for the study was the difference in proportion of subjects gaining 15 letters of BCVA at Day 330 for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing.

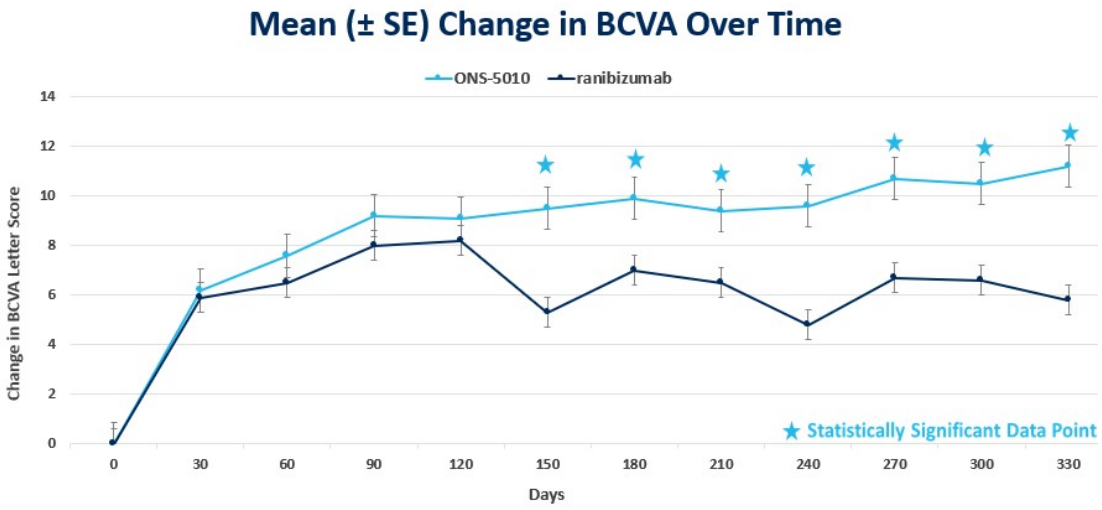
In August 2020, we reported positive proof-of-concept topline results for ONS-5010 as it achieved anticipated safety and efficacy expectations. In the analysis of treatment naïve patients who had a baseline visual acuity of < 67 letters (20/50 or worse) at study entry, 2 of 4 (50%) patients in the ONS-5010 arm and 4 of 9 (44%) patients in the ranibizumab arm achieved > 15 letters at Day 330. This subgroup was the relevant patient population for our pivotal clinical trial of ONS-5010 (NORSE TWO). Additionally, in a key secondary endpoint for the relevant patient population, the ONS-5010 patients achieved a mean improvement in BCVA of 8.3 letters.

NORSE TWO

NORSE TWO was a masked, randomized, pivotal Phase 3 clinical trial that served as the second of our two required clinical trials evaluating ONS-5010 against ranibizumab for wet AMD. A total of 227 primarily treatment naïve patients were enrolled at 39 clinical trial sites in the United States. Patients enrolled in the study were randomized to either ONS-5010 or ranibizumab arms and were treated for 11 months. The primary endpoint for the study was the difference in proportion of subjects gaining 15 letters of BCVA at Day 330 for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen. We reported topline results for NORSE TWO in August 2021.

The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in BCVA score was met and was both highly statistically significant and clinically relevant. In the intent-to-treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% ($p = 0.0052$). The primary endpoint was also statistically significant and clinically relevant in the secondary per-protocol, or PP dataset ($p = 0.04$) where the percentages were almost identical, at 41.0% with ONS-5010, and 24.7% with ranibizumab. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant ($p = 0.0043$). A mean change of 11.2 letters in BCVA score was observed with ONS-5010, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ($p = 0.05$) with a mean change with ONS-5010 of 11.1 letters versus 7.0 letters with ranibizumab. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% ($p = 0.0016$) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% ($p = 0.0116$) of ONS-5010 subjects gaining ≥ 5 letters of vision.





NORSE THREE

NORSE THREE was an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010.

NORSE SEVEN

NORSE SEVEN was initiated to support our ongoing development program for delivering ONS-5010 using a pre-filled syringe. It is a three month study designed to compare the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative AMD, DME, or BRVO. A total of 120 patients are expected to be enrolled in the study with 60 patients receiving ONS-5010 packaged in vials and 60 patients receiving ONS packaged in a pre-filled syringe. Subjects will be treated for three months and the enrollment of subjects in the arm of the study receiving ONS-5010 in vials has been completed. The study is expected to be completed in 2023 and, if successful, will support the submission of a supplemental BLA to the FDA in 2024.

Commercialization, Sales and Marketing

Our commercialization strategy is to provide a safe, effective, and affordable on-label bevacizumab for the retina community while maximizing revenue and patient access to ONS-5010. If approved, we currently intend to launch and market LYTENAVA (bevacizumab-vikg) ourselves in the United States. In September 2022, we entered into a strategic relationship with AmerisourceBergen in preparation for the anticipated commercial launch in the United States of ONS-5010 (LYTENAVA (bevacizumab-vikg)), if approved by the FDA, pursuant to which AmerisourceBergen would provide third-party logistics services and distribution, as well as medical information and pharmacovigilance services in the United States. Outside of the United States, we intend to either market and launch ourselves or work through a strategic partner. We currently own all of the development and commercialization rights to ONS-5010 and have licensed rights only to our joint venture in the People's Republic of China, or PRC, for the greater China market (see "—Collaboration and License Agreements—Syntone-Private Placement and PRC Joint Venture"). If approved, we believe that LYTENAVA (bevacizumab-vikg) will be entitled to 12 years regulatory exclusivity granted in the United States against biosimilar competition, and up to 10 years in Europe.

For many years, anti-VEGF therapy has been the standard of care for many ophthalmic diseases, including wet AMD, DME and BRVO. However, although multiple branded drugs have been approved for these indications (e.g., LUCENTIS, EYLEA, BEOVU, SUSVIMO and VABYSMO), they are very expensive. The initial recently approved biosimilar versions of LUCENTIS are also expensive, although they are available at a discount to the reference drug. Doctors who wish to treat their retinal patients with a less expensive anti-VEGF drug, with minimal reimbursement hurdles, often use off-label bevacizumab. However, because there is no FDA-approved ophthalmic formulation of bevacizumab, doctors must use repackaged bevacizumab (Avastin) provided by compounding pharmacists that is not required to meet the standards for ophthalmic use necessary for an approved product. Despite clinicians' widespread acceptance and use of bevacizumab to treat ophthalmic diseases such as wet AMD, DME and BRVO, no manufacturer has previously sought approval of bevacizumab for these diseases from the FDA.

The repackaged bevacizumab that is provided by compounding pharmacies is not required to meet ophthalmic drug standards and can carry known risks of contamination (including silicone oil droplet contamination from syringes) and inconsistent potency, with potentially severe consequences, as leading retinal societies have reported. For these reasons, the retina community and payors have shown interest in the development of an ophthalmic formulation of bevacizumab that could be an on-label alternative to repackaged bevacizumab from compounding pharmacists. Of 152 U.S. retina physicians surveyed in 2019, nearly 84% indicated they had an interest or high interest in an approved ophthalmic formulation of bevacizumab.

To meet this retinal market need, we are developing ONS-5010 as an investigational ophthalmic formulation of bevacizumab. If approved, it will provide an FDA-approved and European Agency-approved, viable treatment option across the spectrum of anti-VEGF ophthalmic drugs that treat wet AMD, DME and BRVO. Additionally, if approved, it would avoid the safety, sterility, potency, availability and syringe drawbacks that can occur with repackaged bevacizumab from compounding pharmacies.

Furthermore, if ONS-5010 is approved and commercialized, we expect that it will be able to help mitigate the high cost of treatment for retinal diseases. Both in the United States and globally, the high cost of treating retinal diseases such as wet AMD, DME and BRVO can result in patients receiving an insufficient number of treatments, or potentially no treatment at all. We believe in the value of having an affordable, FDA-approved option for patients that is safe, effective, and manufactured under proper guidance. Our commercial strategy for ONS-5010 includes providing an on-label bevacizumab as a first line option for treating retinal diseases. In addition, our approach to responsible price determination is being crafted with the retina community (patients, payors, and providers) to support patient access, maintain physician choice, and accelerate time to treatment. We are committed to keeping the patient at the core of what we do to ensure we provide an affordable option that offers streamlined access to compliant patient support services.

ONS-5010, if approved, has the potential to become the anti-VEGF cornerstone of care for retinal diseases. It may also provide synergies with future long-acting agents and adjunct therapies for advanced treatment of wet AMD, DME and BRVO. ONS-5010 has the potential, if approved and commercialized, to help lower the aggregate costs of treating retinal diseases for the overall healthcare system.

Collaboration and License Agreements

We enter into collaboration and license agreements in the ordinary course of our business. We have in-licensed certain technology from Selexis SA, or Selexis, that we used to research and develop our product candidates. For product candidates developed using the Selexis technology, we enter into commercial license agreements with Selexis that give us rights to commercialize, file investigational new drugs, or INDs and enter into collaborative arrangements with third parties for the further development and commercialization of such biosimilar product candidates. Although we are no longer working on our biosimilar development program, we have licensed rights to these biosimilar product candidates (ONS-3010, ONS-1045 and ONS-1050) in other markets.

Syntone – Private Placement and PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone Ventures LLC, or Syntone, pursuant to which we sold and issued, in a private placement in June 2020, 16,000,000 shares of our common stock at a purchase price of $1.00

per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntone's PRC-based affiliate, pursuant to which we agreed to form a PRC joint venture that is 80% owned by Syntone's PRC-affiliate and 20% owned by us. Upon formation of the PRC joint venture in April 2021, we entered into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

We used approximately $0.9 million of the proceeds from the May 2020 private placement to Syntone to fund our initial capital contribution to the PRC joint venture, and expect to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million within the next three years.

Selexis — Humira (ONS-3010), Avastin (ONS-5010 and ONS-1045) and Herceptin (ONS-1050)

In October 2011, we entered into a research license agreement with Selexis, whereby we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from cell lines created in mammalian cells using the Selexis expression technology, or the Selexis Technology. The research license expired on October 9, 2018, and accordingly, we are no longer using the Selexis Technology in our research.

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for ONS-1045 (which covers ONS-5010), and two of our biosimilar product candidates, ONS-3010 and ONS-1050 (which are no longer in active clinical development). We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

Commercial License Agreements

On April 11, 2013, following the exercise of our option to enter a commercial license under the Selexis research license, we entered into commercial license agreements with Selexis for each of ONS-1045, ONS-3010 and ONS-1050. Under the terms of each commercial license agreement, we acquired a non-exclusive worldwide license under the Selexis Technology to use the cell lines developed under the research license and related materials, to manufacture and commercialize licensed and final products, with a limited right to sublicense.

We were required to pay an upfront licensing fee of CHF 65,000 (approximately $0.1 million) to Selexis for each commercial license and also agreed to pay up to CHF 365,000 (approximately $0.4 million) in milestone payments for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee of CHF 1,750,000 (approximately $1.8 million). The initiation of our Phase 3 clinical program for ONS-5010 in fiscal 2019 triggered a CHF 65,000 (approximately $0.1 million) milestone payment to Selexis under the commercial license agreement, which we paid in November 2019. As of September 30, 2022, we have paid Selexis an aggregate of approximately $0.4 million under the commercial license agreements.

Each of our commercial agreements with Selexis will expire in its entirety upon the expiration of all applicable Selexis patent rights. The licensed patent rights consist of two patent families. The first patent family relates to methods of transferring cells, and is filed in the United States, Australia, Canada, Europe, Japan and Singapore. This patent family begins to expire worldwide in 2022. The second patent family claims DNA compositions of matter useful for having

protein production increasing activity. This patent family is filed in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore and South Africa. This patent family will begin to expire worldwide in 2025. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances.

Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, we have the right to terminate each of the commercial agreements at any time for our convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to the consent of Laboratories Liomont, S.A. de C.V., or Liomont (a licensing partner in Mexico for ONS-3010 and ONS-1045) pursuant to a corresponding letter we executed in conjunction with the standby agreement entered into between Selexis and Liomont on November 11, 2014. The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving our bankruptcy, insolvency or similar circumstances.

Ex-U.S. Collaboration and License Agreements

In addition to pursuing potential strategic collaborations and partnerships for ONS-5010, we have entered into strategic collaborations for our legacy biosimilar drug product candidates that are no longer in active clinical development. Currently, we have a joint participation agreement in place for ONS-3010 with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, whereby we share any future post-Phase 1 development costs with Huahai, and proportionately share the revenues from commercialization of ONS-3010 in the United States, Canada, European Union, Japan, Australia and New Zealand. We could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so, requested by Huahai. However, we do not have any other development and commercialization agreements for the United States or for major ex-U.S. markets, such as the E.U. and Japan.

For emerging markets opportunities, in 2012 and 2013, we established early country-specific partnerships for ONS-3010 and ONS-1045 in China with Huahai, in India with IPCA Laboratories Limited, or IPCA, and in Mexico with Liomont, and in September 2017 we entered into an agreement with BioLexis Pte. Ltd., or BioLexis providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets excluding China, India and Mexico. The Liomont agreement was terminated in April 2021, and the IPCA agreement was terminated with respect to ONS-3010 in August 2022. To date, these agreements have collectively provided an aggregate of $29.0 million in payments as of September 30, 2022.

Until such time as we may enter into a strategic partnership for ONS-5010, aside from our joint participation agreement in place for ONS-3010 with Huahai, whereby we agreed to share post-Phase 1 clinical development costs, and proportionately share the revenues from commercialization of ONS-3010 in the United States, Canada, E.U. and Japan, among other markets, and under which we could be required to form a joint venture with Huahai for ONS-3010 if so requested by Huahai, we do not have any commercial license or development agreements for the United States or for major ex-U.S. markets, such as the E.U. or Japan. We currently have collaboration and license agreements for smaller ex-U.S. markets and, collectively, such agreements have provided an aggregate of $29.0 million in payments as of September 30, 2022 for our most advanced biosimilar product candidates. Our contracts include agreements with IPCA (for ONS-1045 and ONS-1050 in India and other regional markets), Liomont (for ONS-3010 and ONS-1045 in Mexico), Huahai (for ONS-3010 and ONS-1045 in China) and BioLexis (for ONS-3010 and ONS-1045 in emerging markets excluding China, India and Mexico). We have also licensed ONS-5010 to our PRC-joint venture with Syntone which is discussed above. Our arrangements with these partners for our biosimilar product candidates generally include a strategic license for a defined territory for agreed biosimilar product candidates and may also include agreements to assist with research and development to assist our contract counterparty in establishing their own mAb research, development and manufacturing capabilities. Under our existing strategic licensing agreements, we generally received an upfront payment upon execution, and have the ability to earn additional regular milestone payments and the right to receive royalties (generally a mid-single digit to low-teens percentage rate) based on net sales in the agreed territory. Our existing agreements to assist with research and development also included an upfront payment upon execution, and we have the ability to earn additional regular milestone payments, and the right to receive royalties (generally a mid-single digit to low-teens percentage rate) based on net sales in the agreed territory.

Generally, our agreements expire on a product-by-product basis on the date of the expiration of the royalty revenue term for all products in the territory. The royalty revenue term is 10 years from the date of first commercial sale and any renewal is subject to good faith negotiation. The license term for the agreed territory is perpetual. Either party may terminate the agreement in its entirety or with respect to a particular product if the other party materially breaches the agreement, subject to specified notice and cure periods. In addition, we have the right to terminate the agreement in connection with any interference, opposition or challenge of our patent rights. If the agreement is terminated due to our breach, our contract counterparty is generally free to use all applicable technology and know-how that we have provided under the agreement.

As noted above, our collaboration agreements with Huahai also includes a joint participation agreement, which provides for the co-funding of development of ONS-3010 in the United States, Canada, E.U., Japan, Australia and New Zealand and the proportionate sharing of the revenues from commercialization of ONS-3010 in the agreed countries, and also provides for the formation of a joint venture with Huahai to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

In the event Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package," Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed countries. Similarly, revenues from the commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the E.U., among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010.

Throughout the term of the joint participation agreement, we and our affiliates are prohibited from, directly or indirectly, conducting or having conducted or funding any discovery, research, development, regulatory, manufacturing or commercialization activity, alone or in collaboration with a third party, of any biosimilar product having the same reference product as the ONS-3010 compound or corresponding products, for use in the United States, Canada, E.U., Japan, Australia and New Zealand, other than ONS-3010 with Huahai pursuant to the joint participation agreement.

Unless terminated early upon mutual agreement of the parties, or due to a material breach of either party that is uncured, the joint participation agreement will terminate upon entry into a mutually acceptable collaboration agreement between us and Huahai for ongoing development and commercialization of ONS-3010 in the agreed countries, or we and Huahai enter into an agreed license with a third party for such ongoing development and commercialization of ONS-3010 in the agreed countries. If the joint participation agreement is terminated for cause due to our breach, we could be required to refund Huahai any amounts funded by Huahai to develop ONS-3010, as well as pay Huahai a 6% royalty on net sales made by us or an affiliate, as well as 25% of revenues we receive from a sublicensee for commercial sales of ONS-3010 until the aggregate of such payments is equal to 10 times the amount Huahai funded for the development of ONS-3010.

Furthermore, if we were to file a voluntary petition in bankruptcy, or have an involuntary petition filed that we could not dismiss within 120 days, then Huahai would be granted an exclusive license to continue the development and commercialization of ONS-3010 in the agreed countries.

As of September 30, 2022, we have received an aggregate of $5.0 million of payments from IPCA under our various agreements, an aggregate of $3.0 million of payments from Liomont under our various agreements, an aggregate of $16.0 million of payments from Huahai under our various agreements, $10.0 million of which were pursuant to the joint participation agreement, and an aggregate of $5.0 million from BioLexis under our joint development and licensing agreement.

Manufacturing

We are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, to provide product manufacturing in current Good Manufacturing Practices, or cGMP, manufacturing facilities. We have also executed a supply agreement for a best-in-class pre-filled ophthalmic syringe, which we believe will provide both ease-of-use for clinicians and add to ONS-5010's safety profile over the current unapproved therapies that have caused problems

related to syringe malfunction and contamination. We will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed. For a discussion of risks related to our sources and availability of supplies, please see "Risk Factors—Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels." and "Risk Factors—We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business."

Competition

Competition in the area of pharmaceutical research and development is extensive and significantly depends upon multiple scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain regulatory approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours, as well as compounding pharmacies that repackage bevacizumab to treat retinal diseases. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours, and we may also compete against other biotechnology companies in our efforts to find a potential strategic partner for ONS-5010. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the health conditions that we have targeted for product development. We can provide no assurance that developments by others will not render our technology obsolete, noncompetitive or harm our development strategy, that we will be able to keep pace with new technological developments, that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us or that we will be able to enter into a strategic partnership arrangement for ONS-5010. The foregoing factors could have a material adverse effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

We will encounter competition from existing firms that offer competitive solutions in ocular diseases. These competitive companies could develop products that are superior to, or have greater market acceptance than the product candidates being developed by us. We will have to compete against other biotechnology and pharmaceutical companies with greater market recognition and greater financial, marketing and other resources.

Wet-AMD Market

AMD is a medical condition that usually affects older adults and generally results in a loss of vision. AMD occurs in "dry" (non-exudative) and "wet" (exudative) forms. Wet AMD is the advanced form of macular degeneration that involves the formation of abnormal and leaky blood vessels in the back of the eye behind the retina, through a process known as choroidal neovascularization. While the wet form accounts for approximately 15% of all AMD cases, according to the National Eye Institute, it is responsible for 90% of severe vision loss associated with AMD. The National Eye Institute also estimates that the prevalence of wet AMD among adults 40 years or older in the United States is approximately 1.75 million people. In addition, more than 200,000 new cases are diagnosed annually in North America.

