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OUTLOOK  
THERAPEUTICS

2024 CORPORATE  
ANNUAL  
REPORT



**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, 2024

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-37759

**OUTLOOK THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**38-3982704**

(I.R.S. Employer Identification No.)

**111 S. Wood Avenue, Unit #100  
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:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|----------------------------|--------------------------|--|
| 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 | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                                     | Emerging growth company   | <input type="checkbox"/>            |

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

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

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

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

Indicate by check mark whether 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, 2024 (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 \$180.4 million.

As of December 24, 2024, the registrant had outstanding 24,905,635 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, 2024.

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**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.

Currency 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, 2024, or CHF 0.9015 = \$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;
- There is substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional funding to complete the development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-gamma) outside of the European Union (the “EU”) and United Kingdom (the “UK”) and support our operations until we are able to generate sufficient revenue from the sales of ONS-5010/LYTENAVA in the EU and UK. 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, including modifications to our existing convertible securities, 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/LYTENAVA, our only product that has been approved in the EU and UK. If ONS-5010/LYTENAVA does not receive regulatory approval outside the EU and UK, or is not successfully commercialized, our business may be harmed;
- 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;
- 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/LYTENAVA outside of the EU and UK or in any other indications for which we plan to develop the product, 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 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 and maintain 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/LYTENAVA, 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 ONS-5010/LYTENAVA outside the EU and UK, or for any other of our product candidates, or commercialize ONS-5010/LYTENAVA or any other of 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/LYTENAVA. 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 ONS-5010/LYTENAVA or our other 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 ONS-5010/LYTENAVA or any future 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 ONS-5010/LYTENAVA 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;
- 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;
- We and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcome;
- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences, which may adversely affect our business;
- 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, beneficially owns a significant percentage of our common stock and 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

#### Overview

We are a biopharmaceutical company that is the first to receive marketing authorization for an ophthalmic formulation of ONS-5010/LYTENAVA™ (bevacizumab-gamma) for use in treating wet age-related macular degeneration, or wet AMD, in the European Union, or EU, and United Kingdom, or UK. We are developing ONS-5010/LYTENAVA to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. We are also working to receive approval and launch ONS-5010/LYTENAVA in the United States. Our initial goal is to launch directly in the EU and the UK, and in the United States, if approved, as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets, either directly or through a strategic partner, if approved. We have entered into a collaboration agreement with Cencora (formerly AmerisourceBergen Corporation) to support the commercial launch of ONS-5010/LYTENAVA in Europe and the United States.

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 October 2022, we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency (EMA). On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD, which is valid throughout the European Economic Area, or EEA. The marketing authorization in the EEA provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received approval from the Medicine and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD. Additionally, on December 4, 2024, the UK National Institute for Health and Care Excellence (NICE) recommended LYTENAVA™ (bevacizumab gamma), as an option for the treatment of wet AMD. We anticipate commencing our initial commercial launches in the EEA and UK in the first half of calendar 2025.

Separately, in March 2022, we submitted a BLA with the U.S. Food and Drug Association, or the FDA, for ONS-5010/LYTENAVA™. 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/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial demonstrating the effectiveness of ONS-5010/LYTENAVA in the treatment of nAMD, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD.

We agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this trial (NORSE EIGHT) seeking confirmation that, if successful, it would address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA, and in September 2024, we successfully completed enrollment in the NORSE EIGHT trial. As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits, with a final follow-up visit at Week 12.

In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated

an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA.

The pre-specified non-inferiority endpoint at week 8 set forth in the SPA with the FDA was measured by mean change in best corrected visual acuity (BCVA) from baseline to week 8. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met ( $p > 0.025$ ). In the intent-to-treat (ITT) primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm.

|                           | Mean change in BCVA at week 8 | Non-Inferiority                          |
|---------------------------|-------------------------------|--|
| ONS-5010/LYTENAVA 1.25 mg | +4.2 letters                  | 95% CI: (-4.044, -0.470) P-value: 0.0863 |
| Ranibizumab 0.5mg         | +6.3 letters                  |  |

At the week 8 timepoint of NORSE EIGHT, ONS-5010/LYTENAVA was generally well-tolerated with overall ocular adverse event rates comparable to ranibizumab. The safety results demonstrated in NORSE EIGHT are consistent with previously reported safety results from the NORSE ONE, NORSE TWO, and NORSE THREE clinical trials, with no cases of retinal vasculitis reported in either study arm.

Analysis of the data is ongoing as the week 12 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. Previously, through a Type A meeting and additional interactions with the FDA in a series of Type C and Type D meetings, we identified the approaches needed to resolve the CMC comments in the CRL and believe that we have resolved these comments. If the BLA for ONS-5010/LYTENAVA is approved, we expect to receive 12 years of regulatory exclusivity in the United States.

Our BLA and MAA submissions for ONS-5010/LYTENAVA 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/LYTENAVA 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 proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints 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/LYTENAVA — Bevacizumab for Ophthalmic Use — Clinical Development Status — NORSE TWO”. 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/LYTENAVA, 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/LYTENAVA, 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 ( $p = 0.0035$ ). A mean change of 11.2 letters in BCVA score was observed with ONS-5010/LYTENAVA, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ( $p = 0.01$ ) with a mean change with ONS-5010/LYTENAVA of 11.1 letters versus 7.0 letters with ranibizumab. Additionally, the majority of ONS-5010/LYTENAVA subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA  $\geq 0$ ), with at least 80% of ONS-5010/LYTENAVA subjects maintaining BCVA each month. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% ( $p = 0.0016$ ) of ONS-5010/LYTENAVA subjects gaining  $\geq 10$  letters of vision and 68.5% ( $p = 0.0116$ ) of ONS-5010/LYTENAVA subjects gaining

≥ 5 letters of vision. NORSE THREE was an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010/LYTENAVA were available for the initial ONS-5010/LYTENAVA BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010/LYTENAVA. The NORSE BLA registration program was also used to support our successful MAA submissions in the EU and UK.

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/LYTENAVA in vials has been completed.

We have also received agreement from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.

Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if there were an approved bevacizumab drug for the targeted diseases. If approved in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of repackaged bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).

## **Our Strategy**

Our goal is to launch ONS-5010/LYTENAVA as the first, and only, approved bevacizumab for ophthalmic use in the EU, UK, United States and other markets. We plan to do this directly in the United States and either directly or through a strategic partner in the EU and UK and in other markets. 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/LYTENAVA, including licensing commercial rights to ONS-5010/LYTENAVA to a strategic partner outside the United States.
- ***Engaging with regulatory authorities to establish clear guidelines for potential approval of ONS-5010/LYTENAVA outside the EU and UK.*** We have continued our approach of working closely with regulatory authorities to develop and conduct clinical trials that we believe will appropriately support approval of ONS-5010/LYTENAVA outside the EU and UK.
- ***Leveraging the expertise of large partners in the biopharma industry to support launch of ONS-5010/LYTENAVA in the EU and UK, and outside of these countries if the product is approved in other territories.*** We have entered into a strategic commercialization agreement for the distribution of ONS-5010/LYTENAVA, which is intended to provide us with the leverage and capabilities of a large biopharmaceutical company. 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 ONS-5010/LYTENAVA

and other product candidates. We believe this will significantly reduce future overhead costs not directly related to our ONS-5010/LYTENAVA program.

## **Our Pipeline**

### ***ONS-5010/LYTENAVA — Bevacizumab for Ophthalmic Use***

We have one product, ONS-5010/LYTENAVA, an ophthalmic formulation of bevacizumab, approved in the EU and UK. On May 27, 2024, the European Commission granted a marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD. This authorization is valid throughout the EEA. On July 8, 2024, the MHRA also granted a marketing authorization for ONS-5010/LYTENAVA in the UK for the treatment of wet AMD. ONS-5010/LYTENAVA is currently authorized for supply in vials. We also plan, however, to seek a variation to the current authorization to permit approval of supply of the product in pre-filled syringes.

We are actively working towards obtaining FDA approval of ONS-5010/LYTENAVA for the treatment of wet AMD and anticipate resubmitting a BLA in the first calendar quarter of 2025. We are also planning to develop ONS-5010/LYTENAVA for use in the treatment of other retina diseases such as 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.

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.

### ***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, in the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022). Similarly, prior to the marketing authorization of ONS-5010/LYTENAVA in the EU and UK, bevacizumab has been commonly utilized off-label in the treatment of wet AMD in many European countries. There is variability across European countries but in some markets it is believed that up to 80% of all wet AMD intravitreal injections are with bevacizumab. We believe ONS-5010/LYTENAVA 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). The United States accounted for approximately 50% of this market and Europe accounted for approximately 25% in 2020 (Global Data).

### *Clinical Development Status*

The study design for our Phase 3 clinical program to evaluate ONS-5010/LYTENAVA 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 plan for wet AMD, the initial indication planned for ONS-5010/LYTENAVA, consisted 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 was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS) that reported highly statistically significant topline results in August 2021. NORSE THREE was an open-label safety study conducted to ensure the adequate number of safety exposures to ONS-5010/LYTENAVA were available for the ONS-5010/LYTENAVA BLA submission with the FDA. After reviewing our BLA for ONS-5010/LYTENAVA, the FDA issued a CRL indicating that it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. We have agreed to conduct an additional clinical trial (NORSE EIGHT) to support approval of ONS-5010/LYTENAVA for the treatment of wet AMD in the United States. The FDA agreed with our SPA for NORSE EIGHT, and we successfully completed enrollment in the trial in September 2024. NORSE EIGHT is designed as a randomized, controlled non-inferiority clinical trial to assess the safety and efficacy of intravitreal injections of ONS-5010/LYTENAVA compared with ranibizumab (Lucentis) intravitreal injections, in subjects with neovascular age-related macular degeneration (nAMD). In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in SPA with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA, as described in greater detail above under “— Overview”. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025 (see “— Overview”).

We have received agreements from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA 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 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/LYTENAVA in vials has been completed.

### NORSE ONE

NORSE ONE was designed as a randomized, masked clinical experience trial to support our BLA submission with the FDA for ONS-5010/LYTENAVA 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

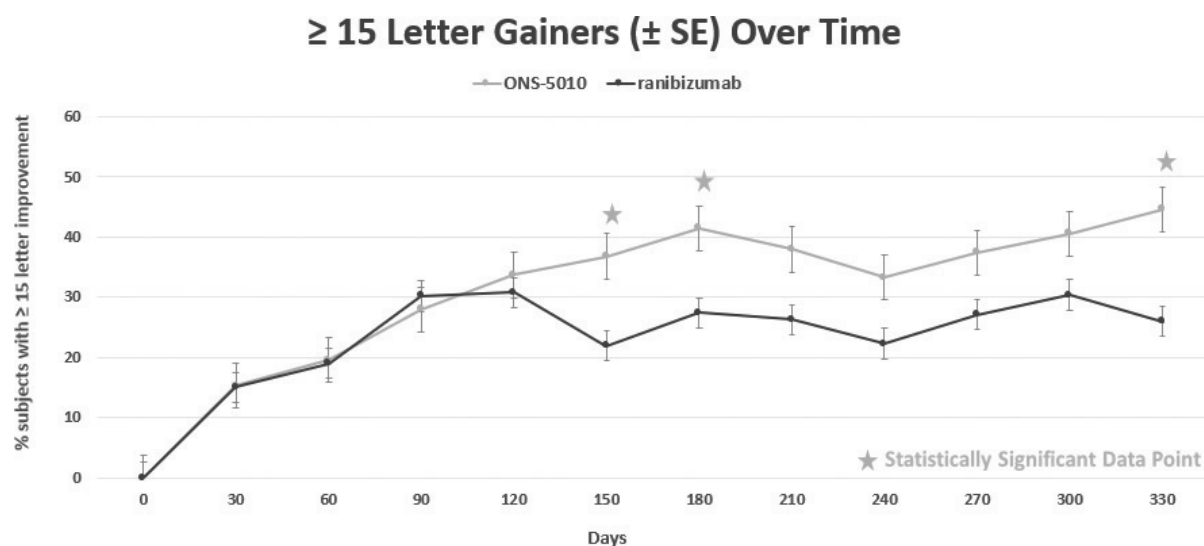
onto treatment arms of ONS-5010/LYTENAVA or ranibizumab. The primary endpoint for the study was the difference in proportion of subjects gaining 15 letters of BCVA at Day 330 for ONS-5010/LYTENAVA dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing.

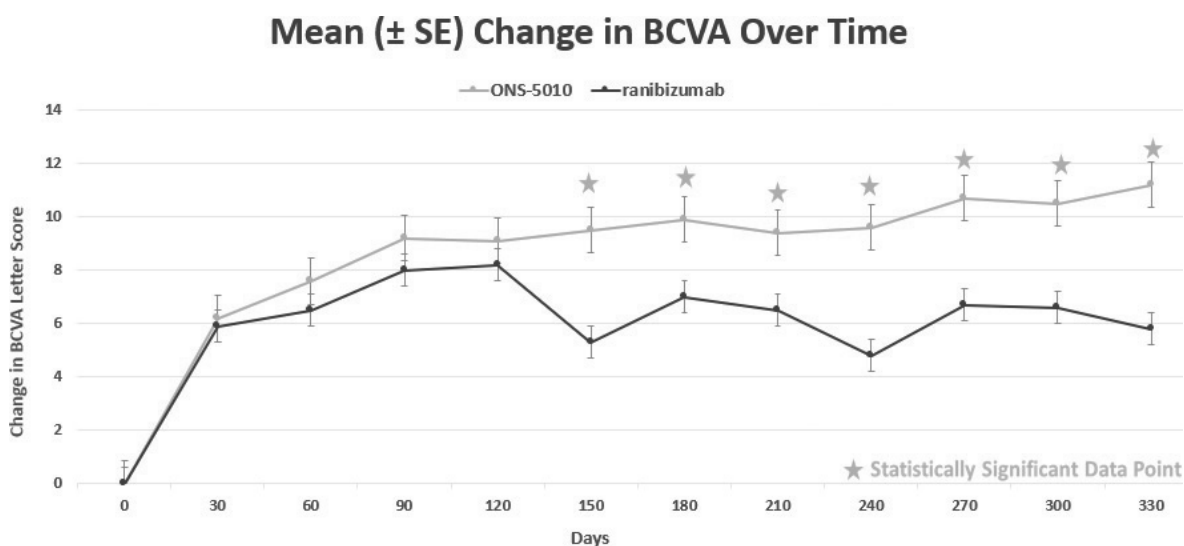
In August 2020, we reported positive proof-of-concept topline results for ONS-5010/LYTENAVA as it achieved anticipated safety and efficacy expectations. In the analysis of treatment naïve patients who had a baseline visual acuity of < 67 letters (20/50 or worse) at study entry, 2 of 4 (50%) patients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

## NORSE TWO

NORSE TWO was a masked, randomized, pivotal Phase 3 clinical trial evaluating ONS-5010/LYTENAVA 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/LYTENAVA 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/LYTENAVA 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/LYTENAVA 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/LYTENAVA, 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/LYTENAVA, 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 ( $p = 0.0035$ ). A mean change of 11.2 letters in BCVA score was observed with ONS-5010/LYTENAVA, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ( $p = 0.01$ ) with a mean change with ONS-5010/LYTENAVA 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/LYTENAVA subjects gaining  $\geq 10$  letters of vision and 68.5% ( $p = 0.0116$ ) of ONS-5010/LYTENAVA subjects gaining  $\geq 5$  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/LYTENAVA were available for the initial ONS-5010/LYTENAVA BLA submission with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010/LYTENAVA.