Competitive Landscape

Off-label use of bevacizumab (Avastin) is estimated to be approximately 50% of the overall market in the United States. The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including EYLEA, BEOVU, LUCENTIS, SUSVIMO and VABYSMO. Recently, BYOOVIZ was approved and launched which will be followed by CIMERLI, both ranibizumab biosimilars. Annual revenue (worldwide) for anti-VEGF therapies was estimated to be $13.1 billion in 2020 (Triangulation of Global Data, Market Scope and Investor Forecasts (2020)). We expect to price ONS-5010 strategically between $500 and $1,000 per dose, which would make it a lower cost alternative to biosimilars and premium branded products, while higher than off-label compounds. The initial recently approved biosimilar versions of LUCENTIS are also expensive, although they are available at a discount to the reference drug. Bevacizumab, BYOOVIZ, CIMERLI, EYLEA, BEOVU, LUCENTIS and VABYSMO are all administered via intravitreal injections directly into the eye. SUSVIMO is an implantable refillable port delivery system that delivers anti-VEGF for 4-6 months, upon which the device is refilled.

In addition to the other treatments used in patients with wet AMD, there are various other companies with product candidates in Phase 1, 2 and 3 clinical trials for the treatment of wet AMD. Programs currently in Phase 2 or Phase 3 clinical trials include, but are not limited to:

- Ranibizumab biosimilar being developed by Bausch & Lomb and Xbrane Biopharma AB;
- Aflibercept biosimilars developed by Bioeq/Formycon (FB-203), Mylan (M-710) and Samsung/Biogen (SB-15) among others;
- Small molecule receptor tyrosine kinase inhibitor sunitinib malate (Graybug, GB-102); and
- Adeno-associated virus (AAV) carrying aflibercept coding sequence (Adverum, ADVM-022).

We believe that ONS-5010 has potential competitive advantages due to the familiarity of physicians in using off-label Avastin. We also believe that an affordable, FDA-approved bevacizumab option, that is safe, effective, and manufactured under proper guidance will garner strong market uptake and patient access to therapy. Furthermore, we have reduced the risk in our clinical program by leveraging our prior work in developing a biosmilar drug product candidate for Avastin as a treatment for cancer. However, clinical trial data from other clinical programs may negatively impact our ability to garner future financing or business collaborations, combinations or transactions with other pharmaceutical and biotechnology companies.

Intellectual Property

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable and to prevent others from infringing our proprietary rights. We seek to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring E.U. oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. As of November 1, 2022, we own three U.S. patents, fourteen foreign patents, four pending U.S. non-provisional applications, and 38 pending international applications that were nationalized from seven Patent Cooperation Treaty, or PCT, applications, which relate to formulations developed for ONS-3010 and ONS-5010/ONS-1045, methods of antibody purification, methods for purifying antibodies to separate isoforms, methods of use, methods of reducing high molecular weight species, and modulating afucosylated species as well as efficiently determining the amino acid sequence of antibodies. Our first PCT application was nationalized in April 2016 in Australia, Canada, China, Europe, Hong Kong, India, Japan, Mexico and the United States. If granted, patents issuing from these nine applications are expected to expire in 2034, absent any adjustments or extensions. Our second PCT application was nationalized in July 2017 in Europe and the United States. If granted, patents issuing from these two applications are expected to expire in 2036, absent any adjustments or extensions. Our third PCT application was nationalized in June 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2036, absent any adjustments or extensions. Our fourth PCT application was nationalized in July 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our fifth PCT application was nationalized in August 2018 in Australia, Canada,

China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our sixth PCT application was nationalized in August 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our seventh PCT application was nationalized in October 2020 in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, Mexico, New Zealand, Russian Federation, Singapore, South Africa and the United States. If granted, patents issuing from these fourteen applications are expected to expire in 2039, absent any adjustments or extensions. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

Regulatory

Government Regulation and Product Approval

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

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and

- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the

product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

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

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars

have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Other U.S. Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market, our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors expose us to broadly applicable healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in cash or in kind, either to induce or award the referral of an individual, for an item or service or the purchasing, recommending or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on, in certain cases, sham consulting and other financial arrangements with physicians. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or federal civil monetary penalties statute.

Additionally, the federal false claims and civil monetary penalties laws, including the civil False Claims Act prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government has used the civil False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to

defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, via the Physician Payments Sunshine Act, imposes annual reporting requirements on certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Certain states also impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states and local governments require the registration of pharmaceutical sales representatives. Additionally, analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. State laws may also apply that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers or other potential referral sources. In addition, certain states require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing. In addition, state and local laws may require the registration of pharmaceutical sales representatives. We may also be subject to state and foreign 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.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, 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, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare Reform

In the United States and some foreign jurisdictions there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality, and expand access to care. For example, in March 2010, President Obama signed into law the Affordable Care Act, which among other things, expanded coverage for the uninsured while at the same time containing overall healthcare costs, expanded and increased industry rebates for drugs covered under Medicaid programs, and made changes to the coverage requirements under the Medicare prescription drug benefit.

There have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. . In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. Accordingly, we continue to evaluate the effect that the Affordable Care Act has on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 led to automatic reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments will remain in effect until 2031 unless additional Congressional action is taken. The COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. Under current legislation, the actual reduction in Medicare payments vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to

submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The Affordable Care Act, the IRA, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could harm our future revenues.

International Regulation

In addition to regulations in the United States, foreign regulations also govern clinical trials, commercial sales and distribution of product candidates within their jurisdiction. The regulatory approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval. In the European Union, the approval of a biosimilar for marketing is based on an opinion issued by the European Medicines Agency and a decision issued by the European Commission. However, substitution of a biosimilar for the innovator is a decision that is made at the local (national) level on a country-by-country basis. Additionally, a number of European countries do not permit the automatic substitution of biosimilars for the reference product. Many countries also have published their own legislation outlining a regulatory pathway for the development and approval of biosimilars. In some cases, countries have either adopted European guidance or are following guidance issued by the World Health Organization. Although similarities are apparent across these various regulatory guidance, there is also the potential for additional country-specific requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and the adequacy of reimbursement from third-party payors, including government health administrative authorities, managed care organizations, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of drug products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly drug products. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, there is no uniform policy for coverage and reimbursement in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Obtaining and maintaining adequate reimbursement for our product candidates, once approved, may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to existing approved biologics and other therapies. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs in the United States, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

Employees and Human Capital Resources

As of September 30, 2022, we had seventeen full-time employees, five of whom were primarily engaged in research and development activities and four of whom have a Ph.D. degree. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

We initially incorporated in January 2010 in New Jersey as Oncobiologics, Inc., and in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation. In November 2018, we changed our name to Outlook Therapeutics, Inc. Our headquarters are located at 485 Route 1 South, Building F Suite 320, Iselin, New Jersey, 08830, and our telephone number at that location is (609) 619-3990. Our website address is www.outlooktherapeutics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be adversely affected. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months.

We are a pre-commercial biopharmaceutical company and we have incurred net losses in each year since our inception in January 5, 2010, including net losses of $66.1 million and $53.2 million for the years ended September 30, 2022 and 2021, respectively.

We have devoted substantially all of our financial resources to identify, develop and manufacture our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation and clinical trials, regulatory filing and communication activities and providing general and administrative support for these operations. To date, none of our product candidates have been approved for sale and we have financed our operations primarily through the sale of equity securities and debt financings, as well as to a limited degree, payments under our co-development and license agreements. The amount of our future net losses will depend, in part, on our ability to generate revenue from product sales, the rate of our future expenditures and our ability to obtain funding through equity or debt financing or our ability to enter into and receive funding under strategic licensing or co-development collaborations.

We expect to continue to incur significant expenses and operating losses for at least the next 12 months. We anticipate that our expenses may increase substantially if and as we:

- prepare to launch and market ONS-5010 (LYTENAVA (bevacizumab-vikg)), if approved;
- continue the clinical development of ONS-5010;
- advance ONS-5010 into additional clinical trials;
- change or add contract manufacturing providers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;

- seek regulatory and marketing approvals for ONS-5010 in the United States and other markets if we successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and for which we retain such rights;
- seek to identify, assess, acquire or develop other product candidates that may be complementary to ONS-5010;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage in litigation, including patent litigation, with respect to our product candidates;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and any future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed clinical trials, conflicting results, safety issues or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

We have never generated any revenue from product sales and may never be profitable.

Although we have received upfront and milestone payments from our license and collaboration agreements for our inactive biosimilar development programs, we have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, ONS-5010 for the treatment of wet AMD, and our other targeted indications, and as appropriate, any of our other product candidates. We currently estimate that we could potentially begin generating revenue from product sales in the fourth quarter of calendar 2023, but this depends heavily on our success in many areas, including but not limited to:

- completing clinical development of ONS-5010 for the treatment of wet AMD and the other targeted indications, and any other product candidates we may develop in the future;
- obtaining regulatory and marketing approvals for ONS-5010 and any other product candidates for which we or our partners complete clinical trials;
- retaining our manufacturing partner for ONS-5010 and any approved product candidates to support clinical development, regulatory requirements and the market demand for any such approved product candidates;
- launching and commercializing ONS-5010 and any other product candidates for which we or our partners obtain regulatory and marketing approval;
- obtaining third-party coverage and adequate reimbursements for our products;

- obtaining market acceptance of ONS-5010 and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if ONS-5010 or one or more of our other product candidates is approved for commercialization, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the FDA, the EMA, other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, preclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon:

- the size of the markets in the territories for which we gain regulatory approval;
- the number of competitors in such markets;
- the market acceptance of our products;
- the accepted price for the product;
- the ability to obtain coverage and adequate reimbursement for the product;
- the quality and performance of our products, including the relative safety and efficacy; and
- whether we own, or have partnered, the commercial rights for that territory.

If the market for ONS-5010 or any other product candidates we may develop in the future, or our share of that market, is not as large as we expect, the number of indications approved by regulatory authorities is narrower than we expect or the target population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products to become profitable. If we are unable to successfully complete development and obtain regulatory approval for ONS-5010, our business will be harmed.

We will need to raise substantial additional funding to complete the development of ONS-5010 (LYTENAVA (bevacizumab-vikg)) and support our operations after the planned launch in late 2023 until we are able to generate sufficient revenue. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing product candidates is an expensive, risky and lengthy process. We are currently advancing ONS-5010 through the regulatory approval process and additional clinical development. Our expenses may increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, ONS-5010.

As of September 30, 2022, our cash and cash equivalents balance was $17.4 million. We expect that our current cash resources together with the net proceeds of $17.8 million from our December 2022 issuance of an unsecured convertible promissory note, $24.0 million from our December 2022 sale of shares of our common stock in the registered direct equity offering, and $1.1 million from the sale of shares of common stock under our "at-the-market" equity offering program, or the ATM Offering since September 30, 2022, will be sufficient to fund our operations into the third calendar quarter of 2023. We will require substantial additional capital to commercialize ONS-5010. Although we continue to pursue discussions with potential strategic partners for ONS-5010, there is no guarantee that we will be successful in reaching any such agreement, nor that such agreement, if successful, will cover the anticipated commercialization costs for ONS-5010. Our operating plan may also change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as through other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

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 product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact 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 securities to decline. The incurrence of indebtedness could 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 may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, in order to obtain necessary funding, any of which may harm our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of any product candidates. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

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

Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funding. 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 securityholder. Debt financing, if available, 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, and may be secured by all or a portion of our assets.

If we secure development funds for ONS-5010 or any future product candidate through entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our 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, terminate product development or future commercialization efforts or to cease operations altogether.

Risks Related to the Discovery and Development of Our Product Candidates

We are highly dependent on the success of ONS-5010, our only product candidate in active development, and if ONS-5010 does not successfully receive regulatory approval, or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to the advancement of ONS-5010, our only product candidate in active development, through clinical trials and the regulatory approval process, and we also expect that we will need to devote significant effort to the commercialization of ONS-5010 following regulatory approval, if received. We cannot assure you that we will be able to successfully obtain regulatory approval and develop sufficient commercial capabilities for ONS-5010 if and when necessary. Accordingly, our business currently depends heavily on the successful regulatory approval and commercialization of ONS-5010.

We cannot be certain that ONS-5010 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval in our targeted markets. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market ONS-5010 in the United States until we receive approval from the FDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

There can be no assurance that our completed and submitted BLA or MAA of ONS-5010 for wet AMD, or planned future, clinical trials for other retina indications, will ultimately meet the requirements sufficient for us to receive regulatory approval. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010 on August 30, 2022. We may receive a Complete Response Letter from FDA at the conclusion of its review of the BLA, rather than approval, in which case our business, financial condition and results of operations would be harmed. Obtaining approval from the FDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of ONS-5010 for many reasons, including:

- we may not be able to demonstrate that ONS-5010 is effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;

- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of ONS-5010 and any future product candidate, or may require that we conduct additional trials;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Due to our limited resources and access to capital, we have, and will continue to need to, prioritize development of certain product candidates; and these decisions may prove to have been wrong and may harm our business.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. We are currently focusing only on one active development program, ONS-5010, and are no longer actively developing ONS-3010, ONS-1045 or the other biosimilar product candidates in our pipeline. We currently do not intend to actively develop such biosimilar product candidates. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect to certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, our business, financial condition and results of operations could be harmed.

Clinical drug development is a lengthy and expensive process and we may encounter substantial delays in our clinical trials or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

ONS-5010, our only product candidate in active development, will require extensive additional clinical testing before we are prepared to submit an application for regulatory approval for other indications besides wet AMD. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we and any collaboration partners must conduct clinical trials to demonstrate the safety and efficacy of the product candidates in humans.

We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule, if at all. For example, enrollment in the NORSE ONE and NORSE TWO studies was delayed from our original expectations. We could experience similar enrollment delays in the remaining NORSE trials (FOUR, FIVE, SIX and SEVEN) once they are initiated. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be

successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- imposition of a clinical hold by regulatory agencies, after review of an IND, application or amendment or equivalent filing, or an inspection of our clinical trial operations or trial sites, or as a result of adverse events reported during a clinical trial;
- further delays in recruiting suitable patients to participate in our clinical trials;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other countries;
- delays in having subjects complete participation in a study or return for post-treatment follow-up, or subjects dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully complete preclinical studies and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional clinical trials to bridge our modified product candidates to earlier versions.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, EMA or other foreign regulatory agencies.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well controlled clinical trials that our product candidates are as safe and effective for use in a specific patient population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate equivalent safety and efficacy to the satisfaction of the FDA, EMA and other foreign regulatory agencies despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still fail in subsequent confirmatory clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than we have, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including but not limited to changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA, EMA and other foreign regulatory agencies may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a Phase 3 clinical trial that has the potential to result in FDA or other agencies' approval. We initially intend to seek approval for ONS-5010 for the treatment of wet AMD. Any of the regulatory authorities may approve a product candidate for fewer indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.

Our product candidates may cause undesirable side effects or have other properties 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 granted.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates 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 foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, toxicity or other safety issues, and could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits that will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other related considerations, and as such, any manufacturing process changes we implement prior to or after regulatory approval could impact product safety.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

If we receive approval, regulatory agencies including the FDA, EMA and other foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, EMA or other foreign regulatory agencies could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance in the amount of $10.0 million per product candidate and we are required to maintain product liability insurance pursuant to certain of our license agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could negatively impact our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. Furthermore, we may also not be able to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective.

Failure to obtain regulatory approval in any targeted jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.

Neither we nor any collaboration partners have initiated marketing efforts in any jurisdiction. In order to market our products in Europe, the United States and other jurisdictions, we and any collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the regulation and recommendation for approval of human medicines in the E.U. This procedure results in a single marketing authorization that is valid in all E.U. countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or any collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within Europe, the United States or in other jurisdictions. Failure to obtain these approvals would harm our business, financial condition and results of operations.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If ONS-5010, or any other product candidates we may pursue, are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, our current and future manufacturing partners will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any non-disclosure agreement, BLA or marketing authorization application. Accordingly, we and our collaborators and suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or any collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue untitled and warning letters;
- impose civil or criminal penalties;

- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our manufacturing facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be negatively impacted.

The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ONS-5010 in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to ONS-5010, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of ONS-5010 or any future product candidates may not be predictive of the results of our later-stage clinical trials.

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

The FDA could delay, limit or deny approval of a product candidate for many reasons, or request additional information similar to their requests in May 2022, including because they:

- may not deem our product candidate to be adequately safe and effective;
- may not agree that the data collected from clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;

- may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010 on August 30, 2022. Generally, public concern regarding the safety of pharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for ONS-5010. We may receive a Complete Response Letter from FDA at the conclusion of its review of the BLA, rather than approval, in which case our business, financial condition and results of operations would be harmed.

If we experience delays in obtaining approval or if we fail to obtain approval of ONS-5010, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials in the United States in any distinct indication, we must submit the results of preclinical and/or other studies to the FDA along with other information, including information about chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of a product candidate in any indication, we must conduct extensive clinical studies to demonstrate its safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by CROs, and other third parties for regulatory submissions for ONS-5010. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

The FDA may require us to conduct additional studies for a product candidate before it allows us to initiate clinical trials under any IND, which could lead to additional delays and increase the costs of our development programs. Any such delays in the commencement or completion of our planned or future clinical trials could significantly affect our product

development costs. We do not know whether planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA disagreeing as to the design or implementation of our clinical studies;
- obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up, including as a result of the ongoing COVID-19 global pandemic;
- subjects choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA.

Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition and prospects significantly.

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

We may not be able to initiate or continue our planned clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as ONS-5010 or any future product candidates we may develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- invasive procedures required to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

These factors can be exacerbated by other situations, such as the ongoing COVID-19 global pandemic, which impacted enrollment in our NORSE 2 clinical trial. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our

clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with ONS-5010 or any future product candidate could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with a product candidate in planned clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by a product candidate could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons, or could result in a delay of FDA approval, similar to our withdrawal of our BLA in May 2022 to provide additional information requested by the FDA. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of ONS-5010 or any future product candidate will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of ONS-5010 or any future product candidate. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if ONS-5010 or any future product candidate is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test a product candidate in larger, longer and more extensive clinical trials including for additional indications, or as the use of ONS-5010 or any future product candidate becomes more widespread following regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, if ONS-5010 or any future product candidate receives marketing approval, and we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;

- such product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ONS-5010 or any future product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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

From time to time, we may publish interim, top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Risks Related to Commercialization of Our Product Candidates

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours. Other products may be approved and successfully commercialized before ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical markets have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and

biotechnology companies we expect to compete with include, for example, Novartis, which currently markets LUCENTIS and BEOVU, Regeneron, with its product EYLEA, Genentech, the marketer of VABYSMO, and both Biogen and Coherus with their biosimilar formulations of LUCENTIS, all of which have been approved for use in patients with wet AMD. Furthermore, the cancer drug Avastin, sold by Roche, is used off-label in wet AMD patients although it has not been approved for use in these patients. Our ONS-5010 is being developed as an approved alternative to the use of off-label Avastin as well as the much more expensive approved therapies. In addition, these companies and other, smaller, biotechnology and pharmaceutical companies are also developing new treatments for wet AMD and are at various stages of pre-clinical and clinical development.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies, and we also compete against such companies for resources from and in securing partnering arrangements with, such large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Product candidates developed by our competitors may render ONS-5010 and any of our other potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.