### NORSE SEVEN

NORSE SEVEN was initiated to support our ongoing development program for delivering ONS-5010/LYTENAVA 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/LYTENAVA 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/LYTENAVA in vials has been completed. If successful, this study will support the submission of a supplemental BLA to the FDA after ONS-5010/LYTENAVA is approved for wet AMD.

### NORSE EIGHT

NORSE EIGHT is a randomized, controlled, parallel-group, masked non-inferiority study of neovascular age-related macular degeneration subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. The primary endpoint is the mean change in BCVA from baseline to Week 8. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. In January 2024, we received confirmation from the FDA that, if successful, this study will address the FDA's requirement for a second adequate and well-controlled clinical trial to support the resubmission of the ONS-5010/LYTENAVA BLA for wet AMD.

A total of 400 patients were enrolled in the study. We successfully completed enrollment in September 2024 and in November 2024 we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met ( $p > 0.025$ ). In the intent-to-treat (ITT) primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm. Analysis

of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025.

### **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/LYTENAVA. As part of our multi-year commercial planning process, we entered into a strategic collaboration agreement with Cencora to support the commercial launch of ONS-5010/LYTENAVA globally. Cencora will provide comprehensive launch support in the EU and UK, including pharmacovigilance, regulatory affairs, quality management, market access support, importation, third-party logistics distribution and field solutions. The collaboration and integrated approach is designed to support market access and efficient distribution of ONS-5010/LYTENAVA in the EU and UK, as well as other regions outside the United States. If approved by the FDA, we currently intend to launch and market ONS-5010/LYTENAVA ourselves in the United States. We currently own all of the development and commercialization rights to ONS-5010/LYTENAVA 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”).

The marketing authorization for ONS-5010/LYTENAVA in the EEA provides eight years of data exclusivity and 10 years of market exclusivity. If approved by the FDA, we believe that ONS-5010/LYTENAVA will be entitled to 12 years of regulatory exclusivity granted in the United States against biosimilar competition.

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, EYLEA HD, BEOVU, SUSVIMO and VABYSMO), they are very expensive. The recently approved biosimilar versions of LUCENTIS and EYLEA 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 in the United States, and there was previously no approved ophthalmic formulation of bevacizumab in the EU or UK until the marketing authorizations of ONS-5010/LYTENAVA in the EU and UK, doctors have used 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.

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. and European 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/LYTENAVA as an investigational ophthalmic formulation of bevacizumab in the United States. ONS-5010/LYTENAVA has been approved for the treatment of wet AMD in the EU and UK and provides a viable treatment option across the spectrum of anti-VEGF ophthalmic drugs that treat wet AMD, avoiding the safety, sterility, potency, availability, and syringe drawbacks that can occur with repackaged bevacizumab from compounding pharmacies. If approved in other indications, ONS-5010/LYTENAVA may also provide a viable alternative for the treatment of DME and BRVO.

Furthermore, we expect that ONS-5010/LYTENAVA will be able to help mitigate the high cost of treatment for retinal diseases in the EU and UK, and also in the United States if the product is approved there. 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 and European Commission-approved option for patients that is safe, effective, and manufactured under proper guidance. Our commercial strategy for ONS-5010/LYTENAVA 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/LYTENAVA has the potential to become the anti-VEGF cornerstone of care for retinal diseases in the EU and UK, and also in the United States if the product is approved there. It may also provide synergies with future long-acting agents and adjunct therapies for advanced treatment of wet AMD, DME and BRVO. ONS-5010/LYTENAVA has the potential to help lower the aggregate costs of treating retinal diseases for the overall healthcare system in the EU and UK, and in the United States if the product is approved and commercialized there.

### **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, 800,000 shares of our common stock at a purchase price of \$20.00 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/LYTENAVA 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 are committed to make additional capital contributions to the PRC joint venture up to approximately \$2.1 million which will be made within four years after the establishment date (April 2021) upon approval of the development plan contemplated in the license agreement or on such other terms as may be determined within such four-year period.

### ***Selexis***

In October 2011, Selexis 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/LYTENAVA), 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/LYTENAVA 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, 2024, 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 began 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.

## **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/LYTENAVA'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. 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/LYTENAVA. 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/LYTENAVA. 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/LYTENAVA. 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. Similarly, it is estimated that the prevalence of wet AMD in Europe is approximately 1.7 million people. Globally, the incidence and prevalence of wet AMD is projected to increase significantly in the future due to an aging population.

### *Competitive Landscape*

In the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022). Off-label repackaged bevacizumab is also commonly utilized in the treatment of wet AMD in Europe. The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including EYLEA, EYLEA HD, BEOVU, LUCENTIS, SUSVIMO and VABYSMO. Recently, BYOOVIZ and CIMERLI were approved and launched, both ranibizumab biosimilars, as well as PAVBLU, an aflibercept biosimilar. 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 strategically price ONS-5010/LYTENAVA to 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 and EYLEA are also expensive, although they are available at a discount to the reference drug. Bevacizumab, BYOOVIZ, CIMERLI, PAVBLU, EYLEA, EYLEA HD, 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, or FDA review, for the treatment of wet AMD. Programs currently in Phase 2 or Phase 3 clinical trials or FDA review include, but are not limited to:

- Bevacizumab (HLX04-O) under development by Shanghai Henlius Biotech, Inc. and Essex Bio-Technology Ltd;
- Ranibizumab biosimilar developed by STADA Arzneimittel AG 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/LYTENAVA has potential competitive advantages due to the familiarity of physicians in using off-label Avastin. We also believe that an affordable, FDA and European Commission-approved ophthalmic 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 biosimilar 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 EU 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 September 30, 2024, we own three U.S. patents, eighteen foreign patents, and two pending international applications that were nationalized from six Patent Cooperation Treaty, or PCT, applications, which relate to formulations developed for our legacy biosimilar program 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. 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 CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL 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 CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, 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, 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. For example, 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 2032 unless additional Congressional action is taken. 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 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, effective 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 began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for negotiation in 2025. Further, in response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. We cannot predict what healthcare reform initiatives may be adopted in the future, particularly in light of the U.S. presidential and Congressional elections. 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.

### ***Clinical Trials in the EU***

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the “EU portal”, the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

### ***EU Review and approval process***

In the EU, medicinal products can only be commercialized after a related marketing authorization, or MA, has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated

as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures — Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of

medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a “conditional” MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

#### *Pediatric Development in the EU*

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA’s Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

#### *Manufacturing Regulation in the EU*

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set

out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

#### *Data and Market Exclusivity*

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

[In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.]

#### *Post-authorization Requirements in the EU*

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to

physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

### *United Kingdom*

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules until the implementation of the Windsor Framework.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland will remain within the scope of EU authorizations in relation to centrally authorized medicinal products until the implementation of the Windsor Framework. Accordingly, from when the Windsor Framework is implemented in Northern Ireland (currently anticipated to be January 1, 2025), products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain. To be used, sold, or supplied in Great Britain, a medicinal product must have been granted a marketing authorization that is effective in Great Britain. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. Following Brexit, the MHRA has also introduced changes to national marketing authorization procedures. There are two national routes to approval, the 150-day assessment procedure (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g. the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK or Great Britain. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110

days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the market in the UK (or Great Britain, if the MA is only valid in Great Britain) within three (3) years shall cease to be in force.

The UK has an initiative known as the Innovative Licensing and Access Pathway, or ILAP which has similar aims to the EU PRIME scheme but significant differences. ILAP can be entered into earlier, notably during non-clinical development. The MHRA and, notably, the National Institute for Health and Care Excellence (the body responsible for assessing which medicines should be funded by the NHS in England and Wales) will assist with the development of a target development profile for medications accepted into ILAP.

### ***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.

In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. In addition, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular

medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.

### ***Privacy Laws***

In the ordinary course of our business, we may process personal or sensitive data, including data related to our clinical trials. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the California Consumer Privacy Act of 2018, or the CCPA, as amended, the EU's General Data Protection Regulation 2016/679, or the EU GDPR, the EU GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or the UK GDPR, collectively the GDPR.

The CCPA and GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance.

These laws impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

### ***Additional Regulation***

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

### ***Employees and Human Capital Resources***

As of September 30, 2024, we had 23 full-time employees, seven of whom were primarily engaged in research and development activities and five 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 111 S. Wood Avenue, Unit #100, Iselin, New Jersey, 08830, and our telephone number at that location is (609) 619-3990. Our website address is [www.outlooktherapeutics.com](http://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 have incurred net losses in each year since our inception in January 5, 2010, including net losses of \$75.4 million and \$59.0 million for the years ended September 30, 2024 and 2023, respectively. We have not generated material revenue from the sales of any product. Our success as a company is substantially dependent on our ability to generate revenue from the sales of ONS-5010/LYTENAVA, which has been approved for the treatment of wet AMD in the EU and UK.

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, only one of our product candidates, ONS-5010/LYTENAVA, has been approved for sale in the EU and UK, 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 in the EU and UK, and in other countries if the product is approved in these territories;
- continue the clinical development of ONS-5010/LYTENAVA;
- advance ONS-5010/LYTENAVA 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/LYTENAVA 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/LYTENAVA;
- 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 the pending securities class action lawsuit, as well as any other potential litigation;
- 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.***

We have one product, ONS-5010/LYTENAVA, approved for commercialization in the EU and UK 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/LYTENAVA 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 Europe as early as the first half of calendar 2025, but this depends heavily on our success in many areas, including but not limited to:

- Securing capital sufficient to fund our commercialization efforts;
- launching and commercializing ONS-5010/LYTENAVA and any other product candidates for which we or our partners obtain regulatory and marketing approval;
- maintaining and obtaining regulatory and marketing approvals for ONS-5010/LYTENAVA and any other product candidates for which we or our partners complete clinical trials;
- retaining our manufacturing partner for ONS-5010/LYTENAVA and any approved product candidates to support clinical development, regulatory requirements and the market demand for any such approved product candidates;
- obtaining third-party coverage and adequate reimbursements of ONS-5010/LYTENAVA and any other product candidates, if approved;
- obtaining market acceptance of ONS-5010/LYTENAVA and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options;
- establishing or demonstrating in the medical community the safety and efficacy of ONS-5010/LYTENAVA and its potential advantages over and side effects compared to existing products used to treat wet AMD;
- 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;
- attracting, hiring and retaining qualified personnel; and
- completing clinical development of ONS-5010/LYTENAVA for the treatment of wet AMD in the United States and the other targeted indications, and any other product candidates we may develop in the future.

We anticipate incurring significant costs to commercialize ONS-5010/LYTENAVA and any of our other product candidates that may be approved for commercialization in the future. Our expenses could increase beyond our expectations if we are required by the FDA, or other regulatory authorities, supranational, 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.

Our ability to generate revenue from the sales of ONS-5010/LYTENAVA in the EU, UK or in any other country where the product is approved, or in relation to any other product candidate that may be approved, will be dependent, in part, upon:

- our ability to execute our sales and marketing strategy for ONS-5010/LYTENAVA in the EU and UK;
- our ability to maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to successfully commercialize ONS-5010/LYTENAVA in the EU and UK;
- 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 ONS-5010/LYTENAVA and any other product candidate that may be approved;
- the accepted price for the product;
- the ability to obtain coverage and adequate reimbursement for ONS-5010/LYTENAVA and any other product candidate that may be approved;
- the quality and performance of ONS-5010/LYTENAVA and any other product candidate that may be approved, 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/LYTENAVA 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/LYTENAVA outside the EU and UK, our business will be harmed.

***There is substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional funding to complete the development of ONS-5010/LYTENAVA outside the EU and UK and support our operations until we are able to generate sufficient revenue from the sales of ONS-5010/LYTENAVA in the EU and UK. 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 have received a marketing authorization from the European Commission and the MHRA for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK, respectively. We are currently advancing ONS-5010/LYTENAVA through additional clinical development and the regulatory approval process in the United States. 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/LYTENAVA outside the EU and UK.

As of September 30, 2024, our cash and cash equivalents balance was \$14.9 million. We do not believe that our existing cash and cash equivalents as of September 30, 2024, together with \$1.7 million in net proceeds from the sale of shares of common stock under an at-the-market sales program since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. 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 December 2022 Note, to Streeterville Capital, LLC, or the Lender. In March 2024, the Lender agreed to extend the maturity of the December 2022 Note from April 1, 2024 until July 1, 2025 to provide us time to negotiate the terms to further extend the maturity of the December 2022 Note. See *“Raising additional capital, including modifications to our existing convertible securities, may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies and product candidates”* for additional information on the effects of an event of default under the terms of the December 2022 Note.

Because our cash and cash equivalents will not be adequate to fund our currently planned operations through at least the next 12 months from the date the consolidated financial statements in this Annual Report on Form 10-K are issued, there is substantial doubt about our ability to continue as a going concern. We will require substantial additional capital to continue to operate as a going concern. Although we continue to pursue discussions with additional potential strategic partners for ONS-5010/LYTENAVA outside of the United States, 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/LYTENAVA. 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. On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against us. We estimate that we will incur approximately \$0.3 million in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs. While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the end of the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.

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. We may experience difficulties in accessing the capital markets due to external factors beyond our control, such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. For example, our ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as has been experienced recently due in part to, among other things, the impacts of inflation, ongoing overseas conflict, and disruptions in access to bank deposits and lending commitments due to bank failure. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will adversely affect our business and our ability to develop our technology and products candidates. 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 ONS-5010/LYTENAVA or any product candidates, if approved. 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, including modifications to our existing convertible securities, 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.

In December 2022, we issued the December 2022 Note to the Lender. Under the December 2022 Note, upon the occurrence of certain events described therein, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 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 December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 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 December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, \$40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) \$40.00 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. If the Conversion Price is below \$3.51 per share, we will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

On January 22, 2024, we entered into an amendment to the December 2022 Note with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025.

Additional 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/LYTENAVA 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 commercialization efforts, including for ONS-5010/LYTENAVA, or grant rights to develop and market ONS-5010/LYTENAVA or other product candidates that we would otherwise prefer to develop and market ourselves, terminate product development or future commercialization efforts, including for ONS-5010/LYTENAVA, 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/LYTENAVA, our only product that has been approved in the EU and UK. If ONS-5010/LYTENAVA does not receive regulatory approval outside the EU and UK, or is not successfully commercialized, our business may be harmed.***

We currently have one product, ONS-5010/LYTENAVA, that is approved for commercial sale in the EU and UK. We may never be able to obtain regulatory approval for ONS-5010/LYTENAVA outside the EU or UK, commercialize ONS-5010/LYTENAVA in the EU or UK, or develop other 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/LYTENAVA, our only approved product and only product candidate in active development. We also expect that we will need to devote significant effort to the commercialization of ONS-5010/LYTENAVA in the EU, UK, and other markets following regulatory approval, if received. We cannot assure you that we will be able to successfully obtain regulatory approval of ONS-5010/LYTENAVA outside of the EU and UK and develop sufficient commercial capabilities for ONS-5010/LYTENAVA if and when necessary. Accordingly, our business currently depends heavily on the successful regulatory approval of ONS-5010/LYTENAVA outside the EU and UK, and commercialization of ONS-5010/LYTENAVA.

We cannot be certain that ONS-5010/LYTENAVA will receive regulatory approval outside of the EU or UK, or be successfully commercialized even in the EU or UK, or any other targeted market in which we receive regulatory approval. 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/LYTENAVA 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.

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/LYTENAVA for many reasons, including:

- we may not be able to demonstrate that ONS-5010/LYTENAVA 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/LYTENAVA 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.

There can be no assurance that our BLA or MAAs of ONS-5010/LYTENAVA for wet AMD, or planned future, clinical trials for other retina indications, will ultimately meet the requirements sufficient for us to receive regulatory approval outside of the EU and UK. 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/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. We received agreement from FDA under the SPA for the NORSE EIGHT trial protocol and completed enrollment in the trial in September 2024. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. There can be no assurance that we will address the deficiencies identified in the CRL to the satisfaction of the FDA.

***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/LYTENAVA, 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/LYTENAVA, our only product that has been approved for the treatment of wet AMD in the EU and UK, and our only product candidate in active development, required an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL, in advance of our resubmission of a BLA for approval of ONS-5010/LYTENAVA to treat wet AMD in the United States and extensive additional clinical testing before we are prepared to

submit an application for regulatory approval for other indications. 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 authorities 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, or positive Ethics Committees opinions;
- imposition of a clinical hold by regulatory authorities, 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 and the European Commission or other comparable foreign regulatory authorities.***

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 European Commission and other comparable foreign regulatory authorities 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 or European Commission and other comparable foreign regulatory authorities 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 authorities' 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/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. Although in January 2024 we reached agreement on a SPA with FDA, this agreement only indicates concurrence with critical trial design concepts; it does not imply that FDA has reviewed, or concurs with, protocol details that do not affect approvability. Moreover, the presence of a SPA agreement does not guarantee that a marketing application will be filed or approved, even if the trial is conducted in accordance with the protocol. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA.

We have received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK. We also intend to seek approval for ONS-5010/LYTENAVA for the treatment of wet AMD outside the EU and UK. 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.

***ONS-5010/LYTENAVA and any future 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 ONS-5010/LYTENAVA and any future 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 ONS-5010/LYTENAVA and any future product candidates may be observed at any time, including in clinical trials or when a product is commercialized.

Undesirable side effects caused by ONS-5010/LYTENAVA and any future 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 ONS-5010/LYTENAVA or any future product candidates or expose us to product liability lawsuits that will harm our business. In such an event, we may be required by regulatory authorities to conduct additional animal or human studies regarding the safety and efficacy of ONS-5010/LYTENAVA or any future 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 ONS-5010/LYTENAVA or any future 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 authority 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, such as ONS-5010/LYTENAVA, 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, vary, or suspend 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, or foreign equivalent strategies;
- 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 ONS-5010/LYTENAVA or any other future product candidate that may be approved, and could significantly harm our business, results of operations and prospects.

We are required by the FDA, MHRA, EEA authorities and other comparable foreign regulatory authorities to 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, MHRA, the national competent authorities of EEA countries or other foreign regulatory authorities could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products, withdrawal, variation or suspension of our approvals or delay in approval or clearance of future product candidates.

***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 ONS-5010/LYTENAVA or any other product candidate and decreased demand for ONS-5010/LYTENAVA or any other product candidate, 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.***

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. We have received a marketing authorization from the European Commission and from the MHRA for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK, respectively. The EU marketing authorization is valid in all EU countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval in other countries 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 European Commission, MHRA or 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 other European countries, 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.***

ONS-5010/LYTENAVA, or any other product candidates we may pursue that are approved, 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 requirements imposed by the EU, other EEA countries and the UK, as well as federal and state requirements in the United States and requirements of other 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, marketing authorization, 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. We must submit new or supplemental applications and obtain approval for certain changes to the marketing authorizations that have been granted for ONS-5010/LYTENAVA in the EU and UK, or for any other 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, suspension, or variation of marketing approval.

If a regulatory authority 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 authority 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 authority or enforcement authority may, among other things:

- issue untitled and warning letters;
- impose civil or criminal penalties;
- suspend, vary or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- total or partial suspension of production, distribution or manufacturing;
- impose restrictions on our operations, including closing our manufacturing facilities;
- suspension of licenses; 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, suspended or varied, 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/LYTENAVA outside of the EU or UK or in any other indications for which we plan to develop the product, 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/LYTENAVA, 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/LYTENAVA 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, 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/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled trial clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. In response to FDA's CRL, we are conducting the NORSE EIGHT clinical trial and completed enrollment in September 2024. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. 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/LYTENAVA. We may not receive approval from the FDA at the conclusion of its review of the BLA that we intend to resubmit following the completion of NORSE EIGHT, in which case our business, financial condition and results of operations would be further harmed.

If we experience additional delays in obtaining approval or if we fail to obtain approval of ONS-5010/LYTENAVA outside the EU and UK, 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/LYTENAVA. 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;
- 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 or Ethics Committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or supranational or comparable foreign regulatory authorities.

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 or comparable foreign regulatory authorities 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 or Ethics Committees 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 approvals of ONS-5010/LYTENAVA outside the EU and UK 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/LYTENAVA 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. 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/LYTENAVA 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 or supranational or comparable foreign regulatory authorities for a number of reasons, or could result in a delay of FDA or comparable foreign regulatory authority 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/LYTENAVA 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/LYTENAVA 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/LYTENAVA 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/LYTENAVA 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, following the marketing authorizations of ONS-5010/LYTENAVA in the EU and UK, or if ONS-5010/LYTENAVA receives FDA approval, or if 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, suspend, or vary 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, or comparable foreign strategies;

- 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/LYTENAVA or any future product candidate that may be 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 authorities 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, both Biogen and Coherus with their biosimilar formulations of LUCENTIS and Amgen with their biosimilar formulation of EYLEA, 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. ONS-5010/LYTENAVA is an approved alternative to the use of off-label Avastin as well as the much more expensive approved therapies in the EU and UK, and is being developed for the same purposes in other markets. 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 in countries where we have not yet received approval for ONS-5010/LYTENAVA 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 in countries where we have not yet received approval for ONS-5010/LYTENAVA, product commercialization and market penetration earlier than we do. Product candidates developed by our competitors may render ONS-5010/LYTENAVA 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 in countries where we have not yet received approval for ONS-5010/LYTENAVA and successfully commercialized before ONS-5010/LYTENAVA, 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, European Commission, MHRA and comparable foreign regulatory authorities, the commercial success of ONS-5010/LYTENAVA or any other product candidates we may pursue will depend in part on the medical community, patients and third-party payors accepting ONS-5010/LYTENAVA or our product candidates as medically useful, cost-effective and safe. Even though we expect that ONS-5010/LYTENAVA will be priced responsibly, there is no guarantee that ONS-5010/LYTENAVA 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 ONS-5010/LYTENAVA or 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/LYTENAVA, or any other product candidates we may pursue that may be approved;
- our ability to maintain compliance with regulatory requirements; and
- labeling or naming imposed by FDA or other regulatory authorities.

Even if ONS-5010/LYTENAVA 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 ONS-5010/LYTENAVA or any other 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 ONS-5010/LYTENAVA or our other future 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/LYTENAVA or any other product candidates we may develop in the future that are approved 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.

***Although ONS-5010/LYTENAVA is approved in the EU and the UK, off-label repackaging of Avastin at compounding pharmacies may continue, which could have a material adverse effect on our business and financial condition.***

In the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022), notwithstanding that such use is off-label and requires repackaging at a compounding pharmacy. Although ONS-5010/LYTENAVA is approved for use as a treatment for wet AMD in the EU and the UK, ONS-5010/LYTENAVA has not yet been approved in the United States. Even though ONS-5010/LYTENAVA is approved for use as a treatment for wet AMD in the EU and UK, or even if it is approved in the United States or other countries for the same use, there is no guarantee that we will be effective in reducing the off-label use of Avastin and other drugs in the EU, UK, United States or other major markets where we plan to seek regulatory approval and commercialize ONS-5010/LYTENAVA, 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/LYTENAVA, our business and financial condition could be adversely affected.

***We currently have no marketing and sales organization. If we are unable to establish and maintain 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 internal marketing or sales organization. We have one product, ONS-5010/LYTENAVA, for which we received a marketing authorization in the EU and the UK. We, as a company, have no experience selling and marketing any pharmaceutical products. To successfully commercialize ONS-5010/LYTENAVA or any other products for which we receive approvals, we will need to develop these

capabilities, either on our own or with others. If we are not able to secure a strategic licensing partner who will commercialize ONS-5010/LYTENAVA or any other product for which we receive approval, we may need to establish our own sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize ONS-5010/LYTENAVA 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. We have entered into a strategic collaboration agreement with Cencora to support the commercial launch of ONS-5010/LYTENAVA globally, with a current focus on the EU, UK, as well as other regions outside of the US, if approved, pursuant to which Cencora would provide third-party logistics services and distribution, as well as medical information and pharmacovigilance services in the EEA and UK, as well as other regions outside the United States. 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/LYTENAVA 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, including through the strategic collaboration agreement with Cencora, 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 have been 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/LYTENAVA, 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/LYTENAVA. 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/LYTENAVA. 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. If we are not able to successfully resolve 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/LYTENAVA, 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/LYTENAVA, or any other product candidates we may develop in the future that may be 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 ONS-5010/LYTENAVA or any other of our product candidates that may be approved, will depend substantially, both domestically and abroad, on the extent to which the costs of ONS-5010/LYTENAVA and any of our other product candidates that may be approved, 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 ONS-5010/LYTENAVA or any other of our product candidates that may be approved. 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. Reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement

status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

We believe the increasing emphasis on cost-containment initiatives in the EU, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. 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/LYTENAVA, or any other product candidates we may develop in the future that may be approved. We expect to experience pricing pressures in connection with the sale of ONS-5010/LYTENAVA, 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.***

We may only promote or market ONS-5010/LYTENAVA in the EEA and the UK, or any other of our product candidates that may be approved, for their specifically approved indications. We will train our marketing and sales force against promoting ONS-5010/LYTENAVA or any other of 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 or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of ONS-5010/LYTENAVA or our future 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. In the EEA, the advertising and promotion of medicinal products are subject to both EU and EEA countries’ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EEA countries and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. 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 authorities. 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 ONS-5010/LYTENAVA or any of our other future 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 EEA, the UK 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 the launch of ONS-5010/LYTENAVA or any of our other future product candidates is further delayed or unsuccessful, or if sales of our marketed products do not meet the levels currently expected, 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 product candidates are discontinued or their clinical development is further delayed, if the launch of new indications for our marketed products or new product candidates is delayed 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. 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/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. In response to this, we conducted an additional clinical trial, NORSE EIGHT. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. 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 ONS-5010/LYTENAVA outside the EU and UK, or for any other of our product candidates, or commercialize ONS-5010/LYTENAVA or any other of 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 EEA countries 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, MHRA, EMA, European Commission, 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 supranational, national, 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.

***Because we may rely on third parties, some of which are or may be sole source vendors for manufacturing and supply of our drug candidates for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels for preclinical, clinical and commercial supply.***

We currently rely on third-party contract manufacturers for our current and future clinical trial product materials and supplies and do not have the infrastructure or capability internally to manufacture supplies of ONS-5010/LYTENAVA, or any other product candidate, for use in clinical development, and we lack the resources and the capability to manufacture ONS-5010/LYTENAVA or any product candidates

on a clinical or commercial scale. If we are unable to manufacture or have manufactured sufficient supplies of ONS-5010/LYTENAVA 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, or FUJIFILM to manufacture and supply us with our product candidates for future clinical development, as well as to establish commercial supplies of ONS-5010/LYTENAVA and 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 ONS-5010/LYTENAVA or our product candidates on a timely basis or on commercially viable terms. Establishing additional or replacement vendors, including FUJIFILM, if required, may not be accomplished quickly. Any delays resulting from manufacturing or supply interruptions associated with our reliance on third-party manufacturing and supply partners could impede, delay, limit or prevent our drug development and commercialization efforts. 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, variation 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/LYTENAVA 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.

We may need to enter into agreements with another third party for contract manufacturing of ONS-5010/LYTENAVA, or any other product candidates that may be approved, in order to produce the quantities necessary to meet anticipated market demand. If we are unable to build and stock ONS-5010/LYTENAVA or any other of our product candidates that may be approved, in sufficient quantities to meet the requirements for the launch of ONS-5010/LYTENAVA or these product 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 ONS-5010/LYTENAVA or 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 or market ONS-5010/LYTENAVA or any other of our product candidates that may be approved.

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

The process of manufacturing our ONS-5010/LYTENAVA 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 MHRA, EEA authorities' or 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 ONS-5010/LYTENAVA or 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 ONS-5010/LYTENAVA or 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 ONS-5010/LYTENAVA or our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of ONS-5010/LYTENAVA or our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for ONS-5010/LYTENAVA or product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

***We depend on third parties for the commercialization of ONS-5010/LYTENAVA in the EU and UK, and may depend on third parties for the commercialization of ONS-5010/LYTENAVA in the United States, if approved. Failure to commercialize in the relevant markets could harm our business and operating results.***

We continue to pursue discussions for the licensing and/or co-development rights to ONS-5010/LYTENAVA 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/LYTENAVA and have only licensed ONS-5010/LYTENAVA 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.

We have also entered into a strategic relationship with Cencora in preparation for the anticipated commercial launch of ONS-5010/LYTENAVA in the EEA, UK, and in the United States, if approved by the FDA, pursuant to which Cencora would provide comprehensive launch support in the EEA and the UK including pharmacovigilance, regulatory affairs, quality management, market access support, importation, field solutions, third-party logistics services and distribution, and medical information, as well as other regions outside the United States. If Cencora is unable to provide services pursuant to the strategic relationship, or otherwise breaches the terms of our agreement with them, our commercialization efforts in the EEA and UK could be delayed or adversely impacted, and our business, financial condition and prospects may be adversely effected.