We expect additional companies to seek approval to manufacture and market anti-VEGF therapies for ophthalmic indications. If other anti-VEGF therapies are approved and successfully commercialized before ONS-5010, we may never achieve significant market share for this product, our revenue would be reduced and, as a result, our business, prospects and financial condition could be harmed.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of ONS-5010 or any other product candidates we may pursue will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Even though we expect that ONS-5010 will be priced responsibly, if approved, there is no guarantee that ONS-5010 or any other product that we bring to the market directly or through a strategic partner will gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety and efficacy of the product in clinical trials, and potential advantages over competing treatments;
- the publication of unfavorable safety or efficacy data concerning our product by third-parties;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- recognition and acceptance of our product candidates over our competitors' products;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;

- the willingness of the target patient population to try our therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide coverage and adequate reimbursement for ONS-5010, or any other product candidates we may pursue, if approved;
- our ability to maintain compliance with regulatory requirements; and
- labeling or naming imposed by FDA or other regulatory agencies.

Even if ONS-5010 or any other product candidate we may develop in the future displays an equivalent or more favorable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product candidate will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other product candidates. Our efforts, or those of any strategic licensing partner, to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If ONS-5010 or any other product candidates we may develop in the future are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

Even if ONS-5010 is approved, off-label repackaging of Avastin at compounding pharmacies may continue, which could have a material adverse effect on our business and financial condition.

It is currently estimated that Avastin accounts for approximately 50% of wet AMD prescriptions in the United States, notwithstanding that such use is off-label and requires repackaging at a compounding pharmacy. Even if ONS-5010 is approved for use as a treatment for wet AMD, there is no guarantee that we will be effective in reducing the off-label use of Avastin and other drugs in the United States or other major markets where we plan to seek regulatory approval and commercialize ONS-5010, directly or through a strategic partner, if approved. If we are not successful in reducing off-label use of Avastin or other drugs with ONS-5010, our business and financial condition could be adversely affected.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights, we may be unable to generate any revenue.

We currently have no marketing or sales organization. We do not yet have any products approved for sale, and we, as a company, have no experience selling and marketing any pharmaceutical products. To successfully commercialize any products, we will need to develop these capabilities, either on our own or with others. If ONS-5010 receives regulatory approval and we are not able to secure a strategic licensing partner who will commercialize such product, we may need to establish our own sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize ONS-5010 or any other product candidates that are approved in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. Further, given our lack of prior experience in marketing and selling our products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives and medical support liaisons to adequately support the commercialization of ONS-5010 or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we

may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. If we are unable to establish sales and marketing capabilities for any approved product, whether on our own or through collaborations, our results of operations will be negatively impacted.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed.

Because we are a pre-commercial biopharmaceutical company, we have found it necessary to enter into alliances with other companies. For example, we entered into a strategic partnership agreement for consulting services for ONS-5010, pursuant to which we paid a monthly fee prior to terminating such arrangement. We have also entered into service agreements for clinical trials, and co-development and license agreements for our biosimilar product candidates, and are potentially pursuing strategic partners for ONS-5010. In the future, we may also find it necessary to form other alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize the inactive biosimilar product candidates in our pipeline and any other product candidates that we may develop. In such alliances, we would expect our collaboration partners to provide substantial capabilities in regulatory affairs, as well as sales and marketing. We may not be successful in entering into any such alliances, including reaching agreement with a potential partner for ONS-5010. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. We may also have disagreements from time to time with our collaboration partners regarding our rights and obligations under such arrangements. For example, one of our contract counterparties for our former biosimilar program filed a complaint claiming breach. See Item 3. “Legal Proceedings.” If we are not able to successfully resolve this or any other disagreements with our contract partners, it could negatively impact our business or reputation. Further, if we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and even if so, we may underestimate our development costs, and such fund may not be sufficient to develop a particular product candidate internally or to bring it to market. Failure to bring ONS-5010, or any other product candidates we may develop in the future, to market will prevent us from generating sales revenue and this will substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be harmed.

The third-party coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Pricing, coverage and reimbursement of ONS-5010, or any other product candidates we may develop in the future, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development costs and potentially achieve profitability. The availability of coverage and adequacy of reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, if approved. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of ONS-5010 and any of our other product candidates will be paid for by third-party payors such as health maintenance, managed care organizations, pharmacy benefit and similar healthcare management organizations, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only at insufficient levels, we may not be able to successfully commercialize our product candidates. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to realize a return on our investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means and/or certain disabilities. The Medicare and Medicaid programs increasingly are used as models for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for seeking favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in the E.U., Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for ONS-5010, or any other product candidates we may develop in the future. We expect to experience pricing pressures in connection with the sale of ONS-5010, or any other product candidates we may develop in the future, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our future marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, or the DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, or HHS, state attorneys general, members of the U.S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries, and investigations, and civil and criminal sanctions by the FDA, DOJ, or comparable foreign bodies. Any actual or alleged

failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for our product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this Annual Report on Form 10-K or our other filings with the Securities and Exchange Commission, or the SEC, should be viewed with caution. Further, the data and statistical information used in this Annual Report on Form 10-K or our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

If sales of our marketed products do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.

If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed (for example in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA and subsequently re-submitted our BLA on August 30, 2022) or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we or our future collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed.

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical development programs. We rely on these parties for execution of our preclinical and clinical trials and we can only control certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply

with cGMP, GCP, and GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our preclinical and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CROs or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with any of these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going preclinical and clinical programs. If 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 data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Changing or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can negatively impact our ability to meet our desired clinical development timelines. We may encounter challenges or delays in the future and these delays or challenges may have an adverse effect on our business, financial condition and prospects.

Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels.

We no longer have the infrastructure or capability internally to manufacture supplies of ONS-5010, or any other product candidate, for use in clinical development, and we lack the resources and the capability to manufacture any product candidates on a clinical or commercial scale. If we are unable to manufacture or have manufactured sufficient supplies of ONS-5010 or any other product candidates, our development efforts would be delayed, which would adversely affect our business and prospects. We have selected FUJIFILM Diosynth Biotechnologies to manufacture and supply us with our product candidates for future clinical development, as well as to establish commercial supplies of our product candidates. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of ONS-5010 or any other product candidates that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical

development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If ONS-5010 or any of our product candidates are approved, we may need to enter into agreements with another third party for contract manufacturing in order to produce the quantities necessary to meet anticipated market demand. If we are unable to build and stock our product candidates in sufficient quantities to meet the requirements for the launch of these candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

Any adverse developments affecting the manufacture of ONS-5010 could substantially increase our costs and limit supply for such product candidate.

The process of manufacturing our ONS-5010 and our other monoclonal antibody product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- failure to establish contracts with CMOs, and device vendors where applicable;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error;
- infringing intellectual property rights of third parties relating to manufacturing and quality testing;
- failure to achieve or maintain compliance with FDA's requirements for acceptance of the applicable manufacturing facilities; and
- labor shortages, natural disasters and power failures.

Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. In addition, if we require a change in CMO, this will add time along with financial and personnel resources to change manufacturing sites. If microbial, viral or other contaminations are discovered in our product candidates or in our manufacturing facilities, our facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may depend on third parties for the commercialization of ONS-5010, and failure to commercialize in those markets could harm our business and operating results.

We continue to pursue discussions for the licensing and/or co-development rights to ONS-5010 outside of the U.S. We may not be successful in reaching agreements with such parties on terms that are as favorable to our company as we would anticipate. We do not have in place any licensing agreements for commercialization of ONS-5010 and have only licensed ONS-5010 to our PRC-joint venture, for commercialization in greater China. Our current arrangements are for our inactive biosimilar product candidates, and aside from one U.S. arrangement for ONS-3010, are for smaller ex-U.S. markets where we would not otherwise intend to commercialize our biosimilar product candidates, such as China and India, among others.

If any entity with whom we enter into a commercialization arrangement fails to exercise commercially reasonable efforts to market and sell our approved products in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements.

Moreover, any disputes with our collaboration partners concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings.

In the event that any of our license agreements terminate, we may need to find another partner in those markets to commercialize and in certain instances, manufacture any product candidates. Further, upon any such termination, our contract counterparties may still have the right to commercialize these product candidates in such markets, which may affect our ability to commercialize in the same markets.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our current and any future product candidates, and we expect to continue to collaborate with third parties on the development of our current and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our collaboration or similar agreements. For example, under our joint participation arrangement with Huahai, we are obligated to share with Huahai certain information relating to the development of ONS-3010, including reports from nonclinical studies and clinical trials. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, CROs, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We are required to co-fund the development of, and proportionately share in the revenue from, the commercialization of ONS-3010 in the United States, Canada, E.U., Japan, Australia and New Zealand under a joint participation agreement with Huahai. We may also be required to form a joint venture to further co-develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

We currently have a joint participation arrangement with Huahai that provides for the co-funding of the development of ONS-3010 in the United States, Canada, E.U., Japan, Australia and New Zealand and the proportionate sharing of the revenue from commercialization of ONS-3010 in such countries. In the event we were to restart the active development of this program, we could also be required to further co-develop and commercialize ONS-3010 with Huahai in the agreed countries pursuant to a joint venture, if so requested by Huahai, as contemplated by our joint participation agreement. Under the joint participation agreement, assuming Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package" for ONS-3010, we will have a 49% value ownership interest with Huahai having a 51% value ownership interest in ONS-3010. Accordingly, our share of any potential revenues from the successful commercialization of ONS-3010 in the agreed countries, including major markets such as the United States and E.U., would also be in proportion to such ownership interests. While we anticipate that we will each act in accordance with the terms of our agreement for the joint development and commercialization of ONS-3010, we cannot control Huahai, nor can we predict with any certainty that our interests will be aligned and that we will successfully collaborate.

We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business.

Our ONS-5010 product candidate is fill-finished by Ajinomoto Bio-Pharma Services, Inc., or Ajinomoto. As such, we are heavily dependent on Ajinomoto for supplying us with sufficient supply of ONS-5010. Additionally, we selected FUJIFILM Diosynth Biotechnologies to conduct all future manufacturing of ONS-5010 bulk drug substance. Although we believe that there are alternate sources for these services, we cannot assure you that identifying and establishing new relationships would not result in significant delay in the development of ONS-5010. Additionally, we may not be able to enter into arrangements with alternative vendors on commercially reasonable terms, or at all. A delay in the development of ONS-5010 or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could negatively impact our business.

Risks Related to Intellectual Property

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. 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 product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We have conducted patent searches for third-party patents with respect to our lead product candidate, and are not aware of third-party patent families with claims that, if valid and enforceable, could be construed to cover such product candidates or their respective methods of manufacture or use. We cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each

and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing. Moreover, we may face claims from non-practicing third-party entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, the scope of patent claims is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the asserted patent claims or that the claims are invalid and/or unenforceable, and we may not be successful.

Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. In proceedings before courts in the E.U., the burden of proving invalidity of a patent also usually rests on the party alleging invalidity. Even if we are successful in litigation, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could harm our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the E.U. states (including Switzerland) seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from a U.S. application with an effective filing date prior to June 8, 1995 that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may be issued to our competitors covering our product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a candidate into the U.S. market.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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 products or pipeline candidates. We may incorrectly determine that our products are not covered by a third party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

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

We have issued patents and when and if we do obtain additional issued patents, we may discover that competitors are infringing these patents. Expensive and time-consuming litigation may be required to enforce our patents. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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 any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a negative impact on the market price of our securities. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals and retain independent contractors and consultants and members on our board of directors who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual

property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in the development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This 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. 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. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products from using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference

proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

In addition to our issued patents, we have patent applications in the United States and other jurisdictions, which are currently pending, directed to various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents that may be issued to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010 on August 30, 2022.

We have filed patent applications directed to our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Humira and Avastin® (AbbVie and Genentech, respectively) own patents directed to formulations for these products. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products that we believe are not covered by valid claims of third-party patents, including AbbVie or Genentech's formulation patents; and we have filed patent applications directed to our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third-party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of adalimumab (Humira) and bevacizumab (Avastin®) would cover the formulations of any competitors. For example, we are aware that Sandoz is developing biosimilar versions of adalimumab (Humira) and has filed patent applications directed to formulations of adalimumab (Humira). We are also aware that Boehringer is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have patents and patent applications directed to aspects of our downstream manufacturing processes for various biosimilars, including ONS-3010. In contrast to our patent applications directed to formulations of ONS-3010, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third-party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility

of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, 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. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. 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.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the America Invents Act, signed into law on September 16, 2011.

As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the America Invents Act. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO via procedures including post-grant and inter partes review. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a patent invalidated in a Patent Office post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could harm our business and financial condition.

Further, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I); BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II); and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents that we might obtain in the future.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and 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, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

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

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other 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 are party to a non-exclusive worldwide commercial license agreements with Selexis, pertaining to clinical testing and sale of its cell line expression technology and we may enter into additional license agreements in the future. Our commercial license agreements with Selexis impose, and we expect that future license agreements will impose, various milestone payments, royalty payments and other obligations on us. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

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

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property through licenses from third parties, including Selexis, to develop ONS-5010/ONS-1045 and ONS-3010. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. 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.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Risks Related to Our Business Operations

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 global pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, including at our headquarters in New Jersey, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 global pandemic, which has resulted in travel and other restrictions, including on certain businesses and operations deemed non-essential, to reduce the spread of the disease. As a result of travel restrictions, quarantines, shelter-in-place, social distancing and other similar developments, we implemented work-from-home policies for all our employees and have made those changes permanent. While certain of these restrictions were lifted and phased re-openings occurred, there can be no certainty that such policies will continue, or that new or similar restrictions will not be imposed to address continued spread of disease. These restrictions have impacted not just our headquarters, but also the clinical trial sites where our NORSE TWO and NORSE THREE trials occurred, and we experienced enrollment delays in NORSE TWO as a result of the COVID-19 pandemic. The continuing effects of these orders, government-imposed quarantines and our work-from-home policies, including the uncertainty and changing nature of such restrictions, may negatively impact productivity, disrupt our business and could further delay our ONS-5010 clinical programs and timelines, including manufacturing of our product candidate and supply chain, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Further, our ongoing clinical trials could be further affected by the COVID-19 outbreak. Patient enrollment and recruitment of NORSE TWO was delayed due to local clinical trial site protocols designed to protect staff and patients from COVID-19 infection, and some patients may not be able to comply with clinical trial protocols if quarantines or other restrictions, which could be reimposed due to the continuing spread of the disease, impede patient movement or interrupt healthcare services. Similarly, our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be disrupted, which would adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may also materially adversely affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve. The ultimate impact of the COVID-19 outbreak or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic or political disruption such as the war between Ukraine and Russia could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our current effort is focused on the potential approval and commercialization of ONS-5010, the long-term success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. 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 product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost, or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would harm our business and could potentially cause us to cease operations.

We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business and our prospects in the continued development and commercialization of ONS-5010 and any future product candidates we may develop. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow our product offering beyond ONS-5010.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our future performance will also depend, in part, on our ability to successfully integrate new executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Healthcare legislative reform measures may harm our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to improve the access to and quality of healthcare, and to contain healthcare costs. For example, in March 2010, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, imposed 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, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, and promoted a new Medicare Part D coverage gap discount program. The Affordable Care Act also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. Accordingly, we continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, led to aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments will stay in effect until 2031 unless additional Congressional action is taken from May 1, 2020 through March 31, 2022, due to the COVID-19 pandemic. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the Affordable Care Act, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product candidates or additional pricing pressures, and may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

We are subject, directly and indirectly, to federal and state healthcare laws and regulations, including fraud and abuse, false claims, physician payment transparency and health information privacy and security laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

Our operations are directly and indirectly through our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject to various federal and state fraud and abuse laws, including without limitation, the federal Anti-Kickback Statute, the civil False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our clinical research, proposed sales, marketing, charitable donations and grants, education programs and patient assistance. In addition, we may be subject to patient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce, reward, or in return for either the referral of an individual for, or the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which can be enforced by private individuals through civil whistleblower or qui tam actions, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other government health programs that are false or fraudulent;

- HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements, including mandatory contractual terms, relating to the privacy, security and transmission of individually identifiable health information on health plans, certain healthcare providers, and healthcare clearinghouses, known as covered entities, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information;

- the federal legislation commonly referred to as the Physician Payments Sunshine Act under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, individual imprisonment, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, 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, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources.

Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have limited international operations of our own and have several international collaborations. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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

Our third-party suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research, development and manufacturing efforts and business operations, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more

stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with existing strategic partners or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

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 alliance or other alternative arrangements for our 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 product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic transactions related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

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

We may pursue the development of our product candidates in combination with other approved therapeutics. If the FDA revokes approval of any such therapeutic, or if safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with one of our product candidates in the future, we may be unable to further develop and/or market our product candidate or we may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We may pursue the development of our product candidates in combination with other approved therapeutics, and we may commence clinical trials of our product candidates in combination with other approved therapeutics, in the future. In such a case, we will not have developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations will likely not have been previously tested and may, among other

things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of our product candidates when used as monotherapy or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

If the FDA revokes its approval of any combination therapeutic, we would not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues were to arise with therapeutics that we seek to combine with, we could experience significant regulatory delays, and the FDA could require us to redesign or terminate the applicable clinical trials. In addition, we may need, for supply, data referencing or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government 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, and the curtailment or restructuring of our operations.

Our business activities will be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws.

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of

our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are subject to attack by computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization and vulnerable to damage therefrom. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to interrupt our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials 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 was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed.

The ongoing armed conflict between Russia and Ukraine could adversely affect our business, financial condition and results of operations.

On February 24, 2022, Russian military forces launched a military action in Ukraine, and sustained conflict and disruption in the region is likely. The length, impact, and outcome of this ongoing military conflict is highly unpredictable and could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage.

Russia's recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military action against Ukraine have led to substantial expansion of sanction programs imposed by the United States, the European Union, the United Kingdom, Canada, Switzerland, Japan, and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including, among others:

- blocking sanctions against some of the largest state-owned and private Russian financial institutions (and their subsequent removal from the Society for Worldwide Interbank Financial Telecommunication payment system) and certain Russian businesses, some of which have significant financial and trade ties to the European Union;

- blocking sanctions against Russian and Belarusian individuals, including the Russian President, other politicians, and those with government connections or involved in Russian military activities; and

- blocking of Russia's foreign currency reserves as well as expansion of sectoral sanctions and export and trade restrictions, limitations on investments and access to capital markets, and bans on various Russian imports.

In retaliation against new international sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets, the Russian authorities also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non-Russian parties, banned exports of various products, and imposed other economic and financial restrictions. The situation

is rapidly evolving, and additional sanctions by Russia on the one hand, and by the other countries on the other hand, could adversely affect the global economy, financial markets, energy supply and prices, certain critical materials and metals, supply chains, and global logistics and could adversely affect our business, financial condition, and results of operations.

We are actively monitoring the situation in Ukraine and Russia and assessing its impact on our business, including our business partners and customers. To date, we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations. We have no way to predict the progress or outcome of the military conflict in Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or the U.S. The extent and duration of the military action, sanctions, and resulting market disruptions could be significant and could potentially have substantial impact on the global economy and our business, operations, operating results and financial condition as well as our ability to raise additional capital when needed on acceptable terms for an unknown period of time. Any such disruption may also magnify the impact of other risks described in our Annual Report on Form 10-K for the fiscal year ended September 30, 2021.

Risks Related to Ownership of Our Securities

The trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses.

The market price of our securities has been and will likely continue to be volatile. The stock market in general and the market in which we operate have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at a profit. The market price of our securities could be subject to wide fluctuations in response to a variety of factors, including but not limited to:

- the success of competitive services, products or technologies;
- adverse results or delays in preclinical or clinical trials;
- any inability to obtain additional funding;
- any delay in filing an IND, BLA or other regulatory submission for ONS-5010, or any of our product candidates when planned, and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for ONS-5010 or any of our other product candidates;
- failure to successfully develop and commercialize ONS-5010 or any of our other product candidates;
- post-marketing safety issues relating to our product candidates generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;

- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of our product candidates; if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general economic, industry or market conditions;
- sales of our securities by us or our stockholders in the future;
- trading volume of our securities;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- the loss of one or more employees constituting our leadership team;
- changes in regulatory requirements that could make it more difficult for us to develop our product candidates; and
- the other factors described in this "Risk Factors" section.