Moreover, any disputes with the third parties on which we rely 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 or our strategic relationship with Cencora terminates, 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 rely, and continue to 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 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 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/LYTENAVA. The loss of any of these suppliers, or any future single source suppliers, could harm our business.***

ONS-5010/LYTENAVA 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/LYTENAVA. Additionally, we selected FUJIFILM Diosynth Biotechnologies to conduct all future manufacturing of ONS-5010/LYTENAVA 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/LYTENAVA. 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/LYTENAVA 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 EU, 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 EU 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 ONS-5010/LYTENAVA 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 ONS-5010/LYTENAVA or any future 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. We are currently experiencing delays in our anticipated timeline for FDA approval of ONS-5010/LYTENAVA due to the FDA requirement to successfully complete an additional adequate and well-controlled trial for ONS-5010/LYTENAVA, which could result in a reduced period of time during which we could market ONS-5010/LYTENAVA under patent protection if ultimately approved by the FDA.

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<sup>®</sup> (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<sup>®</sup>) 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 ONS-5010/LYTENAVA or 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 ONS-5010/LYTENAVA or 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/LYTENAVA/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 materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.***

Disease outbreaks, epidemics and pandemics, in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, 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. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent any future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects, it could also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

### ***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 epidemics, pandemics or ongoing overseas conflict could result in a variety of risks to our business, including weakened demand for ONS-5010/LYTENAVA or any other of 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 of ONS-5010/LYTENAVA outside the EU and UK, and commercialization of ONS-5010/LYTENAVA, 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/LYTENAVA 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/LYTENAVA.

On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. Our focus on the development of ONS-5010/LYTENAVA and other potential future drug candidates will require adequate staffing. We may need to hire and retain new employees to execute our future clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire or retain adequate staffing levels to develop our current and potential future drug candidates or to run our operations or to accomplish all of our objectives. We may experience delays or other difficulties effectuating the transition of certain responsibilities that were previously performed by employees impacted by the workforce reduction, which could result in significant disruptions to our business and delays in our development efforts and timelines. In addition, our workforce reduction could yield unanticipated consequences, such as reputational risk, litigation risk and expense, attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and loss of institutional knowledge and expertise. The workforce reduction could also harm our ability to attract and retain qualified personnel who are critical to our operations. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future.

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 ONS-5010/LYTENAVA or any other of our product candidates, harming future regulatory approvals, sales of ONS-5010/LYTENAVA or any other of our product candidates that may be approved, 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.

***We and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert management’s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcome.***

Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. This risk is especially relevant for us because we often experience significant stock price volatility in connection with our product development activities.

On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to our BLA during the period from December 29, 2022 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys’ fees. Defendants’ motion to dismiss is currently pending before the court.

On October 10, 2024, certain of the company’s officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys’ fees, and other costs.

It is possible that additional lawsuits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from this matter, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive and may detract from our ability to fully focus our internal resources on our business activities. We could be forced to expend significant resources in the settlement or defense of the pending lawsuits and

any potential future lawsuits, and we may not prevail in such lawsuits. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage.

We have not established any reserve for any potential liability relating to the pending lawsuits or any potential future lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests in the pending lawsuits, or in similar or related litigation, could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our business, our stock price, cash flow, results of operations and financial condition.

***Healthcare legislative reform measures and other regulatory reforms 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. For example, 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 2032 unless additional Congressional action is taken. 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 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, effective 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. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for negotiation in 2025. HHS has and will continue to issue and update guidance as these programs are implemented. 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. On December 7, 2023, the Biden administration also announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, particularly in light of the U.S. presidential and Congressional elections. 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.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment was adopted in the EU. This Regulation, which entered into force in January 2022 will apply from January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on 10 April 2024, the Parliament adopted its related position. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and

market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

***We are subject, directly and indirectly, to foreign, 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 foreign, 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 and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign 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, foreign 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 or comparable foreign programs, 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, or comparable foreign requirements.

***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 or a comparable foreign regulatory authority 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 or a comparable foreign regulatory authority 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 or a comparable foreign regulatory authority 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, and comparable foreign regulations. 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 or comparable foreign programs, 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.

***We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, data we collect about trial participants in connection with clinical trials, intellectual property, sensitive third-party data, business plans, transactions, and financial information (collectively, sensitive data).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information.

In the past few years, numerous U.S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights

concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or the CPRA, collectively, the CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, or the EU GDPR, the United Kingdom's GDPR, or the UK GDPR, collectively, the GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or the LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law, or the PIPL impose strict requirements for processing personal data.

For example, under the GDPR, in the event of any non-compliance, companies subject to the laws may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland.

Our employees and personnel use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or the EEA, and the United Kingdom, or the UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as

Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are contractually subject to certain industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security. Our efforts to comply with such contractual obligations may not be successful which may lead to claims against us.

We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations, including our clinical trials.

***If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.***

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data (including data related to our clinical trials) in a variety of contexts, including, without limitation, contract research organizations, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures or patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business, including conducting our clinical trials.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

Material security incidents (whether actual or perceived and whether experienced by us or a third party with whom we work) could cause material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data or data related to our clinical trials); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

## **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/LYTENAVA, 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/LYTENAVA or any of our other product candidates;
- failure to successfully develop and commercialize ONS-5010/LYTENAVA 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 ONS-5010/LYTENAVA in the EU or UK, or any of our product candidates that may be approved;
- 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.

As further discussed in the Risk Factor above entitled “*We and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits and potential similar or related lawsuits, could result in substantial damages, divert management’s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcome*”, we and two of our officers have been named as defendants a class action lawsuit filed in the United States District Court for the District of New Jersey and certain of our officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. Such lawsuits have often been instituted

against companies, including us, whose securities have experienced periods of volatility in market price. The pending lawsuits and any lawsuits brought against us in the future could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could preclude or delay commercialization efforts.

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 beneficially owns a significant percentage of our common stock and 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, 2024, GMS Ventures owned 5,808,074 shares of common stock and a warrant to acquire an additional 3,458,571 shares of common stock. Accordingly, GMS Ventures beneficially owned approximately 33.9% of our common stock as of such date. 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 (including any of its 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 has the ability to influence our company through its ownership position and 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/LYTENAVA and any other product candidates;
- the cost of clinical development for ONS-5010/LYTENAVA 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 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 2024 Equity Incentive Plan, or the 2024 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2024 Plan, the number of shares of our common stock reserved for future issuance as of September 30, 2024 was 4,680,755 shares. 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 2024 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 14,207,622 shares of our common stock, at prices ranging from \$7.70 to \$240.00 per share. Additionally, in December 2022, we issued the December 2022 Note to the Lender. The December 2022 Note is convertible into shares of common stock at the option of the Lender or the Company under certain conditions described in more detail under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Description of Indebtedness."

***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 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.***

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

***Our international operations may subject us to greater than anticipated tax liabilities.***

The amount of taxes we may pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, changes in tax rates, new or revised tax laws or interpretations of existing tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to any future intercompany arrangement or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

***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 Exchange Act 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 1C. Cybersecurity**

##### ***Risk management and strategy***

We depend on the functioning, availability and security of our information systems, including financial, data processing, communications and operating systems. Several information systems, such as software applications and cloud platforms, are provided by third parties. Our cybersecurity risk framework is designed to allow us to identify, assess and manage the cybersecurity risks we face in relation to, our systems and the information we process.

As part of our framework, we maintain certain processes defined to assess, identify and manage risks. For example, we have an incident management and response process under which we communicate the details of certain threats and incidents to management and the board as may be appropriate; use manual and automated processes that are designed to monitor relevant information systems for vulnerabilities, threats and incidents; manage and take certain actions designed to address incidents that may occur; and take actions designed to remediate certain vulnerabilities identified in relevant environments. We employ an array of data security technologies, processes, and methods across our infrastructure designed to protect our systems and sensitive information from unauthorized access. We work with information technology consultants who provide advice and expertise on monitoring evolving industry practices. Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, certain management executives, including our Executive VP and Chief Financial Officer evaluates material risks from cybersecurity threats in connection with our overall business objectives and reports such evaluations to the audit committee of the board of directors as appropriate, which then evaluates our overall enterprise risks.

In addition to the third parties above, we use additional third-party service providers to perform a variety of functions throughout our business, such as enterprise and employee management platforms, labs, contract research organizations, contract manufacturing organizations, and supply chain resources. Depending on the nature of the services provided, the sensitivity of the information systems and data at issue, and the identity of the provider, we take steps designed to address cybersecurity risks that such service providers may present to us, such as conducting diligence into such service providers' cybersecurity practices and risk profiles.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part I. Item 1A. Risk Factors in this Annual Report on Form 10-K, including *If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*

##### ***Governance***

Our cybersecurity risk assessment and management processes are implemented and maintained by certain management, including our Director of Information Technology, who has more than two decades of information technology and information technology leadership experience. Our Director of Information Technology, under the supervision of our Executive VP and Chief Financial Officer, manages and monitors our cybersecurity risk (including that presented by our information technology service providers). Our Director of Information Technology is responsible for informing our Executive VP and Chief Financial Officer of relevant cybersecurity risks including, as relevant, the prevent, detection, mitigation and remediation

of cybersecurity incidents. Our Executive VP and Chief Financial Officer has over two decades of management experience, including oversight over information technology and cybersecurity matters.

Our Board of Directors, with the assistance of the Audit Committee, has oversight for the cybersecurity risks facing us and for our processes designed to identify, prioritize, assess, manage, and mitigate those risks. As part of its oversight responsibilities, the Audit Committee receives periodic updates on cybersecurity and information technology matters and related risk exposures (including, as relevant, those stemming from certain cybersecurity incidents) from our Executive VP and Chief Financial Officer.

## **Item 2. Properties**

Our headquarters are located in Iselin, New Jersey where we occupy approximately 3,726 square feet of office space under a lease that expires in April 30, 2029. In March 2021, we entered into a three-year term corporate office lease for our former corporate headquarters in Iselin, New Jersey that ended on April 30, 2024.

## **Item 3. Legal Proceedings**

On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Exchange Act in connection with allegedly false and misleading statements made by us related to our BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. Defendants' motion to dismiss is currently pending before the court.

On October 10, 2024, certain of the company's officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys' fees, and other costs.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

From time to time, we may also become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no additional 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.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## **PART II**

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

#### **Market Information**

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

#### **Common Stockholders**

As of December 14, 2024, there were approximately 78 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, 2024.

### **Item 6. Reserved.**

## 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 European Commission in the European Union (EU), the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) and the U.S. Food and Drug Administration (FDA), for use in retinal indications. Our initial goal is to launch directly or with a partner in the EU and UK, and, if approved, to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets. On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD. The authorization is valid throughout the European Economic Area, or the EEA, and provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK, followed by a recommendation by the UK National Institute for Health and Care Excellence (NICE) for LYTENAVA™ (bevacizumab gamma), as an option for the treatment of wet AMD on December 4, 2024. Outside of the United States, we are currently assessing options to commercialize either directly or through a strategic partner.

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 October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency (EMA). The MAA was submitted as a 'full-mixed marketing authorization application' based on Article 8.3 of Directive 2001/83/EC. On March 22, 2024, the EMA's Committee for Medicinal Products for Human Use, or CHMP issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) in the EU. In May 2024, the European Commission granted the Marketing Authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU. The decision applied automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, in April 2024, we submitted a MAA to the MHRA in the UK seeking approval of ONS-5010/LYTENAVA (bevacizumab gamma) for the treatment of wet AMD. The submission was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on an authorization received for the same product from one of MHRA's specified Reference Regulators (RRs) when considering an application for marketing authorization in the UK. These RRs include a positive opinion by the EMA's CHMP concerning an application for grant of marketing authorization for the same product in the EU. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK. ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

Separately, in March 2022, we submitted a BLA with the FDA for ONS-5010/LYTENAVA, 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/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation

from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD.

We agreed to conduct an additional adequate, and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. In addition, through a Type A meeting and additional interactions with the FDA, we have identified the approaches needed to resolve the CMC comments in the CRL. We are working to address the open CMC items and have concluded a series of Type C and Type D meetings with the FDA to help to resolve these comments prior to reporting top line results from NORSE EIGHT in the fourth quarter of calendar 2024. We completed enrollment of the NORSE EIGHT trial in September 2024. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025.

Our BLA and MAA submissions for ONS-5010/LYTENAVA 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/LYTENAVA 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 proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010/LYTENAVA.

As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint is the mean change in BCVA from baseline to week 8. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.

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/LYTENAVA in vials has been completed.

We have also received agreement from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.

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 in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).

On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against us. We estimate that we will incur approximately \$0.3 million in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs. While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the end of the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.

### ***Going Concern Consideration***

Through September 30, 2024, we have funded substantially all of our operations with \$530.9 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, 2024 was \$75.4 million. We also had a net loss of \$59.0 million for the year ended September 30, 2023. 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/LYTENAVA or any other product candidate we may develop.

On May 16, 2023, we entered into an At-the-Market Sales Agreement with BTIG, LLC (“BTIG”), as sales agent (the “BTIG ATM Agreement” or the “BTIG ATM Offering”), under which we may issue and sell shares of our common stock having an aggregate offering price of up to \$100.0 million from time to time through BTIG. We incurred financing costs of \$0.4 million, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when we sell common stock under the BTIG ATM Offering.

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

In November 2024 and December 2024, we sold 1,000,000 shares of common stock under the BTIG ATM Agreement generated \$1.7 million in net proceeds after paying fees to BTIG and other issuance costs of \$0.1 million.

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. We do not believe our current cash resources of \$14.9 million as of September 30, 2024, together with \$1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. 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/LYTENAVA, 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/LYTENAVA 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.

### **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, 800,000 shares of our common stock at a purchase price of \$20.00 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/LYTENAVA 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. See Note 8 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail.

### **Components of Our Results of Operations**

#### ***Reverse stock split***

Effective on March 14, 2024, we amended our amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of our common stock. The disclosure of our results of operations reflect the reverse stock split for all periods presented.

## ***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.

### ***Loss on equity method investment***

Loss on equity method investment represents our proportionate share for the period of the net loss of our investee to which the equity method of accounting is applied. We account for equity investments where we own a non-controlling interest, but have the ability to exercise significant influence, under the equity method of accounting.

### ***Interest income***

Interest income is earned from short term investments primarily money market investments.

### ***Interest Expense***

Interest expense consists of cash paid and non-cash interest expense related to our December 2022 Note. The interest expense was associated with the fees incurred for extending the debt and original issue discount and debt issuance costs that were written off upon election to fair value and accounted for as interest.