In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance.

GMS Ventures and Tenshi beneficially own a significant percentage of our common stock, and GMS Ventures has the right to designate members to our board of directors and is able to exert significant control over matters subject to stockholder approval, which could prevent new investors from influencing significant corporate decisions.

As of September 30, 2022, GMS Ventures owned 55,816,786 shares of common stock and a warrant to acquire an additional 1,230,315 shares of common stock and Tenshi Healthcare Pte. Ltd., or Tenshi, owned 22,982,529 shares of our common stock. Accordingly, GMS Ventures and Tenshi beneficially owned approximately 25% and 10% of our common stock, respectively, as of such date. GMS Ventures also acquired 14,230,418 additional shares of our common stock in our December 2022 registered direct equity offering. Under an amended and restated investor rights agreement, with GMS

Ventures, GMS Ventures also currently has the power to designate members of our board of directors proportionate to the aggregate holdings of GMS Ventures and Tenshi (including any of their respective affiliates), and two of our ten board members were designated by GMS Ventures. GMS Ventures' interests may not coincide with the interests of other securityholders. GMS Ventures and Tenshi have the ability to influence our company through their ownership positions and GMS Ventures also has the ability to influence our company through its representation on our board of directors, both of which may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may believe are in your best interest as one of our securityholders.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are out of our control and may be difficult to predict, including but not limited to:

- our ability to successfully develop, market and sell ONS-5010 and any other product candidates;
- the cost of clinical development for ONS-5010 and any other product candidates;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- 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 product candidates or clinical development programs;
- the results of our efforts to discover, develop, manufacture, acquire or in-license additional product candidates;
- 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;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the market price of our securities could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our securities to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

The trading market for our securities depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If any analysts who cover us downgrade our securities or change their opinion of our securities, the market price of our securities would

likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our securities or trading volume to decline.

We are a "smaller reporting company" and, because we have opted to use the reduced reporting requirements available to us, certain investors may find investing in our securities less attractive.

We are a "smaller reporting company" under the SEC's disclosure rules, meaning that we have either: (i) a public float of less than $250 million; or (ii) annual revenues of less than $100 million during the most recently completed fiscal year; and no public float; or a public float of less than $700 million.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies. If investors consider our common shares less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common shares and our share price may be more volatile.

We are also a non-accelerated filer under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common shares less attractive because we are not required to comply with the auditor attestation requirements. We cannot predict if investors will find our securities less attractive because we rely on these available exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the market price of our securities may be more volatile.

We have and will continue to incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results.

As a public company listed in the United States, we have and will continue to incur significant additional legal, accounting and other expenses. The Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and The Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, or as a result of stockholder activism, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report, on the effectiveness of our internal control over financial reporting by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and rely on independent contractors for control monitoring and for the preparation and review of our consolidated financial statements. If we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Future sales and issuances of our common stock or rights to purchase securities, including pursuant to our equity incentive plans or exercise of warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause the market price of our securities to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to the 2015 Equity Incentive Plan, or the 2015 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2015 Plan, the number of shares of our common stock reserved for future issuance as of September 30, 2022 was 13,546,604 shares. The number of shares available for future grant under the 2015 Plan also provides for an "evergreen" increase on an annual basis unless our board of directors determines otherwise. In addition, we have reserved shares for issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, which similarly provides for an annual "evergreen" increase unless determined otherwise by our board of directors. If our board of directors does not elect to reduce the annual increases in the number of shares available for future grant under the 2015 Plan or the ESPP, our stockholders may experience additional dilution, which could cause the market price of our securities to fall. We also currently have issued and outstanding a number of warrants to purchase an aggregate of 6,812,797 shares of our common stock, at prices ranging from $0.9535 to $12.00 per share.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.

The enactment of proposed or future tax legislation may adversely impact our financial condition and results of operations.

On August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA. The IRA contains a number of tax related provisions including a 15% minimum corporate income tax on certain large corporations as well as an exercise tax

on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA, but do not expect it to have a material impact on our financial statements.

We do not intend to pay dividends on our capital stock, and as such any returns will be limited to the value of our securities.

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to securityholders will therefore be limited to the appreciation of their securities.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our securityholders or remove our current management.

Our amended and restated certificate of incorporation, as amended, amended and restated bylaws, as amended and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our charter documents also contain other provisions that could have an anti-takeover effect, such as:

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- providing that directors may only be removed for cause;
- prohibiting cumulative voting for directors;
- requiring super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;
- authorizing the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- prohibiting stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.

These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws, each as amended, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our securityholders to receive a premium for their securities and could also affect the price that some investors are willing to pay for our securities.

Our amended and restated certificate of incorporation and our amended and restated bylaws, each as amended, provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and our amended and restated bylaws, each as amended, provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, each as amended, or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or in our amended and restated bylaws, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

Sales of substantial amounts of our outstanding common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

In addition, in the future, we may issue shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance, including pursuant to any at-the-market agreements, could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters are located in Iselin, New Jersey where we occupy approximately 2,711 square feet of office and warehouse space under a lease that expires in March 2024. In March 2021, we assigned our Monmouth Junction, New Jersey corporate office lease to a third party and as of September 30, 2022, did not have remaining future obligations.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

On July 20, 2020, Liomont filed a complaint against us in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under our June 25, 2014 strategic development, license and supply agreement relating to the biosimilar development program for ONS-3010 and ONS-1045 claiming $3,000,000 in damages. On March 30, 2021, we entered into a confidential settlement agreement with Liomont and the complaint was dismissed on April 11,

2021. We agreed to make an initial settlement payment of $625,000 that was paid in April 2021; and an additional payment of $750,000, which was paid in April 2022. There are no remaining future financial obligations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our units, which comprised one share of our common stock, one-half of a Series A warrant and one-half of a Series B warrant began trading under the symbol "ONSIU" on The Nasdaq Global Market on May 13, 2016 in connection with our initial public offering. Following separation of the units, on June 13, 2016, our shares of common stock and the Series A warrants and Series B warrants began trading under the symbols "ONS," "ONSIW" and "ONSIZ," respectively, and our units were delisted. On February 13, 2018, the listing of our common stock and the Series A Warrants was transferred to The Nasdaq Capital Market. On February 18, 2018, the Series B warrants expired and were delisted on May 16, 2018. Following our name change to "Outlook Therapeutics, Inc.," effective December 4, 2018, our common stock and the Series A warrants began trading under the symbols "OTLK" and "OTLKW," respectively. Prior to our initial public offering, there was no public market for our securities. On February 16, 2022, the Series A warrants expired and were delisted effective February 16, 2022.

On November 30, 2022, the closing sale price of our common stock was $1.04.

Common Stockholders

As of November 30, 2022, there were approximately 96 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during fiscal year ended September 30, 2022.

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

The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A "Risk Factors" in this Annual Report on Form 10-K. See also "Cautionary Note Regarding Forward-Looking Statements and Industry Data." We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.

Overview

We are a biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the U.S. Food and Drug Administration, or FDA, for use in retinal indications. Our goal is to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO. Our plans also include potentially securing a strategic partner for the United Kingdom, Europe, Japan and other markets. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of regulatory exclusivity in the European Union.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In March 2022, we submitted a BLA with the FDA for ONS-5010 (LYTENAVA (bevacizumab-vikg)), an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. Following receipt of further correspondence from the FDA, we confirmed the additional information necessary to re-submit the BLA for ONS-5010 and resubmitted the BLA in August of 2022. In October 2022, we received confirmation from the FDA that our BLA has been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, in October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010 with the European Medicines Agency, or the EMA. On December 22, 2022 our MAA was validated for review by the EMA. The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use, or CHMP, is now set to begin with an estimated decision date expected in early 2024. ONS-5010 is our sole product candidate in active development.

Our BLA and MAA registration program for ONS-5010 in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant. In the ITT primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% ($p = 0.0052$). The primary endpoint was also statistically significant and clinically relevant in the PP dataset ($p = 0.04$) where the percentages were almost identical, at 41.0% with ONS-5010, and 24.7% with ranibizumab. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant ($p = 0.0043$). A mean change of 11.2 letters in BCVA score was observed with ONS-5010, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ($p = 0.05$) with a mean change with ONS-5010 of 11.1 letters versus 7.0 letters with ranibizumab. Results were also positive

for the remaining NORSE TWO secondary endpoints with 56.5% (p = 0.0016) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010 subjects gaining ≥ 5 letters of vision. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010.

Additionally, in November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010 in vials has been completed.

We have also received agreement from the FDA on three Special Protocol Assessments, or SPAs, for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010 to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010 to treat DME. We intend to initiate these studies following the anticipated FDA approval of our BLA for wet AMD.

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. In addition to our BLA submission in the United States, we have submitted an MAA for approval in Europe and plan to submit for regulatory approval in multiple other markets, including the United Kingdom and other major markets. Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of unapproved bevacizumab. Off-label use of unapproved bevacizumab is currently estimated to account for approximately 50% of all wet AMD injections in the United States**.**

Going Concern Consideration

Through September 30, 2022, we have funded substantially all of our operations with $410.6 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements through such date. Our net loss for the year ended September 30, 2022 was $66.1 million. We also had a net loss of $53.2 million for the year ended September 30, 2021. We have not generated any revenue from product sales. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010 or any other product candidate we may develop.

Subsequent to September 30, 2022, we sold 895,391 shares of common stock under our “at-the-market” equity offering program (the “ATM Offering”). We received $1.1 million in gross proceeds from the ATM Offering and the fees paid to the sales agent were immaterial.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 28,460,831 shares of common stock at a purchase price per share of $0.8784 for $24.0 million in net proceeds after payment of placement agent fees and other estimated offering costs. GMS Ventures purchased an aggregate of 14,230,418 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, we issued to M.S. Howells & Co., as placement agent for certain accredited investors in the offering, warrants to purchase up to an aggregate of 515,755 shares of common stock, which will be exercisable commencing on the one-year anniversary of the closing of the offering at an exercise price of $1.05 per share, which warrants have a three-year term.

On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, or the Note, to Streeterville Capital, LLC, or the Lender, the current holder of our outstanding unsecured promissory note maturing on January 1, 2023, or November 2021 Note. The Note has an original issue discount of $1.8 million. We received gross proceeds of $30.0 million upon the closing on December 28, 2022, after

deducting the Lender's transaction costs in connection with the issuance. A portion of the proceeds from the Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. The Note bears interest at 9.5% per annum and matures on January 1, 2024. The Note contains customary covenants, including a restriction on our ability to pledge certain of our assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the Note at an initial conversion price of $2.00 per share. The principal amount and conversion price of the Note are subject to adjustment upon certain triggering events. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Description of Indebtedness" below for additional detail.

We evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. Our current cash resources of $17.4 million as of September 30, 2022, together with the net proceeds of $17.8 million from our December 2022 issuance of the Note, $24.0 million from our December 2022 sale of shares of our common stock in the registered direct equity offering, and $1.1 million from the sale of shares of common stock under our ATM Offering since September 30, 2022, are expected to fund our operations into the third calendar quarter of 2023. These factors raise substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional capital to fund our planned future operations, receive approval for and commercialize ONS-5010, commence and continue clinical trials, or develop other product candidates. We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities and the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Impacts of the COVID-19 Pandemic

We continue to monitor the ongoing COVID-19 global pandemic, which has resulted in travel and other restrictions to reduce the spread of the disease. To date, we have experienced only minor disruptions from the ongoing COVID-19 pandemic, including a brief delay in patient enrollment and recruitment in NORSE TWO due to local clinical trial site protocols designed to protect staff and patients. Given our current infrastructure needs and current strategy, we were able to transition to remote working with limited impact on productivity, as shelter-in-place and other types of local and state orders were imposed. We have confirmed with the Ophthalmic Division of the FDA that it considers both approved and investigational treatments for sight-threatening conditions such as wet AMD not to be elective, and that as such they should continue during any current or potential future COVID-19 restrictions. All clinical and chemistry, manufacturing and control, or CMC, activities are currently active.

All three of our clinical trials required to support our BLA submission are now complete. To date, we have not experienced any significant COVID-19 disruptions to patient follow-up but our clinical trial protocols account for potential delayed or missed visits for any reason, including COVID-19 type interruptions. The FDA has provided guidance in the event of COVID-19 disruptions and we would expect to confer with the FDA and follow the appropriate guidance in the event that any clinical trial experiences an unusually high number of delayed or missed patient visits due to COVID-19.

The safety, health and well-being of all patients, medical staff and our internal and external teams is paramount and is our primary focus. As the pandemic and its resulting restrictions evolve in jurisdictions across the country, we are aware that the potential exists for further disruptions to our projected timelines. We are in close communication with our clinical and manufacturing teams and key vendors and are prepared to take action should the pandemic worsen and impact our business in the future.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of any impacts the evolving COVID-19 pandemic may have on our business, operations, financial position and our clinical and regulatory activities. See also the section titled "Risk Factors" herein for additional information on risks and uncertainties related to the ongoing COVID-19 pandemic.

Collaboration and License Agreements

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our products and/or product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. We have also licensed rights to our legacy biosimilar product candidates (ONS-3010, ONS-1045 and ONS-1050) in other markets.

Syntone – Private Placement and PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone, pursuant to which we sold and issued in a private placement in June 2020, 16,000,000 shares of our common stock at a purchase price of $1.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntone's People's Republic of China, or PRC, based-affiliate, pursuant to which we agreed to form a PRC joint venture that is 80% owned by Syntone's PRC-affiliate and 20% owned by us. Upon formation of the PRC joint venture in April 2021, we entered into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

Selexis SA

In October 2011, we entered into a research license agreement with Selexis whereby we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from cell lines created in mammalian cells using the Selexis expression technology, or the Selexis Technology. The research license expired on October 9, 2018 and accordingly, we are no longer using the Selexis Technology in our research.

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for our ONS-3010, ONS-1045 (which covers ONS-5010) and ONS-1050 product candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee. The initiation of our Phase 3 clinical program for ONS-5010 triggered a CHF 65,000 (approximately $0.1 million) milestone payment under the commercial license agreement, which we paid in November 2019.

Components of Our Results of Operations

Collaboration Revenue

To date, we have derived revenue only from activities pursuant to our emerging market collaboration and licensing agreements related to our inactive biosimilar development program. We have not generated any revenue from commercial product sales. For the foreseeable future, we expect all of our revenue, if any, will be generated from our collaboration and licensing agreements. If any of our product candidates currently under development are approved for commercial sale, we may generate revenue from product sales, or alternatively, we may receive royalties from any collaborator we select to commercialize our product candidates.

Each of our collaboration and licensing agreements was considered to be a multiple-element arrangement for accounting purposes. We determined that there were two deliverables; specifically, the license to our product candidate and the related research and development services that we were obligated to provide. We concluded that these deliverables should be accounted for as a single unit of accounting and revenue was being recognized on a straight-line basis through the estimated period of completion of our obligations under the agreement.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- expenses incurred by us directly, as well as under agreements with contract manufacturing organizations, or CMOs, for manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under a third-party assignment agreement, under which we acquired intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities and other facility-related costs.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials;
- the establishment of commercial manufacturing capabilities;
- the receipt of marketing approvals; and
- the commercialization of product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate

could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Full product commercialization will take several years and millions of dollars in additional costs.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, complexity and duration of later-stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for business development, legal, auditing and tax services and insurance costs.

We anticipate that our general and administrative expenses will increase if and when we believe a regulatory approval of a product candidate appears likely, and we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our product.

Interest Expense

Interest expense consists of cash paid and non-cash interest expense related to our senior secured notes, and unsecured notes with current and former stockholders, equipment loans, lease liabilities and other finance obligations.

Loss on Extinguishment of Debt

During the year ended September 30, 2022, we recorded a loss on extinguishment of $1.0 million in connection with an unsecured promissory note amendment during the year that was accounted for as an extinguishment of the old promissory note.

Change in Fair Value of Warrant Liability

We issued warrants to purchase our common stock in conjunction with our old senior secured notes, which are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations as other (income) expense.

Change in Fair Value of Unsecured Promissory Note

The change in fair value relates to an amended promissory note that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory note. We recorded the convertible promissory note at fair value with changes in fair value recorded in the consolidated statements of operations.

Income Taxes

During the years ended September 30, 2022 and 2021, we had no accruals for foreign withholding taxes in connection with our collaboration and licensing agreements. We did not sell any NOLs or unused research and development tax credits during the years ended September 30, 2022 and 2021.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research and development, or R&D, tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2022, we had federal and state NOL carryforwards of $339.9 million and $175.7 million, respectively, that will begin to expire in 2030

and 2039, respectively. As of September 30, 2022, we had federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2022, we also had federal and state R&D tax credit carryforwards of $10.4 million and $0.8 million, respectively, that will begin to expire in 2032 and 2033, respectively.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after our Initial Public Offering, or IPO, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. 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 be unavailable to offset future income tax liabilities.

On August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA. The IRA contains a number of tax related provisions including a 15% minimum corporate income tax on certain large corporations as well as an exercise tax on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA, but do not expect it to have a material impact on our consolidated financial statements.

Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. 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 be unavailable to offset future income tax liabilities.

Results of Operations

Comparison of Years Ended September 30, 2022 and 2021

	Year ended September 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 42,330,856	$ 38,958,010	$ 3,372,846
General and administrative	20,739,897	12,768,725	7,971,172
Loss from operations	(63,070,753)	(51,726,735)	(11,344,018)
Loss on equity method investment	48,730	46,340	2,390
Interest expense, net	1,487,456	936,127	551,329
Loss on extinguishment of debt	1,025,402	—	1,025,402
Change in fair value of convertible promissory note	882,903	—	882,903
Change in fair value of warrant liability	(465,780)	452,146	(917,926)
Loss before income taxes	(66,049,464)	(53,161,348)	(12,888,116)
Income tax expense	2,800	2,000	800
Net loss	$ (66,052,264)	$ (53,163,348)	$ (12,888,916)

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the years ended September 30, 2022 and 2021:

	Year ended September 30,	
	2022	2021
ONS-5010 development	$ 29,596,954	$ 34,469,098
Compensation and related benefits	2,392,139	1,560,119
Stock-based compensation	2,691,330	953,328
Other research and development	7,650,433	1,975,465
Total research and development expenses	$ 42,330,856	$ 38,958,010

Research and development expenses for the year ended September 30, 2022 increased by $3.4 million compared to the year ended September 30, 2021. The increase was primarily due to an increase in other research and development expenses related to BLA submission fees of $6.2 million incurred during the period, and an increase in stock-based compensation expense of $1.7 million primarily as a result of equity grants that vested during the period upon the achievement of a milestone for performance-based stock options for some of our executives. The increases were partially offset by a decrease in ONS-5010 development costs of $4.9 million as we completed NORSE TWO and NORSE THREE clinical trials in fiscal 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the years ended September 30, 2022 and 2021:

	Year ended September 30,	
	2022	2021
Professional fees	$ 8,637,887	$ 6,038,823
Compensation and related benefits	4,102,783	1,419,954
Stock-based compensation	5,019,474	3,933,959
Facilities, fees and other related costs	2,979,753	1,375,989
Total general and administrative expenses	$ 20,739,897	$ 12,768,725

General and administrative expenses for the year ended September 30, 2022 increased by $8.0 million compared to the year ended September 30, 2021. The increase was due to a $1.1 million increase in stock-based compensation primarily as a result of equity grants that vested during the period upon the achievement of a milestone for performance-based stock options for some of our executives, increased compensation and related benefits of $2.7 million due to increased headcount, a $2.6 million increase in professional fees primarily related to our ongoing pre-launch preparations in anticipation of the potential approval of our BLA for ONS-5010, and a $1.6 million increase in facilities, fees and other expenses associated with increased business insurance premiums and a gain recorded after the assignment of our Monmouth Junction, New Jersey corporate office lease in fiscal 2021.