### ***Loss on Extinguishment of Debt***

We recognized a \$0.6 million loss on extinguishment related to the prepayment and cancellation our November 2021 Note (as defined below) during the year ended September 30, 2023 that was accounted for as an extinguishment.

### ***Change in Fair Value of Promissory Notes***

The change in fair value relates to convertible promissory notes 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 notes. We recorded the convertible promissory note at fair value with changes in fair value recorded in the consolidated statements of operations.

### ***Warrant Related Expenses***

The warrant related expense relates to the excess of the fair value of the warrants upon issuance over the proceeds of the private placements that closed on March 18, 2024 and April 15, 2024.

### ***Change in Fair Value of Warrant Liability***

We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017, 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.

### ***Income Taxes***

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, 2024, we had federal and state NOL carryforwards of \$406.7 million and \$242.5 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, we had federal foreign tax credit carryforwards of \$0.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2024, we also had federal and state R&D tax credit carryforwards of \$13.0 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.

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, 2024 and 2023*

|   | Year ended September 30, |                       |                       |
|---|--------------------------|-----------------------|-----------------------|
|   | 2024                     | 2023                  | Change                |
| Operating expenses:                                 |                          |                       |                       |
| Research and development . . . . .                  | \$ 41,763,047            | \$ 26,452,942         | \$ 15,310,105         |
| General and administrative . . . . .                | 29,940,188               | 26,673,440            | 3,266,748             |
| Loss from operations . . . . .                      | (71,703,235)             | (53,126,382)          | (18,576,853)          |
| Loss on equity method investment . . . . .          | 100,742                  | 10,998                | 89,744                |
| Interest income . . . . .                           | (906,150)                | (971,480)             | 65,330                |
| Interest expense . . . . .                          | 3,156,964                | 2,531,228             | 625,736               |
| Loss on extinguishment of debt . . . . .            | —                        | 577,659               | (577,659)             |
| Change in fair value of promissory notes . . . . .  | 2,457,153                | 3,756,000             | (1,298,847)           |
| Warrant related expenses . . . . .                  | 37,490,012               | —                     | 37,490,012            |
| Change in fair value of warrant liability . . . . . | (38,638,042)             | (50,919)              | (38,587,123)          |
| Loss before income taxes . . . . .                  | (75,363,914)             | (58,979,868)          | (16,384,046)          |
| Income tax expense . . . . .                        | 2,800                    | 2,800                 | —                     |
| Net loss . . . . .                                  | <u>\$(75,366,714)</u>    | <u>\$(58,982,668)</u> | <u>\$(16,384,046)</u> |

### *Research and Development Expenses*

The following table summarizes our research and development expenses by functional area for the years ended September 30, 2024 and 2023:

|   | Year ended September 30, |                     |
|---|--------------------------|---------------------|
|   | 2024                     | 2023                |
| ONS-5010/LYTENAVA development . . . . .           | \$37,355,884             | \$28,718,140        |
| Compensation and related benefits . . . . .       | 2,507,635                | 2,126,772           |
| Stock-based compensation . . . . .                | 800,956                  | 986,598             |
| Other research and development . . . . .          | 1,098,572                | (5,378,568)         |
| Total research and development expenses . . . . . | <u>\$41,763,047</u>      | <u>\$26,452,942</u> |

Research and development expenses for the year ended September 30, 2024 increased by \$15.3 million compared to the year ended September 30, 2023. The increase was primarily due to an \$8.6 million rise in development costs associated with ONS-5010/LYTENAVA related to the commencement and subsequent completion of enrollment in the NORSE EIGHT clinical trial, combined with the effects of a \$6.2 million refund for BLA submission fees from the FDA received in the prior period.

### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the years ended September 30, 2024 and 2023:

|   | Year ended September 30, |                     |
|---|--------------------------|---------------------|
|   | 2024                     | 2023                |
| Professional fees . . . . .                         | \$ 9,866,128             | \$14,522,528        |
| Compensation and related benefits . . . . .         | 6,301,200                | 4,366,447           |
| Stock-based compensation . . . . .                  | 4,584,168                | 4,560,421           |
| Europe prelaunch expenses . . . . .                 | 5,010,687                | —                   |
| Facilities, fees and other related costs . . . . .  | 4,178,005                | 3,224,044           |
| Total general and administrative expenses . . . . . | <u>\$29,940,188</u>      | <u>\$26,673,440</u> |

General and administrative expenses for the year ended September 30, 2024 increased by \$3.3 million compared to the year ended September 30, 2023. During the year ending September 30, 2024, we incurred pre-launch expenses in Europe amounting to \$5.0 million, along with a \$1.9 million increase in compensation and benefits primarily attributed to severance-related costs and adjustments in headcount. These increases were offset by a \$4.7 million decrease in professional fees, which resulted from the discontinuation of U.S. commercial launch activities following the receipt of the CRL in August 2023.

### *Loss on Equity Method Investment*

Loss on equity method investment represents our share of the loss from Beijing Syntone Biopharma Ltd, or Syntone JV.

### *Interest Income*

Interest income for the year ended September 30, 2024 and 2023 was earned from short term investments, primarily consisting of money market investments.

### *Interest Expense*

Interest expense for the year ended September 30, 2024 increased by \$0.6 million compared to prior year. This increase was primarily attributable to convertible promissory note maturity extension fees of \$3.2 million associated with the December 2022 Note incurred during the year, in contrast to \$2.5 million

incurred in the prior year primarily related to the recognition of the original issue discount as interest expense on the December 2022 Note, as result of our adoption the fair value option for accounting purposes.

#### *Loss on Extinguishment of Debt*

We recognized a \$0.6 million loss on extinguishment related to the prepayment and cancellation of our November 2021 Note (as defined below) during the year ended September 30, 2023 that was accounted for as an extinguishment.

#### *Change in Fair Value of Promissory Notes*

The change in fair value relates to the convertible promissory notes 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 notes. We record the convertible promissory notes at fair value with changes in fair value recorded in the consolidated statements of operations.

#### *Warrant Related Expenses*

During the year ended September 30, 2024, we recognized charges associated with warrants issued during the period, which were categorized as liabilities. The warrant related charges amounted to the difference between the fair value of the warrants and the net proceeds received from private placements that closed on March 18, 2024 and April 15, 2024.

#### *Change in Fair Value of Warrant Liability*

We recognized income related to the decrease in the fair value of our common stock warrant liability in both fiscal years 2024 and 2023. This income was attributed to a decline in the price of our common stock during those periods. In fiscal year 2024, we recorded income of \$38.6 million, compared to \$0.1 million in fiscal year 2023. We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with private placements that closed on March 18, 2024 and April 15, 2024. These warrants are categorized 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. The gain recorded during the period was primarily due to the reduction in our stock price per share of common stock during the year.

### **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, 2024, we have funded substantially all of our operations with \$530.9 million in net proceeds from the sale and issuance of our equity securities, debt securities and borrowings under debt facilities.

We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop. We will need substantial additional financing to fund our operations and to commercially launch ONS-5010/LYTENAVA 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 16, 2021, we received \$10.0 million in net proceeds from the issuance of an unsecured promissory note (the “November 2021 Note”), with a face amount of \$10.2 million. The November 2021 Note bore interest at a rate of 9.5% per annum, was due to mature January 1, 2023 and included an original issue discount of \$0.2 million. We could prepay all or a portion of the note at any time by paying 105% of

the outstanding balance elected for prepayment. On December 28, 2022, we prepaid the November 2021 Note in full by paying 105% of the outstanding balance. The total payment was \$11.9 million, which included interest of \$1.2 million and a prepayment fee of \$0.6 million.

During the year ended September 30, 2023, we sold 44,769 shares of common stock under our prior at-the-market offering program for \$1.1 million in net proceeds, and the fees paid to the sales agent were immaterial.

On May 16, 2023, we entered into the BTIG ATM Agreement, under which we may issue and sell shares of common stock having an aggregate offering price of up to \$100.0 million from time to time through BTIG. Under the BTIG ATM Agreement, we pay BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms. No shares of common stock were sold under the BTIG ATM Offering during the year ended September 30, 2024. During the year ended September 30, 2023, we sold 178,911 shares of common stock pursuant to the BTIG ATM Offering, generating \$6.1 million in net proceeds after we paid fees to BTIG of \$0.2 million.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 1,423,041 shares of common stock at a purchase price per share of \$17.568 for \$23.2 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 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 25,787 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 \$21.00 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 December 2022 Note, to Streeterville Capital, LLC, or the Lender, the holder of our November 2021 Note. The December 2022 Note has an original issue discount of \$1.8 million. A portion of the proceeds from the December 2022 Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. We received net proceeds of \$18.1 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance and November 2021 Note repayment. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a \$475,000 extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the "January 2024 Note Amendment") with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of \$2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the January 2024 Note Amendment, the initial conversion price with respect to \$15.0 million in aggregate principal amount of the December 2022 Note was changed to \$7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount has a conversion price of \$40.00 per share. Effective April 1 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least \$3.0 million of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. The December 2022 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. The principal amount and conversion price of the December 2022 Note are subject to adjustment upon certain triggering events. See "Description of Indebtedness" and Note 7 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail.

During the year ended September 30, 2024, an aggregate of principal and accrued interest totaling \$11.3 million of the December 2022 Note was converted into 1,607,093 shares of our common stock.

In March 2024, in a private placement pursuant to a securities purchase agreement entered into in January 2024 with certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of \$7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for \$55.5 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the private placement. The warrants have an exercise price of \$7.70 per share of common stock and will expire on March 18, 2029.

On April 15, 2024, in a private placement with Syntone Ventures, LLC pursuant to a securities purchase agreement entered into in January 2024, we issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for \$4.8 million in gross proceeds on substantially the same terms as those in the private placement closed in March 2024. The warrants have an exercise price of \$7.70 per share of common stock and will expire on April 15, 2029.

In November 2024 and December 2024, we sold 1,000,000 shares of common stock under the BTIG ATM Agreement generated \$1.7 million in net proceeds after paying fees to BTIG and other issuance costs of \$0.1 million.

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, 2024, we had an accumulated deficit of \$543.3 million and \$31.4 million of principal, accrued interest and exit fees due on the December 2022 Note. We do not believe our current cash resources of \$14.9 million, together with \$1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date as a result of the costs associated with the NORSE EIGHT clinical trial and the July 1, 2025 maturity date of the December 2022 Note, as amended in January 2024. 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/LYTENAVA or any other product candidate we may develop. We will need substantial additional financing to fund our operations and to commercially develop ONS-5010/LYTENAVA 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.

While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.

## ***Cash Flows***

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

|  | Year ended September 30, |                     |
|--|--------------------------|---------------------|
|  | 2024                     | 2023                |
| Net cash used in operating activities . . . . .                | \$(68,793,858)           | \$(42,973,398)      |
| Net cash provided by financing activities . . . . .            | 60,329,414               | 48,968,568          |
| Net (decrease) increase in cash and cash equivalents . . . . . | <u>\$ (8,464,444)</u>    | <u>\$ 5,995,170</u> |

### ***Operating Activities***

During the year ended September 30, 2024, we used \$68.8 million of cash in operating activities resulting primarily from our net loss of \$75.4 million. This use of cash was partially offset by \$9.6 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, warrant related expense, change in fair value of warrant liability, loss on equity method investment and depreciation and amortization expense. The net cash outflow of \$3.0 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of \$4.9 million for timing of payments associated with ONS-5010/LYTENAVA development costs relating to clinical trial and drug development costs partially offset by an increase in accounts payable and accrued expenses of \$1.9 million due to professional fees associated with our EU launch activities.

During the year ended September 30, 2023, we used \$43.0 million of cash in operating activities resulting primarily from our net loss of \$59.0 million. This use of cash was partially offset by \$12.4 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, change in fair value of warrant liability, loss on extinguishment of debt, loss on equity method investment and depreciation and amortization expense. We also paid interest on debt of \$1.2 million during the period. The net cash inflow of \$4.8 million from changes in our operating assets and liabilities was primarily due to a net increase in accounts payable and accrued expenses of \$2.4 million and a decrease in prepaid expenses of \$2.6 million related to timing of payments associated with ONS-5010/LYTENAVA development costs, partially offset by an increase in other assets of \$0.2 million.

### ***Financing Activities***

During the year ended September 30, 2024, net cash provided by financing activities was \$60.3 million, primarily attributable to \$60.3 million in net proceeds from private placements in March 2024 and April 2024 of an aggregate of 9,285,709 shares of our common stock and warrants to purchase an aggregate of 13,928,562 shares of our common stock.

During the year ended September 30, 2023, net cash provided by financing activities was \$49.0 million, primarily attributable to \$23.2 million in net proceeds from a registered direct equity offering in December 2022 of an aggregate of 1,423,041 shares of our common stock, \$7.2 million in net proceeds from the sale of common stock under our prior at-the-market offering program and BTIG ATM Offering and \$30.0 million in net proceeds from the issuance of the December 2022 Note with a face amount of \$31.8 million in December 2022. We also made \$10.2 million in debt and finance lease obligation payments and a \$0.8 million payment of financing costs.

### ***Description of Indebtedness***

The December 2022 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. Since April 1, 2023, the Lender has the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and Conversion Price of the December 2022 Note were 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 December 2022 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 \$50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 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 December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 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 December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, \$40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) \$40.00 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. The maturity date of the December 2022 Note was extended from January 1, 2024 to April 1, 2024 in December 2023.

On January 22, 2024, the Company entered into the January 2024 Note Amendment with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of \$2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the January 2024 Note Amendment, the initial conversion price with respect to \$15.0 million in aggregate principal amount of the December 2022 Note was changed to \$7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount is converted at a price of \$40.00 per share. Effective April 1, 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least \$3.0 million of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. If the Conversion Price is below \$3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and 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/LYTENAVA with the FDA and to prepare for the potential launch of ONS-5010/LYTENAVA 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/LYTENAVA 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 do not believe our existing cash and cash equivalents of \$14.9 million as of September 30, 2024, together with \$1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. 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/LYTENAVA 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/LYTENAVA 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/LYTENAVA 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;
- expenses associated with the pending securities class action lawsuit, as well as other potential 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**

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in

fiscal years beginning after December 15, 2024. We are currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures.

**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**

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## **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, 2024 and 2023, the related consolidated statements of operations, stockholders' equity (deficit), 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, 2024 and 2023, 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 from operations 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 and accrued 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 and accrued research and development expenses for contract manufacturing organizations (CMOs) 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 CMOs 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. We examined a sample of (1) statements of work, (2) payments, and (3) communications received from the CMOs related to the status of underlying phases within the statements of work, and compared them to the Company's schedules of costs incurred as of year-end. We also confirmed the status of underlying phases within the statements of work directly with the CMOs. We assessed the sufficiency of audit evidence obtained related to prepaid and accrued research and development expenses related to statements of work with the CMOs 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 27, 2024

**Outlook Therapeutics, Inc.**  
**Consolidated Balance Sheets**

|  | September 30,        |                      |
|--|----------------------|----------------------|
|  | 2024                 | 2023                 |
| <b>Assets</b>  |                      |                      |
| Current assets:  |                      |                      |
| Cash and cash equivalents . . . . .  | \$ 14,927,538        | \$ 23,391,982        |
| Prepaid expenses and other current assets . . . . .  | 12,488,498           | 7,587,216            |
| Total current assets . . . . .   | 27,416,036           | 30,979,198           |
| Operating lease right-of-use assets, net . . . . .   | 274,645              | 26,172               |
| Equity method investment . . . . .   | 693,190              | 793,932              |
| Other assets . . . . .   | 439,283              | 501,299              |
| Total assets . . . . .   | <u>\$ 28,823,154</u> | <u>\$ 32,300,601</u> |
| <b>Liabilities and stockholders' deficit</b>   |                      |                      |
| Current liabilities:   |                      |                      |
| Unsecured convertible promissory note . . . . .  | \$ 29,440,000        | \$ 35,551,000        |
| Finance lease liabilities . . . . .  | —                    | 4,267                |
| Current portion of operating lease liabilities . . . . .   | 50,907               | —                    |
| Accounts payable . . . . .   | 7,968,725            | 6,574,523            |
| Accrued expenses . . . . .   | 3,237,468            | 2,745,740            |
| Income taxes payable . . . . .   | 1,856,629            | 1,856,629            |
| Total current liabilities . . . . .  | 42,553,729           | 46,732,159           |
| Operating lease liabilities . . . . .  | 246,922              | —                    |
| Warrant liability . . . . .  | 59,099,013           | 6,219                |
| Total liabilities . . . . .  | <u>101,899,664</u>   | <u>46,738,378</u>    |
| Commitments and contingencies (Note 8)   |                      |                      |
| Stockholders' deficit:   |                      |                      |
| Preferred stock, par value \$0.01 per share: 10,000,000 shares authorized,<br>no shares issued and outstanding . . . . .   | —                    | —                    |
| Common stock, par value \$0.01 per share; 60,000,000 shares authorized;<br>23,905,635 and 13,012,833 shares issued and outstanding at<br>September 30, 2024 and September 30, 2023, respectively . . . . . | 239,057              | 130,128              |
| Additional paid-in capital . . . . .   | 469,969,333          | 453,350,281          |
| Accumulated deficit . . . . .  | (543,284,900)        | (467,918,186)        |
| Total stockholders' deficit . . . . .  | <u>(73,076,510)</u>  | <u>(14,437,777)</u>  |
| Total liabilities and stockholders' deficit . . . . .  | <u>\$ 28,823,154</u> | <u>\$ 32,300,601</u> |

See accompanying notes to consolidated financial statements

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Operations**

|  | Year ended September 30, |                       |
|--|--------------------------|-----------------------|
|  | 2024                     | 2023                  |
| Operating expenses:  |                          |                       |
| Research and development . . . . .                               | \$ 41,763,047            | \$ 26,452,942         |
| General and administrative . . . . .                             | 29,940,188               | 26,673,440            |
| Loss from operations . . . . .                                   | (71,703,235)             | (53,126,382)          |
| Loss on equity method investment . . . . .                       | 100,742                  | 10,998                |
| Interest income . . . . .  | (906,150)                | (971,480)             |
| Interest expense . . . . .                                       | 3,156,964                | 2,531,228             |
| Loss on extinguishment of debt . . . . .                         | —                        | 577,659               |
| Change in fair value of promissory notes . . . . .               | 2,457,153                | 3,756,000             |
| Warrant related expenses (Note 9) . . . . .                      | 37,490,012               | —                     |
| Change in fair value of warrant liability . . . . .              | (38,638,042)             | (50,919)              |
| Loss before income taxes . . . . .                               | (75,363,914)             | (58,979,868)          |
| Income tax expense . . . . .                                     | 2,800                    | 2,800                 |
| Net loss . . . . .   | <u>\$(75,366,714)</u>    | <u>\$(58,982,668)</u> |
| Per share information:   |                          |                       |
| Net loss per share of common stock, basic and diluted . . . . .  | \$ <u>(4.06)</u>         | \$ <u>(4.72)</u>      |
| Weighted average shares outstanding, basic and diluted . . . . . | <u>18,548,813</u>        | <u>12,508,817</u>     |

See accompanying notes to consolidated financial statements

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**

|   | Stockholders' Equity (Deficit) |                  |                               |                        |   |
|---|--------------------------------|------------------|-------------------------------|------------------------|---|
|   | Common Stock                   |                  | Additional<br>Paid-in Capital | Accumulated<br>Deficit | Total Stockholders'<br>Equity (Deficit) |
|   | Shares                         | Amount           |                               |                        |   |
| Balance at October 1, 2022 . . . . .  | 11,365,486                     | 113,655          | 417,558,434                   | (408,935,518)          | 8,736,571                               |
| Issuance of common stock in<br>connection with conversion of<br>convertible promissory note . . . . . | 625                            | 6                | 24,994                        | —                      | 25,000                                  |
| Sale of common stock, net of<br>issuance costs (Note 9) . . . . .                                     | 1,646,722                      | 16,467           | 30,219,834                    | —                      | 30,236,301                              |
| Stock-based compensation expense . .  | —                              | —                | 5,547,019                     | —                      | 5,547,019                               |
| Net loss . . . . .  | —                              | —                | —                             | (58,982,668)           | (58,982,668)                            |
| Balance at September 30, 2023 . . . . .   | 13,012,833                     | 130,128          | 453,350,281                   | (467,918,186)          | (14,437,777)                            |
| Issuance of common stock in<br>connection with conversion of<br>convertible promissory note . . . . . | 1,607,093                      | 16,072           | 11,233,928                    | —                      | 11,250,000                              |
| Sale of common stock, net of<br>issuance costs (Note 9) . . . . .                                     | 9,285,709                      | 92,857           | —                             | —                      | 92,857                                  |
| Stock-based compensation expense . .  | —                              | —                | 5,385,124                     | —                      | 5,385,124                               |
| Net loss . . . . .  | —                              | —                | —                             | (75,366,714)           | (75,366,714)                            |
| Balance at September 30, 2024 . . . . .   | <u>23,905,635</u>              | <u>\$239,057</u> | <u>\$469,969,333</u>          | <u>\$(543,284,900)</u> | <u>\$(73,076,510)</u>                   |

See accompanying notes to consolidated financial statements

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Cash Flows**

|   | Year ended September 30, |                      |
|---|--------------------------|----------------------|
|   | 2024                     | 2023                 |
| <b>OPERATING ACTIVITIES</b>   |                          |                      |
| Net loss  | \$(75,366,714)           | \$(58,982,668)       |
| Adjustments to reconcile net loss to net cash used in operating activities:                         |                          |                      |
| Depreciation and amortization   | 113,859                  | 44,188               |
| Loss on extinguishment of debt  | —                        | 577,659              |
| Non-cash interest expense   | 2,681,847                | 2,529,830            |
| Stock-based compensation  | 5,385,124                | 5,547,019            |
| Change in fair value of promissory notes  | 2,457,153                | 3,756,000            |
| Warrant related expenses (Note 9)   | 37,490,012               | —                    |
| Change in fair value of warrant liability   | (38,638,042)             | (50,919)             |
| Loss on equity method investment  | 100,742                  | 10,998               |
| Interest paid on debt   | —                        | (1,158,609)          |
| Changes in operating assets and liabilities:  |                          |                      |
| Prepaid expenses and other current assets   | (4,901,282)              | 2,616,925            |
| Other assets  | (5,900)                  | (208,203)            |
| Operating lease liabilities   | 3,413                    | (26,995)             |
| Accounts payable  | 1,394,202                | 3,083,038            |
| Accrued expenses  | 491,728                  | (711,661)            |
| Net cash used in operating activities   | <u>(68,793,858)</u>      | <u>(42,973,398)</u>  |
| <b>FINANCING ACTIVITIES</b>   |                          |                      |
| Proceeds from the sale of common stock and warrants to purchase common stock, net of issuance costs | 60,333,681               | 30,024,213           |
| Proceeds from debt  | —                        | 30,000,000           |
| Payments of finance lease obligations   | (4,267)                  | (11,751)             |
| Repayment of debt   | —                        | (10,220,000)         |
| Payment of financing costs  | —                        | (823,894)            |
| Net cash provided by financing activities   | <u>60,329,414</u>        | <u>48,968,568</u>    |
| Net (decrease) increase in cash and cash equivalents  | <u>(8,464,444)</u>       | <u>5,995,170</u>     |
| Cash and cash equivalents at beginning of year  | <u>23,391,982</u>        | <u>17,396,812</u>    |
| Cash and cash equivalents at end of year  | <u>\$ 14,927,538</u>     | <u>\$ 23,391,982</u> |
| Supplemental disclosure of cash flow information:   |                          |                      |
| Cash paid for interest  | <u>\$ 475,000</u>        | <u>\$ 1,160,008</u>  |
| Supplemental schedule of non-cash financing activities:   |                          |                      |
| Convertible promissory note converted into common stock   | <u>\$ 11,250,000</u>     | <u>\$ 25,000</u>     |
| Recognition of warrant liability  | <u>\$ 97,730,836</u>     | <u>\$ —</u>          |
| Deferred offering costs amortization  | <u>\$ —</u>              | <u>\$ 141,600</u>    |
| Right-of-use asset and lease liability recognized for new operating lease liabilities               | <u>\$ 294,416</u>        | <u>\$ —</u>          |

See accompanying 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/LYTENAVA™ (bevacizumab-gamma), an ophthalmic formulation of bevacizumab for use in retinal indications. The Company is based in Iselin, New Jersey.

In May 2024, the Company received Marketing Authorization from the European Commission for ONS-5010/LYTENAVA, an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (“AMD”) in the European Union (“EU”). Additionally, in July 2024 the Company also received marketing authorization for ONS-5010/LYTENAVA in the United Kingdom (“UK”) from the UK Medicines and Healthcare products Regulatory Agency (MHRA). ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the U.S. Food and Drug Administration (“FDA”) in support of the Company’s Biologics License Application (“BLA”) for ONS-5010/LYTENAVA. In December 2023, the Company submitted a Special Protocol Assessment (“SPA”) to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA’s requirement for a second adequate and well-controlled clinical trial to support its planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, the Company received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA and that, if the NORSE EIGHT trial is successful, it would satisfy the FDA’s requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (“CRL”). In addition, through a Type A meeting and additional interactions, the Company has identified the approaches needed to resolve the chemistry, manufacturing and controls (“CMC”) comments in the CRL. In November 2024, the Company reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025.

## 2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of \$ 543,284,900 as of September 30, 2024. As of September 30, 2024, the Company had \$31,352,857 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued in December 2022 (the “December 2022 Note”), maturing on July 1, 2025, as amended. 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.

In November 2024 and December 2024, the Company sold 1,000,000 shares of common stock under the BTIG ATM Offering and generated \$1,742,343 in net proceeds after paying fees to BTIG and other issuance costs of \$53,918. Refer to Note 9 for further details on the BTIG ATM Offering.

Management does not believe that the Company’s existing cash and cash equivalents as of September 30, 2024, together with \$1,742,343 in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund the Company’s operations through one year from the Form 10-K filing date. As a result, there is substantial doubt about the Company’s ability to continue as a going concern and additional financing will be needed by the Company to fund its operations

in the future and to commercially develop ONS-5010/LYTENAVA and to develop any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations, including but not limited to, the exercise of outstanding warrants to purchase shares of the Company's common stock (subject to meeting the requirements for calling such warrants), proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to the Company's drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offering agreements (refer to Note 9 for further details), 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 consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.

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.

### **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.

#### **Reverse stock split**

Effective on March 14, 2024, the Company amended its amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of its common stock. As a result of the reverse stock split, the Company made corresponding adjustments to the share amounts under its employee incentive plans, outstanding options, and common stock warrant agreements with third parties. The disclosure of common shares and per common share data in the accompanying consolidated financial statements and related notes reflect the reverse stock split for all periods presented.

#### **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, 2024 and 2023, 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:

- 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, 2024 and 2023, the Company's financial instruments included cash and cash equivalents, accounts payable, accrued expenses, unsecured convertible promissory note and warrant liabilities. The carrying amount of accounts payable, and accrued expenses 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 the December 2022 Note. Refer to Note 7 for further details on the December 2022 Note.

### **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, 2024.

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 11. 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.

### **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 convertible debt, warrants, performance-based stock options and units, and stock options 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 losses.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2024 and 2023, as they would be antidilutive:

|   | As of September 30,      |                         |
|---|--------------------------|-------------------------|
|   | 2024                     | 2023                    |
| Performance-based stock units . . . . .   | —                        | 123                     |
| Performance-based stock options . . . . . | 666,500                  | 35,000                  |
| Stock options . . . . .                   | 1,946,646                | 1,197,774               |
| Common stock warrants . . . . .           | 14,207,622               | 366,427                 |
| Convertible debt . . . . .                | 1,171,100 <sup>(i)</sup> | 854,962 <sup>(ii)</sup> |

- (i) The calculation for potentially dilutive securities pertaining to convertible debt is as follows: \$3,750,000 of outstanding principal and accrued interest as of September 30, 2024, is converted at a rate of \$7.00, and the remaining amount is converted based on a fixed conversion price of \$40.00 per share, which is subject to change as described in Note 7.
- (ii) The potentially dilutive securities related to convertible debt are calculated based on a fixed conversion price of \$40.00 per share, which is subject to change as described in Note 7.