Interest Expense, Net

Interest expense increased by $0.6 million to $1.5 million for the year ended September 30, 2022, as compared to $0.9 million for the year ended September 30, 2021. The increase was primarily related to a new unsecured promissory note issued in November 2021.

Loss on Extinguishment of Debt

We recognized a $1.0 million loss on extinguishment related to an unsecured promissory note amendment during 2022 that was accounted for as an extinguishment of the old promissory note.

Change in Fair Value of Unsecured Promissory Note

The change in fair value relates to an amended promissory note that we elected to account for at fair value during 2022. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory note. We record the convertible promissory note at fair value with changes in fair value recorded in the consolidated statements of operations.

Change in Fair Value of Warrant Liability

During the year ended September 30, 2022, we recorded income of $0.5 million related to the decrease in the fair value of our common stock warrant liability as a result of the decrease in the price of our common stock during the period. During the year ended September 30, 2021, we recorded a loss of $0.5 million related to the increase in the fair value of our common stock warrant liability as a result of the increase in the price of our common stock during the period.

Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through September 30, 2022, we have funded substantially all of our operations with $410.6 million in net proceeds from the sale and issuance of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of $29.0 million pursuant to emerging markets collaboration and licensing agreements for our inactive biosimilar development programs.

We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010 or any other product candidate we may develop. We will need substantial additional financing to fund our operations and to commercially launch ONS-5010 or any other product candidate we may develop. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

On November 5, 2020, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note, or the 2020 Note, with a face amount of $10.2 million. The 2020 Note bore interest at a rate of 7.5% per annum, and was due to mature on January 1, 2022, and included an original issue discount of $0.2 million. On November 16, 2021, we entered into an amendment to the 2020 Note, which, among other things, (i) extended the maturity date to January 1, 2023, (ii) increased the interest rate from 7.5% per annum to 10% per annum beginning on January 1, 2022, and (iii) provided for the lender's right to redeem some or all of the outstanding balance of the 2020 Note for shares of our common stock beginning July 1, 2022, subject to certain limitations. On June 30, 2022, we prepaid the 2020 Note in full by paying 105% of the outstanding balance. The total payment was $12,934,484, which included interest of $1,546,038.

In February 2021, we closed an underwritten public offering of our common stock for net proceeds of $35.5 million. We also entered into a securities purchase agreement with Syntone Ventures, for the sale of an additional $3.0 million of shares which concurrent private placement closed in February 2021. Following partial exercise of the underwriters' overallotment option, in a separate concurrent private placement, we issued an additional $1.0 million of shares of common stock to GMS Ventures at a purchase price of $1.00 per share.

During the year ended September 30, 2021, warrants to purchase an aggregate of 3,642,138 shares of common stock with a weighted averaged exercise price of $0.9866 were exercised for aggregate gross proceeds of $3.6 million.

During the year ended September 30, 2021, we sold 2,855,190 shares of common stock under our ATM Offering and generated $7.2 million in gross proceeds from the ATM Offering and paid fees to the sales agent of $0.2 million.

On November 16, 2021, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note, or the 2021 Note, with a face amount of $10.2 million. The 2021 Note bears interest at a rate of 9.5% per annum, matures January 1, 2023 and includes an original issue discount of $0.2 million. We may prepay all or a portion of the 2021 Note at any time by paying 105% of the outstanding balance elected for pre-payment.

In November 2021, we issued in an underwritten public offering an aggregate of 46,000,000 shares of common stock at a purchase price per share of $1.25 for $54.0 million in net proceeds after payment of underwriter discounts and commissions and other offering costs. GMS Ventures purchased an aggregate of 16,000,000 shares of common stock in the public offering at the public offering price. In connection with the underwritten public offering, we issued the underwriter warrants to purchase up to an aggregate of 2,100,000 shares of common stock at an exercise price of $1.5625 per share, which warrants have a five-year term.

During the year ended September 30, 2022, warrants to purchase an aggregate of 400,360 shares of common stock with a weighted average exercise price of $12.00 expired; and warrants to purchase an aggregate of 15,675 shares of common stock with a weighted average exercise price of $12.00 were exercised for cash.

During the year ended September 30, 2022, we sold 4,808,269 shares of common stock under our ATM Offering for $8.6 million in gross proceeds, and paid fees to the sales agent of $0.3 million.

Subsequent to September 30, 2022, we sold an additional 895,391 shares of common stock under our ATM Offering for $1.1 million in net proceeds and the fees paid to the sales agent were immaterial.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 28,460,831 shares of common stock at a purchase price per share of $0.8784 for $24.0 million in net proceeds after payment of placement agent fees and other estimated offering costs. GMS Ventures purchased an aggregate of 14,230,418 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, we issued to M.S. Howells & Co., as placement agent for certain accredited investors in the offering, warrants to purchase up to an aggregate of 515,755 shares of common stock, which will be exercisable commencing on the one-year anniversary of the closing of the offering at an exercise price of $1.05 per share, which warrants have a three-year term.

On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, or the Note, to Streeterville Capital, LLC, or the Lender, the current holder of our outstanding unsecured promissory note maturing on January 1, 2023, or November 2021 Note. The Note has an original issue discount of $1.8 million. We received gross proceeds of $30.0 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance. A portion of the proceeds from the Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. The Note bears interest at 9.5% per annum and matures on January 1, 2024. The Note contains customary covenants, including a restriction on our ability to pledge certain of our assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the Note at an initial conversion price of $2.00 per share. The principal amount and conversion price of the Note are subject to adjustment upon certain triggering events. See "Description of Indebtedness" below for additional detail.

We evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. As of September 30, 2022, we had stockholders' equity of $8.7 million. In addition, the $11.1 million 2021 Note, which bears interest at a rate of 9.5% per annum compounding daily, matures January 1, 2023. Our current cash resources of $17.4 million as of September 30, 2022, together with net proceeds of $17.8 million from our December 2022 issuance of the Note, $24.0 million from our December 2022 sale of shares of our common stock in the registered direct equity offering, and $1.1 million from the sale of shares of common stock under our ATM Offering since September 30, 2022, are expected to fund our operations into the third calendar quarter of 2023. These factors raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010 or any other product candidate we may develop. We will

need substantial additional financing to fund our operations and to commercially develop ONS-5010 or any other product candidate we may develop. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above, (ii) our ability to complete revenue-generating partnerships with pharmaceutical companies, (iii) the success of our research and development, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our proposed future products.

Cash Flows

The following table summarizes our cash flows for each of the years presented:

	Year ended September 30,	
	2022	2021
Net cash used in operating activities	$ (56,674,559)	$ (54,253,288)
Net cash provided by financing activities	59,594,047	56,194,626
Net increase in cash	$ $ 2,919,488	$ $ 1,941,338

Operating Activities

During the year ended September 30, 2022, we used $56.7 million of cash in operating activities resulting primarily from our net loss of $66.1 million. This use of cash was partially offset by $11.1 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, change in fair value of unsecured convertible promissory note, loss on extinguishment of debt, loss on equity method investment and depreciation and amortization expense. The net cash outflow of $1.7 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $3.1 million for prepayments associated with ONS-5010 development costs, partially offset by an increase in accounts payable and accrued expenses of $1.5 million.

During the year ended September 30, 2021, we used $54.3 million of cash in operating activities resulting primarily from our net loss of $53.2 million. This use of cash was partially offset by $6.0 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, gain on settlement of lease termination obligation, loss on equity method investment and depreciation and amortization expense. The net cash outflow of $7.1 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $1.7 million for prepayments associated with ONS-5010 development costs, a decrease in accrued expenses of $5.3 million primarily due to the settlement of lease termination obligation and payments to sites for accrued costs, a decrease in accounts payable of $0.2 million and $0.2 million of payments for operating leases. These outflows were partially offset by a decrease in other assets of $0.3 million.

Financing Activities

During the year ended September 30, 2022, net cash provided by financing activities was $59.6 million, primarily attributable to $54.0 million in net proceeds from an underwritten public offering in November 2021 of an aggregate of 46,000,000 shares of our common stock and accompanying 2,100,000 warrants to purchase shares of our common stock, $0.2 million in net proceeds from exercise of common stock warrants, $8.3 million in net proceeds from the sale of common stock under the ATM Offering and $9.4 million in net proceeds from the issuance of an unsecured promissory note with a face amount of $10.2 million in November 2021. We also made $12.3 million in debt and finance lease obligation payments.

During the year ended September 30, 2021, net cash provided by financing activities was $56.2 million, primarily attributable to $39.5 million in net proceeds from the underwritten public offering and concurrent private placement in February 2021 for an aggregate of 42,607,394 shares of our common stock and accompanying 2,116,364 warrants to purchase shares of our common stock, $6.8 million in net proceeds from the sale of common stock under the ATM Offering and $10.0 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million in November 2020. Additionally, we received $3.6 million in net proceeds from common stock warrants exercised. We also made $3.7 million in debt and finance lease obligations payments.

Description of Indebtedness

On November 16, 2021, we received $10.0 million in net proceeds from the issuance of the 2021 Note, with a face amount of $10.2 million. The 2021 Note bears interest at a rate of 9.5% per annum compounding daily, matures January 1, 2023, and includes an original issue discount of $0.2 million. We may prepay all or a portion of the 2021 Note at any time by paying 105% of the outstanding balance elected for pre-payment.

While the 2021 Note is outstanding, we agreed to keep adequate public information available, maintain our Nasdaq listing, and refrain from undertaking certain "Variable Security Issuances" without the noteholders' consent, subject to certain limited exempt issuances, in addition to other negative covenants. The 2021 Note provides that in the event of default if we breach our negative covenants under the purchase agreements, undertake certain "Fundamental Transactions" (as defined therein), along with other customary events of default, in addition to providing for a default rate of 14%, the noteholder has the right to increase the outstanding balance by 5%.

On December 22, 2022, we entered into the Securities Purchase Agreement and issued the Note to the Lender. The Note has an original issue discount of $1.8 million. The Note bears interest at 9.5% per annum and matures on January 1, 2024. The Note contains customary covenants, including a restriction on our ability to pledge certain of our assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the Note at the Conversion Price (as defined below). The principal amount and Conversion Price of the Note are subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $2.50 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Upon the occurrence of certain events described in the Note, including, among others, the Company's failure to pay amounts due and payable under the Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent, each such event, a Trigger Event, the Lender shall have the right, subject to certain exceptions, to increase the balance of the Note by 10% for a Major Trigger Event (as defined in the Note) and 5% for a Minor Trigger Event (as defined in the Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default, such event, an Event of Default. Following an Event of Default, the Lender may accelerate the Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Under the Note, "Conversion Price" means, prior to a Major Trigger Event, $2.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $2.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. While the Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt. Lender will also have a 10% participation right in any future debt or equity financings.

Funding Requirements

We plan to focus in the near term on supporting the review of our BLA submission for ONS-5010 with the FDA and to prepare for the potential launch of LYTENAVA™, if approved, to support the generation of commercial revenues. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able

to initiate commercialization of ONS-5010 if, among other things, the FDA does not approve our BLA when we expect, or at all, or if we are not able to secure sufficient funding of our expected post-launch commercial costs.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, manufacturing and facility costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the marketing and development of our lead product candidate and any other product candidates we may choose to pursue.

We believe our existing cash and cash equivalents as of September 30, 2022 of $17.4 million, together with net proceeds of $17.8 million from our December 2022 issuance of an unsecured promissory note, $24.0 million from our December 2022 sale of shares of our common stock in the registered direct equity offering, and $1.1 million from the sale of shares of common stock under our ATM Offering since September 30, 2022, are expected to fund our operations into the third calendar quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will need to raise substantial additional capital in order to complete our planned ONS-5010 development program. We plan to finance our future operations with a combination of proceeds from potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Further, due to current market volatility, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. There are no assurances that we will be successful in obtaining an adequate level of financing for the commercialization of ONS-5010 or the development of any other current or future product candidates. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010 in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of manufacturing our product candidates and any drugs we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

See Item 1A “Risk Factors” for additional risks associated with our substantial capital requirements**.**

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be 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 and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and 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 service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers require advance payments; however, some invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our prepaid expenses and accrued expenses as of each balance sheet date in the consolidated 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 prepaid and accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities
- CMOs for the production of preclinical and clinical trial materials;
- CROs in connection with clinical trials; and
- clinical trial sites.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In many instances payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In recognizing 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 or prepaid 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, we have not made any material adjustments to our prior estimates of prepaid and accrued research and development expenses.

Recently Issued Accounting Pronouncements

There have been no other accounting pronouncements issued but not yet adopted by us which are expected to have a material impact on our consolidated financial position, results of operations or cash flows.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a “Smaller Reporting Company”, this Item and the related disclosure is not required.

Item 8. Consolidated Financial Statements and Supplementary Data

OUTLOOK THERAPEUTICS, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Outlook Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Outlook Therapeutics, Inc. and subsidiaries (the Company) as of September 30, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of prepaid research and development expenses

As discussed in Note 3 to the consolidated financial statements, research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, as well as regulatory compliance costs. At the end of each reporting period, the Company compares the payments made to third-party service providers to the estimated progress towards completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense related to these costs.

We identified the evaluation of prepaid research and development expenses for a certain contract manufacturing organization (CMO) used by the Company for supply and manufacturing of pre-clinical and clinical trial materials and commercial materials, including manufacturing validation batches, as a critical audit matter. Specifically, evaluating the sufficiency of audit evidence obtained over associated costs incurred for the services provided by the selected CMO required especially subjective auditor judgment due to the nature of evidence available regarding progress towards completion of underlying phases within the statements of work.

The following are the primary procedures we performed to address this critical audit matter. For the selected CMO, we examined (1) statements of work, (2) payments, and (3) communications received from the CMO related to the status of underlying phases within the statements of work, and compared them to the Company's schedule of costs incurred as of year-end. We also confirmed the status of underlying phases within the statements of work directly with the selected CMO. We assessed the sufficiency of audit evidence obtained related to prepaid research and development expenses related to statements of work with the selected CMO by evaluating the cumulative results of the audit procedures.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Philadelphia, Pennsylvania
December 29, 2022

Outlook Therapeutics, Inc.
Consolidated Balance Sheets

	September 30, 2022	September 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 17,396,812	$ 14,477,324
Prepaid expenses and other current assets	10,123,634	7,030,823
Total current assets	27,520,446	21,508,147
Property and equipment, net	—	163,625
Operating lease right-of-use assets, net	70,360	111,429
Equity method investment	804,930	853,660
Other assets	132,015	174,590
Total assets	$ 28,527,751	$ 22,811,451
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 10,915,015	$ 904,200
Current portion of finance lease liabilities	11,751	26,464
Current portion of operating lease liabilities	26,995	42,854
Accounts payable	3,491,485	2,196,349
Accrued expenses	3,427,900	1,725,721
Income taxes payable	1,856,629	1,856,629
Total current liabilities	19,729,775	6,752,217
Long-term debt	—	10,885,854
Finance lease liabilities	4,267	16,018
Operating lease liabilities	—	26,995
Warrant liability	57,138	522,918
Total liabilities	19,791,180	18,204,002
Commitments and contingencies (Note 9)		
Convertible preferred stock:		
Series A convertible preferred stock, par value $0.01 per share: 1,000,000 shares authorized, no shares issued and outstanding	—	—
Series A-1 convertible preferred stock, par value $0.01 per share: 200,000 shares authorized, no shares issued and outstanding	—	—
Total convertible preferred stock	—	—
Stockholders' equity:		
Preferred stock, par value $0.01 per share: 7,300,000 shares authorized, no shares issued and outstanding	—	—
Series B convertible preferred stock, par value $0.01 per share: 1,500,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value $0.01 per share; 325,000,000 shares authorized; 227,310,572 and 176,461,628 shares issued and outstanding at September 30, 2022 and September 30, 2021, respectively	2,273,105	1,764,616
Additional paid-in capital	415,398,984	345,726,087
Accumulated deficit	(408,935,518)	(342,883,254)
Total stockholders' equity	8,736,571	4,607,449
Total liabilities, convertible preferred stock and stockholders' equity	$ 28,527,751	$ 22,811,451

See accompanying notes to consolidated financial statements

Outlook Therapeutics, Inc.
Consolidated Statements of Operations

	Year ended September 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 42,330,856	$ 38,958,010
General and administrative	20,739,897	12,768,725
Loss from operations	(63,070,753)	(51,726,735)
Loss on equity method investment	48,730	46,340
Interest expense, net	1,487,456	936,127
Loss on extinguishment of debt	1,025,402	—
Change in fair value of unsecured convertible promissory note	882,903	—
Change in fair value of warrant liability	(465,780)	452,146
Loss before income taxes	(66,049,464)	(53,161,348)
Income tax expense	2,800	2,000
Net loss	$ (66,052,264)	$ (53,163,348)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.31)	$ (0.35)
Weighted average shares outstanding, basic and diluted	212,079,472	152,676,145

See accompanying notes to consolidated financial statements

Outlook Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

	Stockholders' Equity				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at October 1, 2020	127,183,109	$1,271,831	$ 291,274,366	$(289,719,906)	$ 2,826,291
Issuance of common stock in connection with exercise of warrants	3,815,935	38,159	3,555,221	—	3,593,380
Sale of common stock, net of issuance costs	45,462,584	454,626	46,009,213	—	46,463,839
Stock-based compensation expense	—	—	4,887,287	—	4,887,287
Net loss	—	—	—	(53,163,348)	(53,163,348)
Balance at September 30, 2021	176,461,628	1,764,616	345,726,087	(342,883,254)	4,607,449
Issuance of common stock in connection with exercise of warrants	15,675	157	187,943	—	188,100
Issuance of common stock in connection with exercise of stock options	25,000	250	17,500	—	17,750
Sale of common stock, net of issuance costs	50,808,269	508,082	61,756,650	—	62,264,732
Stock-based compensation expense	—	—	7,710,804	—	7,710,804
Net loss	—	—	—	(66,052,264)	(66,052,264)
Balance at September 30, 2022	227,310,572	$2,273,105	$ 415,398,984	$(408,935,518)	$ 8,736,571

See accompanying notes to consolidated financial statements.

Outlook Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended September 30,	
	2022	**2021**
OPERATING ACTIVITIES		
Net loss	$ (66,052,264)	$ (53,163,348)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	204,694	262,140
Loss on extinguishment of debt	1,025,402	—
Non-cash interest expense	1,655,340	893,886
Stock-based compensation	7,710,804	4,887,287
Change in fair value of unsecured convertible promissory note	882,903	—
Change in fair value of warrant liability	(465,780)	452,146
Gain on settlement of lease termination obligation	—	(552,340)
Loss on equity method investment	48,730	46,340
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,092,811)	(1,729,944)
Other assets	—	298,523
Operating lease liability	(42,854)	(150,346)
Accounts payable	1,295,136	(198,469)
Accrued expenses	156,141	(5,299,163)
Net cash used in operating activities	(56,674,559)	(54,253,288)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of issuance costs	62,307,307	46,301,841
Proceeds from debt	10,000,000	10,000,000
Payment of debt issuance costs	—	(8,032)
Proceeds from exercise of common stock warrants	188,100	3,593,380
Proceeds from exercise of stock options	17,750	—
Payments of finance lease obligations	(26,464)	(29,778)
Repayment of stockholder notes	—	(3,612,500)
Repayment of debt	(12,292,646)	(50,285)
Payment of financing costs	(600,000)	—
Net cash provided by financing activities	59,594,047	56,194,626
Net increase in cash and cash equivalents	2,919,488	1,941,338
Cash and cash equivalents at beginning of year	14,477,324	12,535,986
Cash and cash equivalents at end of year	$ 17,396,812	$ 14,477,324
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,556,691	$ 46,239
Supplemental schedule of non-cash financing activities:		
Deferred offering costs amortization	$ 42,575	$ —

See accompanying notes to consolidated financial statements.