#### Recently issued accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures.

#### 4. Fair Value Measurements

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

|   | September 30, 2024 |             |                     |
|---|--------------------|-------------|---------------------|
|   | (Level 1)          | (Level 2)   | (Level 3)           |
| <b>Liabilities</b>                              |                    |             |                     |
| Unsecured convertible promissory note . . . . . | \$ —               | \$ —        | \$29,440,000        |
| Warrant liability . . . . .                     | —                  | —           | 59,099,013          |
| Total . . . . .                                 | <u>\$ —</u>        | <u>\$ —</u> | <u>\$88,539,013</u> |

|   | September 30, 2023 |             |                     |
|---|--------------------|-------------|---------------------|
|   | (Level 1)          | (Level 2)   | (Level 3)           |
| <b>Liabilities</b>                              |                    |             |                     |
| Unsecured convertible promissory note . . . . . | \$ —               | \$ —        | \$35,551,000        |
| Warrant liability . . . . .                     | —                  | —           | 6,219               |
| Total . . . . .                                 | <u>\$ —</u>        | <u>\$ —</u> | <u>\$35,557,219</u> |

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 the December 2022 Note for the years ended September 30, 2024 and 2023:

|  | Unsecured Convertible<br>Promissory Note | Warrants             |
|--|--|----------------------|
| Balance at October 1, 2022 . . . . .   | \$ —                                     | \$ 57,138            |
| Fair value at issuance . . . . .   | 31,820,000                               | —                    |
| Accrued interest converted to common stock . . . . .                             | (25,000)                                 | —                    |
| Change in fair value . . . . .   | <u>3,756,000</u>                         | <u>(50,919)</u>      |
| Balance at September 30, 2023 . . . . .  | 35,551,000                               | 6,219                |
| Issued in connection with sale of common stock . . . . .                         | —  | 97,730,836           |
| Promissory note maturity extension fee added to outstanding<br>balance . . . . . | 2,681,847                                | —                    |
| Principal and accrued interest converted to common stock . . . . .               | (11,250,000)                             | —                    |
| Change in fair value . . . . .   | <u>2,457,153</u>                         | <u>(38,638,042)</u>  |
| Balance at September 30, 2024 . . . . .  | <u>\$ 29,440,000</u>                     | <u>\$ 59,099,013</u> |

As further described in Note 7, the Company elected the fair value option to account for the December 2022 Note. The fair value of the December 2022 Note is estimated using a binomial lattice model, which evaluates the payouts under hold, convert or call decisions. Significant estimates in the binomial lattice model include the Company's stock price, volatility, risk-free rate of return, and credit-adjusted discount rate.

The fair values of the December 2022 Note as of September 30, 2024 and 2023 were estimated using a binomial lattice model with the following assumptions:

|   | September 30, |        |
|---|---------------|--------|
|   | 2024          | 2023   |
| Term (years) . . . . .                  | 0.8           | 0.3    |
| Volatility . . . . .                    | 91.0%         | 71.0%  |
| Risk-free rate . . . . .                | 4.2%          | 5.5%   |
| Dividend yield . . . . .                | —%            | —%     |
| Credit-adjusted discount rate . . . . . | 20.4%         | 22.8%  |
| Stock price . . . . .                   | \$5.34        | \$4.40 |

The warrants related to the Note and Warrant Purchase Agreement dated December 22, 2017 are classified as liabilities as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrants issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 are classified as liabilities as the Company assessed that they are not indexed to the Company's own stock and must be classified as liabilities. For further details on the evaluation refer to Note 9.

The above warrant liabilities are revalued each reporting period with the change in fair values recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair values of the warrant liabilities are estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

|  | September 30, |         |
|--|---------------|---------|
|  | 2024          | 2023    |
| Risk-free interest rate . . . . .                        | 3.58%         | 5.30%   |
| Remaining contractual term of warrants (years) . . . . . | 4.5           | 1.4     |
| Expected volatility . . . . .                            | 125.0%        | 158.3%  |
| Annual dividend yield . . . . .                          | —%            | —%      |
| Fair value of common stock (per share) . . . . .         | \$ 5.34       | \$ 4.40 |

## 5. 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/LYTENAVA 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 is committed to making capital contributions to Syntone JV of approximately \$2,100,000, based upon the development plan contemplated in the license agreement. 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.

## 6. Accrued Expenses

Accrued expenses consists of:

|                                    | September 30,      |                    |
|------------------------------------|--------------------|--------------------|
|                                    | 2024               | 2023               |
| Compensation . . . . .             | \$1,012,962        | \$ 919,970         |
| Professional fees . . . . .        | 1,798,767          | 165,192            |
| Research and development . . . . . | 41,373             | 1,234,192          |
| Other accrued expenses . . . . .   | 384,366            | 426,386            |
|                                    | <u>\$3,237,468</u> | <u>\$2,745,740</u> |

## 7. Debt

Debt consists of:

|  | September 30, |               |
|--|---------------|---------------|
|  | 2024          | 2023          |
| Unsecured convertible promissory note (measured at fair value) . . | \$ 29,440,000 | \$ 35,551,000 |
| Less: current portion . . . . .                                    | (29,440,000)  | (35,551,000)  |
| Long-term debt . . . . .   | <u>\$ —</u>   | <u>\$ —</u>   |

### December 2022 Note

On December 22, 2022, the Company entered into a Securities Purchase Agreement and issued the December 2022 Note with a face amount of \$31,820,000 to Streeterville Capital, LLC (the “Lender”), the

holder of the Company's unsecured promissory note issued in November 2021 (the "November 2021 Note"). The December 2022 Note has an original issue discount of \$1,820,000. The Company received net proceeds of \$18,052,461 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. See below for additional disclosures relating to the November 2021 Note.

In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a \$475,000 extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024.

The December 2022 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 had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company had the right to convert all or any portion of the outstanding balance under the December 2022 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 \$50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 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 December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 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 December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, \$40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) \$40.00 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. If the Conversion Price is below \$3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the "January 2024 Note Amendment") with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of \$2,681,847 (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. The extension fee was included in interest expense in the consolidated statement of operations for the year ended September 30, 2024.

Under the January 2024 Note Amendment, the initial conversion price with respect to \$15,000,000 in aggregate principal amount of the December 2022 Note was changed to \$7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount has a conversion price of \$40.00 per share. Effective April 1, 2024, the December 2022 Note bears interest at the

prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least \$3,000,000 of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the January 2024 Note Amendment) and continuing until the December 2022 Note is repaid in full.

During the year ended September 30, 2024, an aggregate of principal and accrued interest totaling \$11,250,000 of the December 2022 Note was converted into 1,607,093 shares of the Company's common stock.

The Company elected to account for the December 2022 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the original issue discount of \$1,820,000 and debt issuance costs were written off upon election to fair value and accounted for as interest. During the year ended September 30, 2024, the Company recognized \$3,156,847 of interest expense related to extension fees. During the year ended September 30, 2023, the Company recognized \$2,074,964 of interest expense related to original issue discount of \$1,820,000 and other third party debt issuance costs of \$254,964.

#### *November 2021 Note*

On November 16, 2021, the Company received \$10,000,000 in net proceeds from the issuance of the November 2021 Note with a face amount of \$10,220,000. Debt issuance costs totaling \$820,000 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 term of the underlying debt using the effective interest method. The note bore interest at a rate of 9.5% per annum compounding daily and was set to mature on January 1, 2023. The Company could prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for prepayment.

As discussed above, the November 2021 Note was cancelled using proceeds from the December 2022 Note issued to the same lender. The total repayment was \$11,947,539, which represented 105% of the outstanding balance and included \$1,158,609 of interest expense. The transaction has been accounted for as an extinguishment of the November 2021 Note. As a result, the Company recorded a loss on debt extinguishment of \$577,659, which included \$8,729 of unamortized debt discount, and prepayment fees of \$568,930.

During the year ended September 30, 2023, the Company recognized \$454,866 of interest expense related to the unsecured promissory note, of which \$190,775 was related to the amortization of debt discount.

## **8. 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, 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 \$332,779 (based on an exchange rate on September 30, 2024 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 November 3, 2023, a securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by the Company related to the Company's BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that the Company violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that the Company and/or their manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time the Company's BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve the Company's BLA, and that the Company's stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. Defendants' motion to dismiss is currently pending before the court.

On October 10, 2024, certain of the company's officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the Company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys' fees, and other costs.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and the Company may not prevail. In addition, the Company may incur substantial legal fees and costs in connection with such lawsuits. The Company currently is not able to estimate the possible cost to it from these matters, as the pending lawsuits are currently at an early stage, and the Company cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that the Company may be required to pay. Such amounts could be material to the Company's financial statements if it does not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if it does prevail. The Company has not

established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that the Company could, in the future, incur judgments or enter into settlements of claims for monetary damages.

## Leases

### *Corporate office*

In March 2021, the Company entered into a three-year term corporate office lease in Iselin, New Jersey that ended on April 30, 2024.

In March 2024, the Company entered into a five-year term corporate office lease for its new corporate headquarters in Iselin, New Jersey that commenced on May 1, 2024.

### *Equipment leases*

As of September 30, 2024, all equipment leases had expired. The Company had equipment leases with terms between 12 and 36 months and had recorded those leases as finance leases. The equipment leases bore interest between 4.0% and 13.0% per annum. Payments due under the lease contracts included minimum payments that the Company was obligated to make under the non-cancelable initial terms of the leases as the renewal terms were at the Company's option. Lease expense was 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, 2024 and 2023 were as follows:

|   | <u>Year ended September 30,</u> |                 |
|---|---------------------------------|-----------------|
|   | <u>2024</u>                     | <u>2023</u>     |
| <b>Lease cost:</b>                      |                                 |                 |
| Interest on lease liabilities . . . . . | \$ 116                          | \$ 1,399        |
| Total finance lease cost . . . . .      | 116                             | 1,399           |
| Operating lease cost . . . . .          | 57,973                          | 44,867          |
| Total lease cost . . . . .              | <u>\$58,089</u>                 | <u>\$46,266</u> |

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

|   | <u>September 30,</u> |             |
|---|----------------------|-------------|
|   | <u>2024</u>          | <u>2023</u> |
| <b>Operating leases:</b>                              |                      |             |
| Right-of-use asset . . . . .                          | \$274,645            | \$26,172    |
| Operating lease liabilities . . . . .                 | 297,829              | —           |
| <b>Finance leases:</b>                                |                      |             |
| Right-of-use asset . . . . .                          | \$ —                 | \$ —        |
| Financing lease liabilities . . . . .                 | —                    | 4,267       |
| <b>Weighted-average remaining lease term (years):</b> |                      |             |
| Operating leases . . . . .                            | 4.6                  | 0.6         |
| Finance leases . . . . .                              | —                    | 0.3         |
| <b>Weighted-average discount rate:</b>                |                      |             |
| Operating leases . . . . .                            | 9.9%                 | 7.5%        |
| Finance leases . . . . .                              | —                    | 13.0%       |

Other information related to leases for the years ended September 30, 2024 and 2023 are as follows:

|  | <b>Year ended September 30,</b> |             |
|--|---------------------------------|-------------|
|  | <b>2024</b>                     | <b>2023</b> |
| <b>Cash paid for amounts included in the measurement of lease obligations:</b> |                                 |             |
| Operating cash flows from finance leases . . . . .                             | \$ 116                          | \$ 1,399    |
| Operating cash flows from operating leases . . . . .                           | 14,514                          | 27,675      |
| Financing cash flows from finance leases . . . . .                             | 4,267                           | 11,751      |
| <b>Right-of-use assets obtained in exchange for lease obligations:</b>         |                                 |             |
| Operating leases . . . . .   | \$294,416                       | \$ —        |

Future minimum payments under noncancelable leases at September 30, 2024 are as follows for the years ending September 30:

|   | <b>Operating<br/>leases</b> |
|---|-----------------------------|
| 2025 . . . . .                              | \$ 78,091                   |
| 2026 . . . . .                              | 79,954                      |
| 2027 . . . . .                              | 81,817                      |
| 2028 . . . . .                              | 83,680                      |
| 2029 . . . . .                              | 49,447                      |
| Total undiscounted lease payments . . . . . | 372,989                     |
| Less: Imputed interest . . . . .            | 75,160                      |
| Total lease obligations . . . . .           | <u>\$297,829</u>            |

## **Employee Benefit Plan**

The Company maintains a defined contribution 401(k) plan (the “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, 2024 and 2023, the expense relating to the matching contribution was \$177,309 and \$136,914, respectively.

## **9. Stockholders’ Equity**

### **Common stock**

On March 7, 2024, following receipt of stockholder approval at the Company’s 2024 annual meeting of stockholders, the number of authorized shares of common stock under the Company’s Certificate of Incorporation was increased from 21,250,000 shares to 60,000,000 shares.

On March 18, 2024, in a private placement (the “Private Placement”) pursuant to a securities purchase agreement entered in January 2024 with certain institutional and accredited investors, including GMS Ventures and Investments (“GMS Ventures”), the Company’s largest stockholder, the Company issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of \$7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for \$55,498,311 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The Warrants have an exercise price of \$7.70 per share of common stock and will expire on March 18, 2029.

On April 15, 2024, in a private placement with Syntone pursuant to a securities purchase agreement entered into in January 2024 (the “Syntone Private Placement”), the Company issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for \$4,835,371

in net proceeds on substantially the same terms as those in the Private Placement. The warrants have an exercise price of \$7.70 per share of common stock and will expire on April 15, 2029.

The Company evaluated the equity classification for the common stock warrants and considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The Company determined that the warrants did not meet the "fixed for fixed" settlement provision set forth in Step 2 of the indexation guidance and as a result they are not indexed to the Company's own stock and must be classified as liabilities. The warrants were measured at fair value at issuance and recorded as a liability and will be remeasured to fair value at each subsequent reporting date, with changes in fair value recorded in current earnings. The net proceeds from the Private Placement were allocated first to the warrants at fair value, with the residual amount recorded as common stock at par value. The Company will continue to classify such warrants as liabilities until they are exercised, expire, or are no longer required to be classified as liabilities.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, the Company issued 1,423,041 shares of common stock at a purchase price per share of \$17.568 for \$23,208,679 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 shares of common stock in the registered direct equity offering. 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 25,787 shares of common stock at an exercise price of \$21.00 per share, which warrants have a three-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, 2024.

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

On March 26, 2021, the Company entered into an At-the-Market Offering Agreement with H.C. Wainwright & Co., as sales agent ("Wainwright"), (the "Wainwright ATM Agreement" or the "Wainwright ATM Offering"), 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 \$40,000,000 from time to time through Wainwright. The Company incurred financing costs of \$197,654 which were capitalized and were being reclassified to additional paid in capital on a pro rata basis when the Company sold common stock under the Wainwright ATM Offering.

Under the Wainwright ATM Offering, the Company paid Wainwright a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the Wainwright ATM Agreement. The Company terminated the Wainwright ATM Agreement effective May 15, 2023. As a result, the Company wrote off unamortized deferred costs under the Wainwright ATM Agreement. During the year ended September 30, 2023, the Company sold 44,769 shares of common stock under the Wainwright ATM Offering and generated \$1,089,105 in net proceeds after paying fees to Wainwright of \$38,799.

#### **BTIG, LLC At-the-Market Offering Agreement**

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG"), as sales agent (the "BTIG ATM Agreement" or the "BTIG ATM Offering"), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$100,000,000 from time to time through BTIG. The Company incurred financing costs of \$353,688, 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 BTIG ATM Offering. As of September 30, 2024, \$331,512 of such deferred costs are included in other assets on the consolidated balance sheets.

Under the BTIG ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of

common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms.