OUTLOOK THERAPEUTICS, INC.
Notes to Consolidated Financial Statements

1. Organization and Operations

Description of the Business

Outlook Therapeutics, Inc. ("Outlook" or the "Company") was incorporated in New Jersey on January 5, 2010, started operations in July 2011, reincorporated in Delaware by merging with and into a Delaware corporation in October 2015 and changed its name to "Outlook Therapeutics, Inc." in November 2018. The Company is a biopharmaceutical company focused on developing and commercializing ONS-5010, an ophthalmic formulation of bevacizumab for use in retinal indications. The Company is based in Iselin, New Jersey.

The Company has been actively monitoring the COVID-19 pandemic and its impact globally. Given the Company's current infrastructure needs and current strategy, the Company was able to transition to remote working with limited impact on productivity, as shelter-in-place and similar government orders were imposed. All development activities are currently active in support of the Company's Biologics License Application ("BLA") registration program for ONS-5010 for wet age-related macular degeneration ("wet AMD"). In fiscal year 2022, the Company submitted the BLA and received confirmation from the U.S. Food and Drug Administration ("FDA") that the BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, the Company submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA), which has been validated for review with an estimated decision date expected in early 2024.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. Management believes the financial results for the year ended September 30, 2022 were not significantly impacted by COVID-19.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $408.9 million as of September 30, 2022. As of September 30, 2022, the Company had $11.1 million of principal and accrued interest due under an unsecured promissory note maturing on January 1, 2023 ("the November 2021 note"). As a result, there is substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Subsequent to September 30, 2022, the Company sold 895,391 shares of common stock under its "at-the-market" equity offering program (the "ATM Offering"). The Company received $1.1 million in net proceeds from the ATM Offering.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures and Investments, or GMS Ventures, the Company's largest stockholder, the Company issued 28,460,831 shares of common stock at a purchase price per share of $0.8784 for $24.0 million in net proceeds after payment of placement agent fees and other estimated offering costs. GMS Ventures purchased an aggregate of 14,230,418 shares of common stock in the registered direct equity offering at the offering price per share. In connection with the registered direct equity offering, the Company issued to M.S. Howells & Co., the placement agent, warrants to purchase up to an aggregate of 515,755 shares of common stock at an exercise price of $1.05 per share, which warrants have a three-year term.

On December 22, 2022, the Company entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, (the " Note"), to Streeterville Capital, LLC, or the Lender, the current holder of the Company's outstanding unsecured promissory note maturing on January 1, 2023. The Note has an original

issue discount of $1.8 million. The Company received net proceeds of $17.8 million upon the closing on December 28, 2022 after deducting the Lender's transaction costs in connection with the issuance and a full payment of the remaining outstanding principal and accrued interest on the November 2021 Note. The November 2021 Note was cancelled upon repayment. The Note bears interest at 9.5% per annum and matures on January 1, 2024. The Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the Note at the Conversion Price (as defined below). The principal amount and conversion price of the Note are subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $2.50 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Upon the occurrence of certain events described in the Note, including, among others, the Company's failure to pay amounts due and payable under the Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent, each such event, a Trigger Event, the Lender shall have the right, subject to certain exceptions, to increase the balance of the Note by 10% for a Major Trigger Event (as defined in the Note) and 5% for a Minor Trigger Event (as defined in the Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default, such event, an Event of Default. Following an Event of Default, the Lender may accelerate the Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Under the Note, "Conversion Price" means, prior to a Major Trigger Event, $2.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $2.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. While the Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt. Lender will also have a 10% participation right in any future debt or equity financings.

Management believes that the Company's existing cash and cash equivalents as of September 30, 2022 together with the net proceeds of $17.8 million from the December 2022 issuance of the Note, $24.0 million from the December 2022 sale of shares of common stock in the registered direct equity offering, and $1.1 million in net proceeds from the sale of shares of common stock under the ATM Offering since September 30, 2022 are expected to fund its operations into the third calendar quarter of 2023. Additional financing will be needed by the Company to fund its operations in the future and to commercially launch ONS-5010 and develop any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may also include, but are not limited to, proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. There can be no assurance that these future funding efforts will be successful.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company's ability to successfully begin marketing of its product candidates or complete revenue-generating partnerships with other companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products.

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3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying consolidated financial statements include the accounts of the Company and Outlook Therapeutics Pty Ltd, its wholly-owned subsidiary incorporated in Australia (the "Subsidiary"). All intercompany accounts and transactions have been eliminated in consolidation. The Company has determined the functional currency of the Subsidiary to be the U.S. dollar. The Company translates assets and liabilities of its foreign operations at exchange rates in effect at the balance sheet date. The Company records remeasurement gains and losses on monetary assets and liabilities, such as incentive and tax receivables and accounts payables, which are not in the functional currency of the operation. These remeasurement gains and losses are recorded in the consolidated statements of operations as they occur.

Cash and cash equivalents

Cash and cash equivalents include cash-on-hand and demand deposits with financial institutions and other short-term investments with maturities of less than three months when acquired and convertible to known cash amounts. At September 30, 2022 and 2021, the Company's cash equivalents consist of a money market account.

Equity method investment

The Company accounts for equity investments where it owns a non-controlling interest, but has the ability to exercise significant influence, under the equity method of accounting. Under the equity method of accounting, the original cost of the investment is adjusted for the Company's share of equity in the earnings or loss of the equity investee and reduced by dividends and distributions of capital received, unless the fair value option is elected, in which case the investment balance is marked to fair value each reporting period and the impact of changes in fair value of the equity investment are reported in earnings. The Company has not elected the fair value option. The Company assesses its investment for other-than-temporary impairment when events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable and recognize an impairment loss to adjust the investment to its then-current fair value.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

Fair value of financial instruments

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

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

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

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

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

At September 30, 2022 and 2021, the Company's financial instruments included cash, accounts payable, accrued expenses and the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The carrying amount of accounts payable, accrued expenses, and the PPP loan approximates fair value due to the short-term maturities of these instruments.

Fair Value Option

The Company elected the fair value option to account for its amended unsecured convertible promissory note. Refer to Note 8 for further details on the amended unsecured convertible promissory note. The fair value of the amended unsecured convertible promissory note at issuance and subsequent to issuance was estimated using a discounted cash flow model. Significant estimates in the cash flow model include the discount rate and the probability and timing of redemption.

Fair Value of Other Financial Instruments

As of September 30, 2022, the carrying value of the unsecured promissory note of $10.9 million approximates fair value due to the short maturity of this instrument.

Property and equipment

Property and equipment are recorded at cost. Depreciation and amortization is determined using the straight-line method over the estimated useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the term of the lease or the estimated useful life of the assets, whichever is shorter. Expenditures for maintenance and repairs are expensed as incurred while renewals and betterments are capitalized. When property and equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in operations.

Long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell.

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Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less ("Short-Term Leases"). For Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the consolidated balance sheet. The Company had no Short-Term Leases as of September 30, 2022.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the re-measured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received, and any initial direct costs incurred are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

Stock-based compensation

The Company measures equity classified stock-based awards based on the estimated fair value on the date of grant and recognizes compensation expense of those awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of stock option awards as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which is described more fully in Note 12. The fair value of each restricted stock award is measured as the fair value per share of the Company's common stock on the date of grant.

Research and development

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use. Research and development expenses are recorded net of expected refunds of eligible research and development costs paid to Australian vendors pursuant to the Australian research and development tax incentive program and GST incurred on services provided by Australian vendors. During the year ended September 30, 2021, the Company recorded $0.1 million in its consolidated statements of operations related to the cash refund it expected to receive from the Australian research and development tax incentive program. During the year ended September 30, 2022, there was no eligible spending as part of this incentive program and as result no amount was recorded on the Company's consolidated statements of operations.

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Income taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, 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. 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 deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Net loss per share

Basic net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. For purposes of calculating diluted net loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, performance-based stock options and units, and stock options and non-vested restricted stock unit ("RSU") awards using the treasury stock method. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Company's loss.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2022 and 2021, as they would be antidilutive:

	As of September 30,	
	2022	2021
Performance-based stock units	2,470	2,470
Performance-based stock options	700,000	1,000,000
Stock options	20,124,581	16,110,015
Common stock warrants	6,812,794	5,128,829

Recently issued accounting pronouncements

There have been no other accounting pronouncements issued but not yet adopted by the Company which are expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

4. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis:

	September 30, 2022		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 57,138

	September 30, 2021		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 522,918

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The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability and unsecured convertible promissory note for the years ended September 30, 2022 and 2021:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2020	$ —	$ 70,772
Fair value at issuance date	12,051,581	—
Change in fair value	—	452,146
Balance at September 30, 2021	12,051,581	522,918
Change in fair value	882,903	(465,780)
Repayment	(12,934,484)	—
Balance at September 30, 2022	$ —	$ 57,138

As further described in Note 8, the Company elected the fair value option to account for its amended unsecured convertible promissory note. The fair value of the amended unsecured convertible promissory note at issuance and subsequent to issuance was estimated using a discounted cash flow model. Significant estimates in the cash flow model include the discount rate and the probability and timing of redemption. The amended unsecured convertible promissory note was repaid in full during the year ended September 30, 2022.

The warrants issued in connection with convertible senior secured notes originally issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017, are classified as liabilities on the accompanying consolidated balance sheets as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrant liability is revalued each reporting period with the change in fair value recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair value of the warrant liability is estimated using the Black-Scholes option pricing model using the following weighted-average assumptions:

	September 30, 2022	2021
Risk-free interest rate	4.23 %	0.62 %
Remaining contractual term of warrants (years)	2.4	3.4
Expected volatility	92.5 %	124.7 %
Annual dividend yield	— %	— %
Fair value of common stock (per share)	$ 1.22	$ 2.17

5. Property and Equipment

Property and equipment, net, consists of:

	September 30, 2022	2021
Laboratory equipment	$ 1,067,351	$ 1,067,351
Less: accumulated depreciation	(1,067,351)	(903,726)
	$ —	$ 163,625

Depreciation expense for the years ended September 30, 2022 and 2021 was $163,625 and $163,624, respectively.

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6. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures LLC ("Syntone Ventures"), the U.S. based affiliate of Syntone Technologies Group Co. Ltd. ("Syntone PRC") on May 22, 2020, the Company and Syntone PRC entered into a joint venture agreement pursuant to which they agreed to form a People's Republic of China ("PRC") joint venture, Beijing Syntone Biopharma Ltd ("Syntone JV"), that is 80% owned by Syntone PRC and 20% owned by the Company. As the Company can exert significant influence over, but does not control, Syntone JV's operations through voting rights or representation on Syntone JV's board of directors, the Company accounts for this investment using the equity method of accounting. Upon formation of Syntone JV in April 2021, the Company entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

The Company made the initial investment of $900,000 in June 2020 and expects to be required to make an additional capital contribution to Syntone JV of approximately $2,100,000, which will be made within four years after the establishment date in accordance with the development plan contemplated in the license agreement or on such other terms within such four-year period. The maximum exposure to a loss as a result of the Company's involvement in Syntone JV is limited to the initial investment and the future capital contributions totaling approximately $2,100,000.

7. Accrued Expenses

Accrued expenses consists of:

	September 30, 2022	2021
Compensation	$ 1,976,252	$ 753,808
Research and development	744,154	808,780
Interest payable	—	12,909
Professional fees	564,423	—
Other accrued expenses	143,071	150,224
	$ 3,427,900	$ 1,725,721

8. Debt

Debt consists of:

	September 30, 2022	2021
Unsecured convertible promissory note (measured at fair value)	$ —	$ 10,938,145
Unsecured promissory note	11,114,518	—
Paycheck Protection Program term loan	—	904,200
Total debt	11,114,518	11,842,345
Less: unamortized loan costs	(199,503)	(52,291)
Total debt, net of unamortized loan costs	10,915,015	11,790,054
Less: current portion	(10,915,015)	(904,200)
Long-term debt	$ —	$ 10,885,854

Unsecured convertible promissory note

On November 5, 2020, the Company received $10,000,000 in net proceeds from the issuance of an unsecured promissory note with a face amount of $10,220,000, which was amended in November 2021 and became convertible. Debt issuance costs totaling $228,032 were recorded as debt discount and were deducted from the principal in the accompanying consolidated balance sheets. The debt discount was amortized as a component of interest expense over the 14-month term

of the underlying debt using the effective interest method. The note bore interest at a rate of 7.5% per annum and was due to mature January 1, 2022. On November 16, 2021, the Company entered into a note amendment, which, among other things, (i) extended the maturity date to January 1, 2023, (ii) increased the interest rate from 7.5% per annum to 10% per annum beginning on January 1, 2022, and (iii) provided for the lender's right to redeem some or all of the outstanding balance of the note for shares of the Company's common stock beginning July 1, 2022, subject to certain limitations. The amendment was accounted for as an extinguishment of the old promissory note. As a result, the Company recorded a loss on debt extinguishment of $1,025,402, which is the difference between the fair value of the amended promissory note and the net carrying value of the old promissory note, which includes $26,488 of unamortized debt discount and lender fees of $552,633. The amended promissory note included redemption options whereby beginning on July 1, 2022, the holder had the option to redeem up to $2,000,000 of outstanding principal and accrued and unpaid interest per calendar month for shares of the Company's common stock at a redemption price equal to 75% of the lowest closing bid price in the three trading days immediately preceding the date the holder delivers written notice. The Company elected to account for the amended promissory note at fair value (Note 4) and was not required to bifurcate the redemption options as derivatives.

The Company prepaid the note in full on June 30, 2022 by paying 105% of the outstanding balance. The total payment was $12,934,484, which included interest of $1,546,038.

Unsecured promissory note

On November 16, 2021, the Company received $10,000,000 in net proceeds from the issuance of an unsecured promissory note with a face amount of $10,220,000. Debt issuance costs totaling $820,000 were recorded as debt discount and are deducted from the principal in the accompanying consolidated balance sheets. The debt discount is amortized as a component of interest expense over the term of the underlying debt using the effective interest method. The note bears interest at a rate of 9.5% per annum compounding daily and matures January 1, 2023. The Company may prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for pre-payment.

During the years ended September 30, 2022 and 2021, the Company recognized $1,655,340 and $893,886, respectively, of interest expense related to the unsecured promissory notes, of which $646,299 and $175,741, respectively, are related to the amortization of debt discount.

Paycheck Protection Program term loan

On May 4, 2020, the Company received $904,200 in proceeds from a loan granted pursuant to the PPP of the CARES Act. The PPP term loan was evidenced by a promissory note containing the terms and conditions for repayment of the PPP term loan. The PPP term loan provided for an initial six-month deferral of payments and any amount owed on the loan had a two-year maturity (May 2022), with an interest rate of 1% per annum. Commencing October 15, 2021, the Company began to pay the lender equal monthly payments of principal and interest as required to fully amortize any principal amount outstanding on the PPP term loan as of October 15, 2021 by May 2, 2022. The loan was fully repaid on May 2, 2022. Interest expense on the PPP loan for the years ended September 30, 2022 and 2021 was $2,718 and $9,219, respectively.

Future maturities of indebtedness at September 30, 2022 are as follows for the years ending September 30:

2023	$ 11,114,518

9. Commitments and Contingencies

Selexis Commercial License Agreements

In April 2013, the Company entered into commercial license agreements with Selexis for each of the ONS-3010, ONS-1045 and ONS-1050 biosimilar product candidates (which agreements were subsequently amended on May 21,

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2014). Under the terms of each commercial license agreement, the Company acquired a non-exclusive worldwide license under the Selexis Technology to use the applicable Selexis expression technology along with the resulting Selexis materials/cell lines, each developed under the research license, to manufacture and commercialize licensed and final products, with a limited right to sublicense.

The Company paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, the Company is required to pay a low single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by the Company or any of the Company's affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, the Company has the right to terminate its royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

Each of the Company's commercial agreements with Selexis will expire upon the expiration of all applicable Selexis patent rights. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, the Company has the right to terminate each of the commercial agreements at any time at its convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to the licensee's consent pursuant to a corresponding letter the Company executed in conjunction with the standby agreement entered into between Selexis and Laboratories Liomont, S.A. de C.V. ("Liomont") in November 2014.

The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving the Company's bankruptcy, insolvency or similar circumstances.

Technology license

The Company entered into a technology license agreement with Selexis that will require milestone payments of $355,737 (based on an exchange rate on September 30, 2022 for converting Swiss Francs to U.S. dollars) to the licensor by the Company upon achievement of certain clinical milestones and pay a single digit royalty on net sales by the Company utilizing such technology. The Company also has the contractual right to buy out the royalty payments at a future date.

Litigation

On July 20, 2020, Liomont, filed a complaint against the Company in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under the June 25, 2014 strategic development, license and supply agreement relating to the biosimilar development program for ONS-3010 and ONS-1045 claiming $3,000,000 in damages. On March 30, 2021, the Company entered into a confidential settlement agreement with Liomont, and the complaint was dismissed on April 11, 2021. The Company agreed to make an initial settlement payment of $625,000 that was paid in April 2021; and an additional payment of $750,000, which was paid in April 2022. There are no remaining future financial obligations.

Leases

Corporate office

In March 2021, the Company assigned its Monmouth Junction, New Jersey corporate office lease to a third party and as of September 30, 2021, did not have remaining future obligations. In March 2021, the Company entered into a new three-year term corporate office lease in Iselin, New Jersey which commenced on April 23, 2021.

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Equipment leases

The Company has equipment leases with terms between 12 and 36 months and has recorded those leases as finance leases. The equipment leases bear interest between 4.0% and 13.0% per annum.

Certain lease agreements contain provisions for future rent increases. Payments due under the lease contracts include minimum payments that the Company is obligated to make under the non-cancelable initial terms of the leases as the renewal terms are at the Company's option. Lease expense is recorded as research and development or general and administrative based on the use of the leased asset.

The components of lease cost for the years ended September 30, 2022 and 2021 were as follows:

	Year ended September 30, 2022	2021
Lease cost:		
Amortization of right-of-use assets	$ —	$ —
Interest on lease liabilities	3,141	5,093
Total finance lease cost	3,141	5,093
Operating lease cost	44,867	106,879
Total lease cost	$ 48,008	$ 111,972

Amounts reported in the consolidated balance sheets for leases where the Company is the lessee were as follows:

	September 30, 2022	2021
Operating leases:		
Right-of-use asset	$ 70,360	$ 111,429
Operating lease liabilities	26,995	69,849
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	16,018	42,482
Weighted-average remaining lease term (years):		
Operating leases	1.6	2.6
Finance leases	1.3	1.7
Weighted-average discount rate:		
Operating leases	7.5%	7.5%
Finance leases	13.0%	9.5%

Other information related to leases for the years ended September 30, 2022 and 2021 are as follows:

	Year ended September 30, 2022	2021
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 3,141	$ 5,093
Operating cash flows from operating leases	46,652	158,708
Financing cash flows from finance leases	26,464	29,778
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ 128,473

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Future minimum payments under noncancelable leases at September 30, 2022 are as follows for the years ending September 30:

	Operating leases	Finance leases
2023	$ 27,675	$ 13,149
2024	—	4,383
Total undiscounted lease payments	27,675	17,532
Less: Imputed interest	680	1,514
Total lease obligations	$ 26,995	$ 16,018

Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company matches 100% of the first 3% of employee contributions. The Company assumes all administrative costs of the Plan. For the years ended September 30, 2022 and 2021, the expense relating to the matching contribution was $83,266 and $40,305, respectively.

10. Stockholders' Equity

Common stock

In February 2021, the Company issued in an underwritten public offering an aggregate of 38,593,767 shares of common stock at a purchase price per share of $1.00 for $35.5 million in net proceeds after payment of underwriter discounts and commissions and other underwriter offering costs. GMS Ventures purchased an aggregate of 8,360,000 shares of common stock in the public offering at the public offering price per share. In a separate concurrent private placement, the Company issued 3,000,000 shares of common stock to Syntone Ventures at a purchase price of $1.00 per share for aggregate gross proceeds of $3.0 million.

Following partial exercise of the underwriters' overallotment option subsequent to the initial closing, and pursuant to the Investor Rights Agreement dated as of September 11, 2017 and as amended, by and among the Company, BioLexis and GMS Ventures, the Company sold an additional 1,013,627 shares of common stock to GMS Ventures in a private placement for aggregate gross proceeds to the Company of $1.0 million at the public offering price per share of $1.00.

In connection with the underwritten public offering (including the partial exercise of the overallotment option) the Company issued the underwriter warrants to purchase up to an aggregate of 2,116,364 shares of common stock at an exercise price of $1.25 per share, which warrants have a 5-year term.

On March 24, 2021, following receipt of stockholder approval at the Company's 2021 annual meeting of stockholders, the number of authorized shares of common stock was increased from 200,000,000 shares to 325,000,000 shares.

In November 2021, the Company issued 46,000,000 shares of common stock in an underwritten public offering at a purchase price per share of $1.25 for $54.0 million in net proceeds after payment of underwriter discounts and commissions and other underwriter offering costs. GMS Ventures, the Company's largest stockholder and strategic partner, purchased an aggregate of 16,000,000 shares of common stock in the public offering at the public offering price per share. In connection with the underwritten public offering, the Company issued the underwriter warrants to purchase up to an aggregate of 2,100,000 shares of common stock at an exercise price of $1.5625 per share, which warrants have a five-year term.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are

entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through September 30, 2022.

H.C. Wainwright & Co. At-the-Market Offering Agreement

On March 26, 2021, the Company entered into an At-the-Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., as sales agent ("Wainwright" or the "Agent"), under which the Company may issue and sell shares of its common stock from time to time through Wainwright as sales agent. The Company filed a prospectus supplement, dated March 26, 2021, with the Securities and Exchange Commission pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to up to $40.0 million from time to time through Wainwright. The Company incurred financing costs of $197,654 which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the ATM Offering. As of September 30, 2022, $119,422 of such deferred costs are included in other assets on the consolidated balance sheets.

Under the Agreement, the Company pays Wainwright a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the Agreement. The offering of common stock pursuant to the Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Agreement or (ii) termination of the Agreement in accordance with its terms.

During the year ended September 30, 2022, the Company sold 4,808,269 shares of common stock under the ATM Offering and generated $8.6 million in gross proceeds. The Company paid fees to the sales agent of $0.3 million.

During the year ended September 30, 2021, the Company sold 2,855,190 shares of common stock under the ATM Offering and generated $7.2 million in gross proceeds. The Company paid fees to the sales agent of $0.2 million.

Common stock warrants

As of September 30, 2022, the Company had the following warrants outstanding to acquire shares of its common stock:

Expiration Date		Shares of common stock issuable upon exercise of warrants		Exercise Price Per Share
December 22, 2024	(i)	277,128	$	12.00
April 13, 2025	(i)	145,686	$	12.00
May 31, 2025	(i)	62,437	$	12.00
February 24, 2025		172,864	$	1.27
February 26, 2024		1,747,047	$	0.9535
June 22, 2025		191,268	$	1.51875
January 28, 2026		2,116,364	$	1.25
November 23, 2026		2,100,000	$	1.5625
		6,812,794		

(i) The warrants were issued in connection with the convertible senior secured notes originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017 and are classified as liabilities on the accompanying consolidated balance sheets, as the warrants include cash settlement features at the option of the holders under certain circumstances. Refer to Note 4 for fair value measurements disclosures.

During the year ended September 30, 2022, warrants to purchase an aggregate of 400,360 shares of common stock with a weighted average exercise price of $12.00 expired; and warrants to purchase an aggregate of 15,675 shares of common stock with a weighted average exercise price of $12.00 were exercised for cash.

OUTLOOK THERAPEUTICS, INC.
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During the year ended September 30, 2021, warrants to purchase an aggregate of 3,642,138 shares of common stock with a weighted averaged exercise price of $0.9866 were exercised for aggregate gross proceeds to the Company of $3,593,380. In addition, warrants to purchase an aggregate of 397,251 shares of common stock with a weighted averaged exercise price of $1.51875 were exercised on a cashless basis and the Company issued 173,797 shares of common stock in connection with these cashless exercises.

11. Preferred Stock

The Company's board of directors has the authority, without further action by its stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. The Company's board of directors has previously designated 1,000,000 shares as "Series A Convertible Preferred Stock," 200,000 shares as "Series A-1 Convertible Preferred Stock" and 1,500,000 shares as "Series B Convertible Preferred Stock." At September 30, 2022 and 2021, there were no shares of preferred stock issued and outstanding.

Series A Convertible Preferred Stock

The Series A Convertible preferred stock, or Series A Convertible, accrued dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A Convertible. The Series A Convertible was also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of common stock or other securities. The initial conversion rate was subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the common stock.

Series A-1 Convertible Preferred Stock

The Series A-1 Convertible preferred stock, or the Series A-1, accrued dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A-1. The Series A-1 was also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of Common Stock or other securities. The holders of the Series A-1 had the right to vote on matters submitted to a vote of the Company's stockholders on an as-converted basis, voting with the Company's other stockholders as a single class. In addition, without the prior written consent of a majority of the outstanding shares of Series A-1, the Company would not take certain actions, including amending its certificate of incorporation or bylaws, or issuing securities ranking pari passu or senior to the Series A-1.

Series B Convertible Preferred Stock

The Series B Convertible preferred stock, or Series B Convertible, were non-voting, did not accrue dividends nor did the shares of Series B Convertible had any specific rights or preferences, and had a par value of $0.01 per share and were convertible into 2,112,676 shares of common stock. The Series B Convertible were not convertible into common stock if the holder thereof would beneficially own more than 9.99% of the common stock, or, if during the first six-month period following the closing of the exchange, 7.50%, but automatically converted into common stock in part from time to time if the holder beneficially owned below a certain beneficial ownership threshold of the common stock.

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Notes to Consolidated Financial Statements

12. Stock-Based Compensation

2011 Equity Incentive Plan

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, RSUs, performance-based awards ("PSUs"), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. As of September 30, 2022, PSUs representing 2,470 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, (the "2015 Plan") no future awards under the 2011 Plan will be granted.

2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Company's 2015 Plan is 34,565,837. As of September 30, 2022, 13,546,604 shares remained available for grant under the 2015 Plan.

Stock options and RSUs granted under the Company's 2015 Plan generally vest over a period of one to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and share of RSU over its vesting period.

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations for the years ended September 30, 2022 and 2021:

	Year ended September 30,	
	2022	2021
Research and development	$ 2,691,330	$ 953,328
General and administrative	5,019,474	3,933,959
	$ 7,710,804	$ 4,887,287

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Stock options

The following table summarizes all of the Company's stock option activity for the years ended September 30, 2021 and 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2020	3,762,143	$ 2.01		
Granted	12,461,645	1.29		
Forfeited or expired	(113,773)	0.76		
Balance at September 30, 2021	16,110,015	1.46		
Granted	4,039,566	1.60		
Exercised	(25,000)	0.71		$ 38,960
Balance at September 30, 2022	20,124,581	$ 1.49	8.3	$ 4,521,960
Exercisable	8,353,802	$ 1.53	7.9	$ 2,067,210
Vested and expected to vest at September 30, 2022	20,124,581	$ 1.49	8.3	$ 4,521,960

The aggregate intrinsic value represents the total amount by which the fair market value of the common stock subject to options exceeds the exercise price of the related options.

The Company estimated the fair value of each stock option award on the grant date using the Black-Scholes option pricing model, wherein expected volatility is based on a weighted average of the Company's historical volatility and the volatilities of similar entities within the Company's industry which are commensurate with the expected term assumption. The expected term calculation is based on the "simplified" method described in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment*, and SAB No. 110, *Share-Based Payment*, since the simplified method provides a reasonable estimate in comparison to actual experience. The risk-free interest rate is based on the U.S. Treasury yield at the date of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield is zero since the Company has never paid cash dividends on its common stock and has no present intention to pay cash dividends. Options granted under the 2015 Plan generally vest over one to four years and have a term of 10 years.

The weighted average grant date fair value of the options awarded to employees and directors for the years ended September 30, 2022 and 2021 was $1.23 and $0.98 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Year ended September 30, 2022	2021
Risk-free interest rate	1.77 %	0.58 %
Expected term (years)	6.0	6.0
Expected volatility	95.3 %	94.5 %
Expected dividend yield	—	—

As of September 30, 2022, there was $11,016,572 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.7 years.

Performance-based stock options

The Company granted certain officers of the Company option awards where vesting was contingent upon meeting certain company-wide performance goals. The performance stock options were granted "at-the-money" and have a term of 10 Years.

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The fair value of each option grant under the performance share option plan was estimated on the date of grant using the same option valuation model used for non-statutory options above. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

The following table summarizes all of the Company's performance-based stock option activity for the years ended September 30, 2021 and 2022.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2020	—	$ —		
Granted	1,000,000	2.42		
Balance at September 30, 2021	1,000,000	2.42		
Granted	1,900,000	1.44		
Forfeited or expired	(2,200,000)	1.89		
Balance at September 30, 2022	700,000	$ 1.44	9.2	$ —
Exercisable	700,000	$ 1.44	9.2	$ —
Vested and expected to vest at September 30, 2022	700,000	$ 1.44	9.2	$ —

The weighted average grant date fair value of the performance stock options awarded for the years ended September 30, 2022 and 2021 was $1.03 and $1.76 per option, respectively. During the year ended September 30, 2022, an aggregate of 700,000 performance-based stock options vested as a result of achieving one of the set performance conditions related to the Company's BLA submission that resulted in the Company recognizing stock-based compensation expense of $718,950 during the year ended September 30, 2022. During the year ended September 30, 2022, an aggregate of 2,200,000 performance-based stock options were forfeited because certain performance conditions were not achieved. During the year ended September 30, 2021, no expense was recognized because the performance conditions were not considered probable of achievement. As of September 30, 2022, there were no remaining performance conditions. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Year ended September 30,	
	2022	2021
Risk-free interest rate	1.26 %	0.88 %
Expected term (years)	5.2	5.4
Expected volatility	91.5 %	93.1 %
Expected dividend yield	—	—

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Performance-based stock units

The Company has issued PSUs, which generally have a ten-year life from the date of grant. Upon exercise, the PSU holder receives common stock or cash at the Company's discretion. The following table summarizes the activity related to PSUs during the years ended September 30, 2021 and 2022:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2020	2,470	$ 49.97		
Forfeitures	—	—		
Balance at September 30, 2021	2,470	$ 49.97		
Forfeitures	—	—		
Balance at September 30, 2022	2,470	$ 49.97	2.0	$ —
Vested and exercisable at September 30, 2022	2,470	$ 49.97	2.0	$ —
Vested and expected to vest at September 30, 2022	2,470	$ 49.97	2.0	$ —

Restricted stock

In January 2020, in connection with the consulting agreements entered into by the Company and four principals of MTTR, the Company issued an aggregate of 7,244,739 shares of its common stock. Refer to Note 14 for further details on the consulting agreements and terminated strategic partnership agreement. The shares may not be sold until the earlier of (i) six months following FDA approval of ONS-5010, (ii) the date the Company publicly announces not to pursue development of ONS-5010, (iii) a change in control or (iv) January 2025. In addition, the Company has the right to repurchase the shares for $0.01 per share if the consultant terminates his agreement other than for good reason or the Company terminates the agreement for cause. The repurchase right lapses, in tiered percentages, based upon the completion of enrollment of the Company's NORSE TWO clinical trial of ONS-5010 by certain dates. The repurchase right may also lapse as to 50% or 100% of the shares if the Company enters into certain agreements pertaining to ONS-5010 that meet certain value thresholds or the Company's share price meets certain predefined targets. The repurchase right also lapses as to 100% of the shares upon the earliest to occur of (i) filing of the BLA for ONS-5010, (ii) termination of the agreement by the consultant for good reason or by the Company other than for cause, (iii) in the event of disability, or (iv) upon a change in control.

The grant date fair value of the restricted shares was $0.54 per share and equal to the closing stock price of the Company's common stock at the time of grant. Compensation expense is recognized over the shorter of the explicit service period or derived service period which was determined to be 4.8 years at the time of grant. Compensation expense may be accelerated when certain performance conditions become probable and the corresponding purchase right has lapsed. During the years ended September 30, 2022 and 2021, the Company recognized compensation expense related to the restricted stock of $2,003,946 and $607,060, respectively. As of September 30, 2022, there was no unrecognized compensation expense related to the restricted stock.

13. Collaboration Arrangements

Syntone Strategic Partnership and PRC Joint Venture

In connection with a stock purchase agreement entered in May 2020 between the Company and Syntone, the Company and Syntone entered into a joint venture agreement pursuant to which they agreed to form a PRC joint venture that will be 80% owned by Syntone and 20% owned by the Company. Upon formation of the PRC joint venture in April 2021, the Company entered into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

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The Company made the initial investment of $900,000 in June 2020. The Company expects to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million, which will be made within four years after the establishment date in accordance with the development plan contemplated in the license agreement or on such other terms within such four-year period.

14. Related-Party Transactions

MTTR - Strategic Partnership Agreement (ONS-5010)

In February 2018, the Company entered into a strategic partnership agreement with MTTR to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, the Company's bevacizumab therapeutic product candidate for ophthalmic indications.

In November 2018, the board of directors of the Company appointed Mr. Terry Dagnon as Chief Operating Officer, and Mr. Jeff Evanson as Chief Commercial Officer. Both Mr. Dagnon and Mr. Evanson initially provided services to the Company pursuant to the February 2018 strategic partnership agreement with MTTR, as amended. Mr. Dagnon and Mr. Evanson were both principals in MTTR. The Company did not pay Mr. Dagnon or Mr. Evanson any direct compensation as consultants or as employees during the period from October 1, 2019 through March 19, 2020. Both Mr. Dagnon and Mr. Evanson were compensated directly by MTTR for services provided to the Company as the Company's Chief Operating Officer and Chief Commercial Officer, respectively, pursuant to the strategic partnership agreement until such agreement, as amended, was terminated effective March 19, 2020. The Company began compensating Mr. Dagnon and Mr. Evanson directly as consultants effective March 19, 2020 pursuant to their respective consulting agreements with the Company, which became effective March 19, 2020 following stockholder approval of the share issuances contemplated therein. Mr. Dagnon and Mr. Evanson have also agreed to provide consulting services to an affiliate of BioLexis pursuant to a separate arrangement.

On January 27, 2020, the Company entered into a termination agreement and mutual release with MTTR to terminate the strategic partnership agreement. Pursuant to the agreement, the Company agreed (x) to issue to the four principals of MTTR (who include two of its named executive officers, Messrs. Dagnon and Evanson), an aggregate of 7,244,739 shares of its common stock, subject to stockholder approval, (y) to enter into consulting agreements with each of the four principals setting forth the terms of his respective compensation arrangement, and (z) to pay MTTR a one-time settlement fee of $110,000, upon effectiveness of the agreement.

Concurrently, the Company also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of his respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of common stock to be issued pursuant hereto. The termination agreement, and the consulting agreements, became effective upon stockholder approval of the share issuance on March 19, 2020. Refer to Note 12 for the accounting of the restricted stock issued and compensation expense recognized.

MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $526,435 and $1,089,408 during the years ended September 30, 2022 and 2021, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 12). As of September 30, 2022 and 2021, the amounts payable to former MTTR principals as consultants of $18,333 and $89,762, respectively, were included in accounts payable in the accompanying consolidated balance sheets.

On December 21, 2021, the Company entered into employment agreements with each of Mr. Dagnon and Mr. Evanson, which superseded and replaced their prior consulting agreements. Pursuant to their new employment agreements, each of Mr. Dagnon and Mr. Evanson will receive a base salary of $450,000 and a discretionary annual cash bonus with a target amount equal to 50% of his respective base salary. In connection with their entry into the employment agreements, each of Mr. Dagnon and Mr. Evanson received a grant of 800,000 options to purchase common stock, one quarter of which will

vest on the first anniversary of the grant and the remainder of which will vest in monthly installments over the succeeding three years, subject to their continued service through each vesting date. In addition, each of Mr. Dagnon and Mr. Evanson received a performance grant of 200,000 options to purchase common stock, which will vest upon the Company's achievement of certain milestones. An aggregate of 200,000 performance-based stock options vested as a result of achieving the performance condition related to the Company's BLA submission. Refer to Note 12 for further details on performance-based stock options.

15. Income Taxes

Income tax benefit for the years ended September 30, 2022 and 2021 consists of the following:

	Year ended September 30,	
	2022	2021
State tax	$ 2,800	$ 2,000

The Company did not sell any New Jersey State net operating losses ("NOLs") or unused research and development tax credits during the years ended September 30, 2022 and 2021.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year ended September 30,	
	2022	2021
U.S. federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(7.1)	(7.0)
Net operating loss	—	1.9
Permanent differences	—	0.4
Research and development credit	(3.5)	(3.7)
Change in valuation allowance	32.1	30.7
Other	(0.5)	(1.3)
Effective income tax rate	(0.0)%	(0.0)%

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The tax effects of the temporary differences that gave rise to deferred taxes were as follows:

	September 30,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 83,971,779	$ 67,778,970
Stock-based compensation	4,331,889	2,168,228
Lease liability	7,588	31,577
Research and development credit carryforward	11,166,153	8,842,001
Foreign tax credits	2,357,309	2,357,309
Accruals and others	815,310	348,605
Gross deferred tax assets	102,650,028	81,526,690
Less: valuation allowance	(102,630,250)	(81,449,372)
	19,778	77,318
Deferred tax liabilities:		
Property and equipment	—	(45,995)
Right-of-use assets	(19,778)	(31,323)
Net deferred tax assets	$ —	$ —

As of September 30, 2022, the Company has approximately $339.9 million and $175.7 million of U.S. federal and New Jersey NOLs that will begin to expire in 2030 and 2039, respectively. As of September 30, 2022, the Company has federal and state research and development tax credit carryforwards of $10.4 million and $0.8 million, respectively, available to reduce future tax liabilities which will begin to expire in 2032 and 2033, respectively. As of September 30, 2022, the Company has federal foreign tax credit (“FTC”) carryforwards of $2.4 million available to reduce future tax liabilities which will begin to expire starting in 2023, of which $1.9 million of the FTC carryforward is included in the balance of unrecognized tax benefits. Realization of the deferred tax asset is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax asset does not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Company’s deferred tax assets as of September 30, 2022 and 2021. The valuation allowance increased by $21.2 million and $16.3 million during the year ended September 30, 2022 and 2021, respectively.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely-than-not be realized. The determination as to whether the tax benefit will more-likely-than-not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties accrued on any unrecognized tax benefits within the provision for income taxes in its consolidated statements of operations.

The 2017 Tax Cuts and Jobs Act (the "Act"), which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 34% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. For the fiscal year ending September 30, 2018, the federal tax rate is 24.3%; for the fiscal year ending September 30, 2019, the federal tax rate is 21.0%. The Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of the Company's foreign subsidiaries to U.S. taxation as global intangible low-taxed income.

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Notes to Consolidated Financial Statements

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year ended September 30,	
	2022	2021
Balance at beginning of year	$ 1,856,629	$ 1,856,629
Changes based on tax positions related to the current year	—	—
Balance at end of year	$ 1,856,629	$ 1,856,629

The Company does not anticipate material change in the unrecognized tax benefits in the next 12 months. These unrecognized tax benefits, if recognized, would affect the annual effective tax rate. The Company's income tax returns for the years from 2011 through 2021 remain open for examination by the Internal Revenue Service as well as various states and municipalities.

Due to the change in ownership provisions of the Code, the availability of the Company's NOL carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax assets with an offsetting reduction in the valuation allowance.

On August 16, 2022, President Biden signed the Inflation Reduction Act ("the IRA"). The IRA contains a number of tax related provisions including a 15% minimum corporate income tax on certain large corporations as well as an exercise tax on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. The Company is in the process of evaluating the IRA, but does not expect it to have a material impact on the Company's consolidated financial statements.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective as of September 30, 2022.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted account principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of September 30, 2022.

As a smaller reporting company, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K because we intend to file our definitive Proxy Statement for our next Annual Meeting of the Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, or the 2023 Proxy Statement, no later than January 30, 2023, and certain information to be included in the 2023 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is to be included in our 2023 Proxy Statement as follows:

- The information relating to our directors and nominees for director is to be included in the section entitled "Election of Directors";
- The information relating to our executive officers is to be included in the section entitled "Executive Officers";
- The information regarding compliance with Section 16(a) of the Exchange Act is to be included in the section entitled "Delinquent Section 16(a) Reports";
- The information regarding family relationships is to be included in the section entitled "Election of Directors – Family Relationships";
- The information relating to our Code of Ethics is to be included in the section entitled "Information Regarding the Board of Directors and Corporate Governance – Code of Ethics"; and
- The information relating to our audit committee and audit committee financial expert is to be included in the section entitled "Information Regarding the Board of Directors and Corporate Governance – Audit Committee".

Item 11. Executive Compensation

The information required by this item is to be included in our 2023 Proxy Statement under the section entitled "Executive Compensation" and is incorporated herein by reference, provided that if the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

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

The information required with respect to equity compensation plans is to be included in our 2023 Proxy Statement under the section entitled "Equity Compensation Plan Information" and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our 2023 Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference, provided that if the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

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

The information required by this item is to be included in our 2023 Proxy Statement under the sections entitled "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance – Independence of the Board of Directors" and is incorporated herein by reference, provided that if the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

Item 14. Principal Accounting Fees and Services

The information required by this item is to be included in our 2023 Proxy Statement under the section entitled "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference, provided that if the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.

(2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on December 6, 2018).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 18, 2019).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 26, 2021).
3.5	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed with the SEC on March 26, 2021).
4.1	Description of Registrant's securities.
10.1#	2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.2#	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.3#	2015 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 99.1 to the Registrant's current report on Form 8-K filed with the SEC on September 18, 2020).
10.4#	Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.5#	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 12, 2016).

10.6#	Form of Indemnity Agreement, by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.7#¥	Consulting Agreement between the Company and The Dagnon Group LLC (Dagnon), dated as of January 27, 2020 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.8#¥	Consulting Agreement between the Company and Scott Three Consulting, LLC (Evanson), dated as of January 27, 2020 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.9#	Amendment No. 1 to Consulting Agreement dated November 8, 2021, by and between the Registrant and Scott Three Consulting, LLC (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on November 12, 2021).
10.10#	Amendment No. 1 to Consulting Agreement dated November 8, 2021, by and between the Registrant and the Dagnon Group LLC (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the SEC on November 12, 2021).
10.11†	ONS-3010 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.12†	ONS-1045 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.13†	ONS-1050 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.14	Form of Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit B to the Note and Warrant Purchase Agreement filed as Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
10.15	Amended and Restated Investor Rights Agreement by and between the Registrant and GMS Ventures and Investments, dated April 21, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 22, 2022).
10.16	Form of Securities Purchase Agreement, dated February 24, 2020, by and among the Company and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.17	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.18	Securities Purchase Agreement by and between the Company and GMS Ventures and Investments dated February 24, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).

10.19	Form of GMS Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.20	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.21	Stock Purchase Agreement dated May 22, 2020, by and between the Registrant and Syntone Ventures LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 28, 2020).
10.22	Form of Securities Purchase Agreement dated June 22, 2020, by and among the Registrant and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC June 23, 2020).
10.23	Securities Purchase Agreement dated June 22, 2020 by and between the Registrant and Syntone Ventures LLC (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC June 23, 2020).
10.24	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC June 23, 2020).
10.25	Note Purchase Agreement dated November 4, 2020, between the Registrant and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC November 6, 2020).
10.26	Promissory Note dated November 4, 2020 between the Registrant and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC November 6, 2020).
10.27	Note Purchase Agreement dated November 16, 2021, between the Registrant and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC November 16, 2021).
10.28	Promissory Note dated November 16, 2021, between the Registrant and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC November 16, 2021).
10.29	Note Amendment dated November 16, 2021, between the Registrant and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC November 16, 2021).
10.30	Securities Purchase Agreement dated January 28, 2021, between the Registrant and Syntone Ventures LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 2, 2021).
10.31	At The Market Offering Agreement between the Company and H.C. Wainwright & Co. dated March 26, 2021 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
10.32	Form of underwriter warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on February 2, 2021).

10.33	Securities Purchase Agreement, dated February 9, 2021, by and between the Company and GMS Ventures and Investments (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on February 11, 2021).
10.34#	Executive Employment Agreement by and between C. Russell Trenary III and Outlook Therapeutics, Inc, dated July 6, 2021 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on July 9, 2021).
10.35#	Amended and Restated Executive Employment Agreement by and between Lawrence Kenyon and Outlook Therapeutics, Inc, dated June 2, 2022 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on June 7, 2022).
10.36#	Executive Employment Agreement by and between Terry Dagnon and Outlook Therapeutics, Inc, dated December 21, 2021 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on December 23, 2021).
10.37#	Executive Employment Agreement by and between Jeff Evanson and Outlook Therapeutics, Inc, dated December 21, 2021 (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the SEC on December 23, 2021).
10.38#*	Outlook Therapeutics, Inc. Non-Employee Director Compensation Policy as Amended and Restated Effective October 1, 2020.
10.39**	Securities Purchase Agreement, dated as of December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 22, 2022).
10.40	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on December 22, 2022).
10.41	Form of Securities Purchase Agreement, dated December 23, 2022, by and among the Company and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2022).
10.42	Letter Agreement, dated December 22, 2022, by and between the Company and M.S. Howells & Co. (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2022).
10.43	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2022).
21.1	Subsidiaries of the Registrant
23.1	Consent of independent registered public accounting firm.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

† Confidential treatment has been granted for certain information contained in this document pursuant to an order of the SEC. Such information (indicated by asterisks) has been omitted and been filed separately with the SEC.

¥ Certain portions of this exhibit (indicated by "[***]") have been omitted because they are not material.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

# Indicates management contract or compensatory plan.

** Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the Securities and Exchange Commission upon its request.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 29, 2022

By: /s/ C. Russell Trenary III
Name: C. Russell Trenary III
Title: President and Chief Executive Officer

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Ralph H. Thurman Ralph H. Thurman	Executive Chairman	December 29, 2022
/s/ C. Russell Trenary III C. Russell Trenary III	President, Chief Executive Officer and Director *(Principal Executive Officer)*	December 29, 2022
/s/ Lawrence A. Kenyon Lawrence A. Kenyon	Chief Financial Officer, Treasurer, Secretary and Director *(Principal Financial and Accounting Officer)*	December 29, 2022
/s/ Yezan Haddadin Yezan Haddadin	Director	December 29, 2022
/s/ Kurt J. Hilzinger Kurt J. Hilzinger	Director	December 29, 2022
Julia A. Haller /s/ Julia A. Haller	Director	December 29, 2022
/s/ Faisal G. Sukhtian Faisal G. Sukhtian	Director	December 29, 2022
/s/ Julian Gangolli Julian Gangolli	Director	December 29, 2022
/s/ Gerd Auffarth Gerd Auffarth	Director	December 29, 2022
/s/ Andong Huang Andong Huang	Director	December 29, 2022

Description of Registrant's Securities

The following is a description of the capital stock of Outlook Therapeutics, Inc. (the "Company," "we," "our," or "us"). The following summary description is based on the provisions of our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), our Amended and Restated Bylaws, (the "Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). This information may not be complete in all respects and is qualified entirely by reference to the provisions of our Certificate of Incorporation, our Bylaws and the DGCL. Our Certificate of Incorporation and our Bylaws are filed as exhibits to our Annual Report on Form 10-K to which this description is filed as Exhibit 4.1.

General

Our authorized capital stock consists of 325,000,000 shares of common stock, par value $0.01 per share (the "Common Stock"), and 10,000,000 shares of preferred stock, par value $0.01 per share (the "Preferred Stock").

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of 662⁄3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our Certificate of Incorporation, including provisions relating to amending our Bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. Our Board of

Directors has previously designated 1,000,000 shares as "Series A Convertible Preferred Stock," 200,000 shares as "Series A-1 Convertible Preferred Stock" and 1,500,000 shares as "Series B Convertible Preferred Stock." As of September 30, 2022, we did not have any shares of preferred stock issued and outstanding.

Stockholder Registration Rights

Certain holders of our securities, including certain holders of 5% of our capital stock who are affiliated with certain of our directors, are entitled to certain rights with respect to registration of such securities under the Securities Act of 1933, as amended. These securities are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of registration rights agreements. In general, the registration of shares of our common stock pursuant to the exercise of registration rights enables the holders to trade such shares without restriction under the Securities Act when the applicable registration statement is declared effective. We generally have agreed to pay the registration expenses for such registration statements, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered. Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. We must use commercially reasonable efforts to keep the registration statement effective until the earlier of the date on which all registrable securities covered by such registration statement have been sold, or at such time that the holders of the registrable securities can sell their shares under Rule 144 of the Securities Act during any three-month period.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Section 203 of the DGCL

We are subject to Section 203 of the DCGL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 662⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder; any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder;

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation; and

- in general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as Amended

Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;

- provide that the authorized number of directors may be changed only by resolution of our board of directors;

- provide that our board of directors is classified into three classes of directors;

- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least a majority of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and

- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions requires approval by the holders of at least 662⁄3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated

preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our Certificate of Incorporation and our Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty to us or our stockholders; any action asserting a claim against us arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable.

Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "OTLK".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219.

OUTLOOK THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

AS AMENDED AND RESTATED EFFECTIVE OCTOBER 1, 2020

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of Outlook Therapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Policy***") for his or her Board service with respect to the Company's fiscal year beginning on October 1 (each, a "***Fiscal Year***"). This Non-Employee Director Compensation Policy will be effective as of October 1, 2020 (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board (the "***Committee***"). The terms and conditions of this Policy shall supersede any prior Non-Employee Director Compensation Policy of the Company.

Annual Cash Compensation

Eligible Directors are eligible to receive the following annual cash compensation in the amounts and subject to the terms and conditions as set forth below. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment. In addition, each Eligible Director may elect to receive all of the annual cash compensation set forth below that the Eligible Director is eligible to earn beginning with the Fiscal Year commencing on October 1, 2020 and each subsequent Fiscal Year in the form of stock options granted pursuant to the Company's 2015 Equity Incentive Plan, as amended (the "***Plan***") subject to the terms and conditions as set forth below.

1. Annual Board Service Retainers:
   a. All Eligible Directors: $40,000
   b. Chairman of the Board Service Retainer (in addition to Annual Board Service Retainer): $30,000
   c. Executive Chairman of the Board Service Retainer (in addition to Annual Board Service Retainer): $120,000

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $4,000
   d. Member of the Executive Committee: $30,000

3. Annual Committee Chair Service Retainer (in lieu of Annual Committee Member Service Retainer):
   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $10,000
   c. Chairman of the Nominating and Corporate Governance Committee: $8,000

Timing of Elections Regarding Annual Cash Compensation; Time and Form of Payment

1. *Current Eligible Directors*: If an Eligible Director's service as an Eligible Director commences prior to the beginning of a Fiscal Year, then the Eligible Director must make an election, prior to the beginning of such Fiscal Year, to receive the Eligible Director's (i) Annual Board Service Retainer(s) for such Fiscal Year and (ii) any Annual Committee Member Service Retainer(s) or Annual Committee Chair Service Retainer(s) that is or may become payable for such Fiscal Year (each, a "***Retainer***") in the form of either cash or stock options. The Retainer(s) will be paid or granted as follows:

- *Cash*: If the Eligible Director elects to receive the Retainers in cash, (i) the Retainers other than the Executive Chairman of the Board Service Retainer will be paid in the form of cash in arrears in equal installments over the applicable number of fiscal quarters during such Fiscal Year, with payment occurring on the last day of the applicable fiscal quarter (i.e., December 31st, March 31st, June 30th or September 30th), and (ii) the Executive Chairman of the Board Service Retainer will be paid in the form of cash in arrears in equal monthly installments on the last day of each month.

- *Stock Options*: If the Eligible Director elects to receive the Retainers in the form of stock options, such stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day in October of such Fiscal Year. Any such award will vest as follows: (i) 25% will vest on the last day of the first fiscal quarter during such Fiscal Year; and (ii) 25% will vest on the last day of each subsequent fiscal quarter during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Notwithstanding the foregoing, if the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board after the third business day in October of such Fiscal Year, then the portion (if any) of his or her Annual Committee Chair Service Retainer, Chairman of the Board Service Retainer or Executive Chairman of the Board Service Retainer, as applicable, that is to be granted in the form of stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day after the date that the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board, as applicable. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.

2. *New Eligible Directors*: If an Eligible Director's service as an Eligible Director commences on or after the beginning of a Fiscal Year, then the Eligible Director must make an election, within 30 days following the commencement of such service, with respect to his or her Retainers that are or may become payable for such Fiscal Year; provided, however, that (a) such election will be applicable only to the portion of the applicable Retainer payable for any fiscal quarter during such Fiscal Year that begins after the date of such election, and (b) no such election may be made if such service commences during the final fiscal quarter of such Fiscal Year. Each such Retainer will be paid or granted as follows:

- *Cash*: If the Eligible Director elects to receive the Retainers in cash, (i) any Retainers other than the Executive Chairman of the Board Service Retainer with respect to any fiscal quarter during such Fiscal Year that begins after the date of such election will be paid in the form of cash in arrears in equal installments over the applicable number of fiscal quarters during such Fiscal Year, with payment occurring on the last day of the applicable fiscal quarter, and (ii) the Executive Chairman of the Board Service Retainer with respect to the remaining portion of the Fiscal Year that begins after the date of such election will be paid in the form of cash in arrears in equal monthly installments on the last day of each month.

- *Stock Options*: If the Eligible Director elects to receive the Retainers in the form of stock options, with respect to any fiscal quarter (or month with respect to the Executive Chairman of the Board Service Retainer) during such Fiscal Year that begins after the date of such election, such stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the first business day of the first fiscal quarter that begins after the date of such election. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Notwithstanding the foregoing, if the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board after the first business day of the first fiscal quarter that begins after the date of such election, then the portion (if any) of his or her Annual Committee Chair Service Retainer, Chairman of the Board Service Retainer or Executive Chairman of the Board Service Retainer, as applicable, that is to be granted in the form of stock options, will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day after the date that the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board, as applicable. Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.

Terms of Elections Regarding Annual Cash Compensation:

- Once an election is submitted for a Fiscal Year, it will be irrevocable with respect to such Fiscal Year.

- An Eligible Director must submit a new election for each Fiscal Year.

- Elections with respect to an Eligible Director's Retainers must be allocated 100% in either cash or stock options. An Eligible Director may not make an election to receive cash or stock options with respect to an individual Retainer or any portion thereof.

Terms of Stock Options Granted Pursuant to Elections:

- Any stock options granted pursuant to an Eligible Director's election will be granted under the Plan and will be subject to the terms and conditions of (i) this Policy, (ii) the Plan and (iii) the form stock option grant notices and agreements approved by the Board for the grant of such awards to Non-Employee Directors (as defined in the Plan).

- The actual number of shares subject to any stock options granted pursuant to this Policy and an Eligible Director's election to receive the Retainers in the form of stock options will be determined by dividing the Retainers by the "fair value" of a share of the Company's common stock ("***Common Stock***") on the third business day in October of the Fiscal Year in which the stock option is granted, determined using a Black-Scholes or binominal valuation model regularly used by the Company.

- The shares subject to any stock options granted pursuant to an Eligible Director's election will vest in installments subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting dates on the terms specified above; provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control (as defined in the Plan), subject in each case to the Eligible Director's Continuous Service as of immediately prior to the Change in Control.

- Any stock options granted pursuant to this Policy will be nonqualified stock options, will have an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant and will have a term of ten years from the date of grant (subject to earlier termination in connection with the Eligible Director's termination of service or certain corporate transactions and in accordance with the terms of the Plan). Any such stock option will become exercisable when vested and the vested portion of any such stock option will remain exercisable in accordance with the stock option grant notice and agreement governing the stock option.

Equity Compensation

The equity compensation set forth below will be granted under the Plan, and will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from

the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: On the date of the Eligible Director's initial election to the Board, for each Eligible Director who is first elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 25,000 shares. The shares subject to each such stock option will vest in three equal installments on the first, second and third anniversary of the date of grant (with the first two tranches rounded down and the third tranche rounded up to the nearest share) such that the stock option will be fully vested as of the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service through such vesting dates, provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control, subject in each case to the Eligible Director's Continuous Service as of immediately prior to the Change in Control.

2. Annual Grant: On the date of each annual stockholders meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase Common Stock with an aggregate "fair value" of $35,000 as of such date, determined using a Black-Scholes or binominal valuation model regularly used by the Company. The shares subject to each such stock option will vest on the first anniversary of the date of grant, provided that such shares will in any case be fully vested on the date of Company's next annual stockholders meeting, subject in each case to the Eligible Director's Continuous Service through such vesting date, provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control, subject in each case to the Eligible Director's Continuous Service as of immediately prior to the Change in Control.

Exhibit 21.1

Subsidiaries of the Registrant

Name of Subsidiary	**State or Other Jurisdiction**
Outlook Therapeutics Pty Ltd	Australia
Outlook Therapeutics Limited (dormant subsidiary)	England and Wales
Outlook Therapeutics Limited	Republic of Ireland

This list does not include joint ventures in which the Company has an ownership interest.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-211362, 333-216081, 333-223064, 333-229685, 333-234024, 333-236471, 333-238318, 333-254777 and 333-262731) on Form S-8 and (Nos. 333-222387, 333-223063 and 333-254778) on Form S-3 of our report dated December 29, 2022, with respect to the consolidated financial statements of Outlook Therapeutics, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
December 29, 2022

Exhibit 31.1

CERTIFICATIONS

I, C. Russell Trenary III, certify that:

1. I have reviewed this Annual Report on Form 10-K of Outlook Therapeutics, Inc. (the "registrant"); and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 29, 2022
/s/ C. Russell Trenary III
C. Russell Trenary III
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Outlook Therapeutics, Inc. (the "registrant"); and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 29, 2022
/s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, C. Russell Trenary III, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, certifies that the Annual Report of Outlook Therapeutics, Inc. on Form 10-K for the year ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: December 29, 2022

By: /s/ C. Russell Trenary III
Name: C. Russell Trenary III
Title: Chief Executive Officer
(Principal Executive Officer)

I, Lawrence A. Kenyon, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, certifies that the Annual Report of Outlook Therapeutics, Inc. on Form 10-K for the year ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: December 29, 2022

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.