During the year ended September 30, 2024, no shares of common stock were sold under the BTIG ATM Offering. During the year ended September 30, 2023, the Company sold 178,911 shares of common stock under the BTIG ATM Offering and generated \$6,080,088 in net proceeds after paying fees to BTIG and other issuance costs of \$188,044.

### Common stock warrants

As of September 30, 2024, the Company had the following warrants outstanding to acquire shares of its common stock:

| Expiration Date             |      | Shares of<br>common stock<br>issuable upon<br>exercise of<br>warrants | Exercise<br>Price<br>Per Share |
|-----------------------------|------|---|--------------------------------|
| December 22, 2024 . . . . . | (i)  | 13,850  | \$240.00                       |
| February 24, 2025 . . . . . |      | 8,642   | \$ 25.40                       |
| April 13, 2025 . . . . .    | (i)  | 7,284   | \$240.00                       |
| May 31, 2025 . . . . .      | (i)  | 3,121   | \$240.00                       |
| June 22, 2025 . . . . .     |      | 9,563   | \$ 30.38                       |
| December 28, 2025 . . . . . |      | 25,787  | \$ 21.00                       |
| January 28, 2026 . . . . .  |      | 12,576  | \$ 25.00                       |
| February 2, 2026 . . . . .  |      | 93,238  | \$ 25.00                       |
| November 23, 2026 . . . . . |      | 104,999   | \$ 31.25                       |
| March 18, 2029 . . . . .    | (ii) | 12,857,133  | \$ 7.70                        |
| April 15, 2029 . . . . .    | (ii) | 1,071,429   | \$ 7.70                        |
|                             |      | <u>14,207,622</u>   |                                |

- (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.
- (ii) The warrants were issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 and are exercisable only for cash, except in limited circumstances, at any time after the date of issuance. The Company evaluated the warrants under ASC 815-40 guidance and determined that the warrants did not meet Step 2 of the indexation. As a result they are not indexed to the Company's own stock and must be classified as liabilities. Refer to the disclosure above under the header "— Common stock" for further details. A holder of warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than a specified percentage of the outstanding common stock (4.99%, 9.99% or 19.99%, as applicable), immediately after giving effect to such exercise, which may be increased or decreased at the holders' option (not to exceed 19.99%), effective 61 days after written notice to the Company. In addition, the Company may require the holders to cash exercise the warrants under certain circumstances as follows: (i) if the daily volume weighted average price (the "VWAP") of the common stock equals or exceeds \$20.00 per share (subject to adjustment in the event of stock splits, combinations or similar events, such as the reverse stock split implemented prior to closing) for 30 consecutive days (the "Stock Price Condition") at any time after the Company publicly announces topline data from its NORSE EIGHT clinical trial evidencing satisfaction of the trial's primary endpoints (the "NORSE EIGHT Announcement"), upon the consent of a majority of the members of the Company's board of directors, the Company may require the holders to exercise up

to 20% of the aggregate number of warrants issued to such holder on the issue date; and (ii) the Company may require up to the remainder of the warrants be exercised (A) if the Stock Price Condition is satisfied at any time after the Company publicly announces approval from the FDA of its BLA for ONS-5010/LYTENAVA, upon the consent of a majority of the members of the board of directors or (B) if the Stock Price Condition is satisfied at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Company's Board of Directors present at a duly called meeting.

## **10. Preferred Stock**

On May 13, 2024, the Company filed a Certificate of Elimination to its Certificate of Incorporation, as then amended, with the Secretary of State of the State of Delaware to eliminate from the Certificate of Incorporation all matters set forth in the Certificates of Designation filed with the Secretary of State of the State of Delaware on September 8, 2017 (with respect to its Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock) and July 18, 2018, as amended on March 19, 2020 (with respect to its Series A-1 Convertible Preferred Stock) and returning each of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series. There were no outstanding shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock or Series A-1 Convertible Preferred Stock as of May 13, 2024. Immediately following the filing of the Certificate of Elimination, the Company filed a Restated Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware, which restates and integrates but does not further amend the Company's Certificate of Incorporation, as then amended. The number of authorized shares of preferred stock under the Company's Certificate of Incorporation is 10,000,000 shares.

## **11. 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, restricted stock units ("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, 2024, there were no equity awards 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.

### **2024 Equity Incentive Plan**

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provided 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. In August 2024, the Company's stockholders approved the amendment and restatement of the 2015 Plan and, in connection with amending and restating the 2015 Plan, the name of the 2015 Plan was updated to the Outlook Therapeutics, Inc. 2024 Equity Incentive Plan (the "2024 Plan"). The 2024 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 2024 Plan is 7,293,901. As of September 30, 2024, 4,680,755 shares remained available for grant under the 2024 Plan.

Stock options and RSUs granted under the Company's 2024 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, 2024 and 2023:

|                                      | Year ended September 30, |                    |
|--------------------------------------|--------------------------|--------------------|
|                                      | 2024                     | 2023               |
| Research and development . . . . .   | \$ 800,956               | \$ 986,598         |
| General and administrative . . . . . | 4,584,168                | 4,560,421          |
|                                      | <u>\$5,385,124</u>       | <u>\$5,547,019</u> |

## Stock options

The following table summarizes all of the Company's stock option activity for the years ended September 30, 2024:

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic Value |
|--|---------------------|---------------------------------------|---|------------------------------|
| Balance at October 1, 2023 . . . . .                   | 1,197,774           | \$28.72                               |   |                              |
| Granted . . . . .                                      | 817,729             | 6.69                                  |   |                              |
| Forfeited . . . . .                                    | (59,212)            | 26.27                                 |   |                              |
| Expired . . . . .                                      | (9,645)             | 34.50                                 |   |                              |
| Balance at September 30, 2024 . . . . .                | <u>1,946,646</u>    | \$19.51                               | 7.7   | \$53,985                     |
| Vested and exercisable at September 30, 2024 . . . . . | <u>1,006,079</u>    | \$26.84                               | 6.5   | \$53,985                     |

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 2024 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, 2024 and 2023 was \$6.04 and \$19.40 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, |        |
|-----------------------------------|--------------------------|--------|
|                                   | 2024                     | 2023   |
| Risk-free interest rate . . . . . | 4.3%                     | 3.7%   |
| Expected term (years) . . . . .   | 6.0                      | 5.9    |
| Expected volatility . . . . .     | 131.4%                   | 111.6% |
| Expected dividend yield . . . . . | —                        | —      |

As of September 30, 2024, there was \$7,508,106 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 1.3 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.

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, 2024.

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic Value |
|--|---------------------|--|---|------------------------------|
| Balance at October 1, 2023 . . . . .                   | 35,000              | \$28.80                                  |   |                              |
| Granted . . . . .                                      | 634,000             | 6.78                                     |   |                              |
| Forfeited . . . . .                                    | (2,500)             | 6.78                                     |   |                              |
| Balance at September 30, 2024 . . . . .                | <u>666,500</u>      | \$ 7.94                                  | 9.3   | \$ —                         |
| Vested and exercisable at September 30, 2024 . . . . . | <u>35,000</u>       | \$28.80                                  | 6.3   | \$ —                         |

The weighted average grant date fair value of the performance stock options awarded for the years ended September 30, 2024 and 2023 was \$6.52 and \$18.20 per option, respectively. During the year ended September 30, 2024, no expense was recognized because the performance conditions were not considered probable of achievement. As of September 30, 2024, the Company assessed that the performance conditions related to the performance options granted were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore no compensation costs were recognized. 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, |       |
|-----------------------------------|--------------------------|-------|
|                                   | 2024                     | 2023  |
| Risk-free interest rate . . . . . | 4.3%                     | 3.8%  |
| Expected term (years) . . . . .   | 10.0                     | 10.0  |
| Expected volatility . . . . .     | 125.6%                   | 91.3% |
| Expected dividend yield . . . . . | —                        | —     |

## 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, 2024:

|  | Number<br>of<br>PSUs | Exercise<br>Price<br>Per PSU | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic Value |
|--|----------------------|------------------------------|---|------------------------------|
| Balance at October 1, 2023 . . . . .                   | 123                  | \$999.40                     |   |                              |
| Expired . . . . .                                      | <u>(123)</u>         | 999.40                       |   |                              |
| Balance at September 30, 2024 . . . . .                | <u>—</u>             | \$ —                         | —   | \$ —                         |
| Vested and exercisable at September 30, 2024 . . . . . | <u>—</u>             | \$ —                         | —   | \$ —                         |

## 12. 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/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.

The Company made the initial investment of \$900,000 in June 2020. The Company is committed to making up to \$2,100,000 in additional capital contributions to the PRC joint venture, based upon the development plan contemplated in the license agreement or on such other terms.

## 13. Income Taxes

Income tax benefit for the years ended September 30, 2024 and 2023 consists of the following:

|           | Year ended September 30, |         |
|-----------|--------------------------|---------|
|           | 2024                     | 2023    |
| State tax | \$2,800                  | \$2,800 |

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, |         |
|-------------------------------------|--------------------------|---------|
|                                     | 2024                     | 2023    |
| U.S. federal statutory rate         | (21.0)%                  | (21.0)% |
| State taxes, net of federal benefit | (6.2)                    | (7.3)   |
| Deferred true-up                    | 0.2                      | 0.1     |
| Permanent differences               | 2.5                      | (0.7)   |
| Foreign tax credits                 | 1.7                      | 1.3     |
| Research and development credit     | (2.4)                    | (1.3)   |
| Change in valuation allowance       | 25.3                     | 29.0    |
| Other                               | (0.1)                    | (0.1)   |
| Effective income tax rate           | 0.0%                     | 0.0%    |

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

|  | September 30,  |               |
|--|----------------|---------------|
|  | 2024           | 2023          |
| Deferred tax assets:                         |                |               |
| Net operating loss carryforwards             | \$ 102,906,140 | \$ 92,961,718 |
| Capitalized research and development costs   | 15,200,918     | 6,531,508     |
| Stock-based compensation                     | 6,463,068      | 5,066,375     |
| Lease liability                              | 83,720         | —             |
| Research and development credit carryforward | 13,748,600     | 11,953,956    |
| Foreign tax credits                          | 290,188        | 1,562,639     |
| Accruals and others                          | 144,079        | 1,656,239     |
| Gross deferred tax assets                    | 138,836,713    | 119,732,435   |
| Less: valuation allowance                    | (138,759,510)  | (119,725,078) |

|                                   | September 30, |             |
|-----------------------------------|---------------|-------------|
|                                   | 2024          | 2023        |
|                                   | 77,203        | 7,357       |
| Deferred tax liabilities:         |               |             |
| Property and equipment . . . . .  | —             | —           |
| Right-of-use assets . . . . .     | (77,203)      | (7,357)     |
| Net deferred tax assets . . . . . | <u>\$ —</u>   | <u>\$ —</u> |

As of September 30, 2024, the Company had approximately \$406.7 million and \$242.5 million of U.S. federal and New Jersey NOLs that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, the Company had federal and state research and development tax credit carryforwards of \$13.0 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, 2024, the Company has federal foreign tax credit (“FTC”) carryforwards of \$0.3 million available to reduce future tax liabilities which began to expire starting in 2023, of which \$0.3 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, 2024 and 2023. The valuation allowance increased by \$19.0 million and \$17.1 million during the year ended September 30, 2024 and 2023, 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.

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

|  | Year ended September 30, |                    |
|--|--------------------------|--------------------|
|  | 2024                     | 2023               |
| 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 . . . . .                                     | <u>\$1,856,629</u>       | <u>\$1,856,629</u> |

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 2023 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.

#### 14. Subsequent Events

##### Departure of Chief Executive Officer

On December 3, 2024, C. Russell Trenary III stepped down as the President and Chief Executive Officer the Company and as a member of the Company’s Board of Directors (the “Board”), effective

immediately (the “Effective Date”). The Board has resolved to reduce its size to nine directors immediately upon Mr. Trenary’s resignation.

Mr. Trenary’s departure constituted a termination of employment without “cause” for purposes of any employment, equity compensation or benefit agreement, plan or arrangement of the Company and its subsidiaries to which Mr. Trenary is a party or otherwise participates, including that certain executive employment agreement, dated as of July 6, 2021, by and between Mr. Trenary and the Company (the “Employment Agreement”). Accordingly, subject to Mr. Trenary’s execution and non-revocation of a separation agreement containing a release of claims against the Company, Mr. Trenary is entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then unvested equity awards, and reimbursement of expenses owed to him through the date of his termination.

On December 3, 2024, Lawrence A. Kenyon, the Company’s Chief Financial Officer, was appointed Interim Chief Executive Officer of the Company, effective as of the Effective Date, to serve while the Board conducts a formal search process to identify and appoint a permanent Chief Executive Officer.

### **Reduction in Workforce**

On December 10, 2024, the Board approved a reduction of the Company’s workforce in connection with its plans to reduce operating expenses and preserve capital. On December 13, 2024, the Company reduced its workforce by five people, or approximately 23% of its existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against the Company. The Company estimates that it will incur approximately \$336,000 in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs.

## **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 Interim Chief Executive Officer and Chief Financial Officer, has 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 Interim 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, 2024.

#### **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 accounting 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, 2024.

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, 2024 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**

During the fiscal year covered by this Annual Report, none of our directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any “non-Rule 10b5-1 trading arrangement” as such term is defined in Item 408(a) of Regulation S-K.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

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 2025 Proxy Statement, no later than January 28, 2025, and certain information to be included in the 2025 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 2025 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 of the Company”;
- If required, 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 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”.

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Business Conduct and Ethics is publicly available on our website under the Investors & Media section at [ir.outlooktherapeutics.com](http://ir.outlooktherapeutics.com). This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this Annual Report on Form 10-K. We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees and by us. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K.

### **Item 11. Executive Compensation**

The information required by this item is to be included in our 2025 Proxy Statement under the section entitled “Executive Compensation” and is incorporated herein by reference, provided that if the 2025 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 2025 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 2025 Proxy Statement under the section entitled “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference, provided that if the 2025 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 2025 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 2025 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 2025 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 2025 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.

## 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            | Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on May 15, 2024).  |
| 3.2            | 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#          | 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2024).   |
| 10.6#          | Form of Stock Option Grant Notice and Stock Option Agreement under the 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2024).                                  |
| 10.7#          | 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).   |
| 10.8#          | 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 Registrant's current report on Form 8-K filed with the SEC on July 9, 2021).               |
| 10.9#          | 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 Registrant's current report on Form 8-K filed with the SEC on June 7, 2022). |
| 10.10#         | 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 Registrant's current report on Form 8-K filed with the SEC on December 23, 2021).               |

| Exhibit Number | Description  |
|----------------|--|
| 10.11#         | Outlook Therapeutics, Inc. Non-Employee Director Compensation Policy, as amended and restated, effective as of October 1, 2024.  |
| 10.12#         | 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).  |
| 10.13†         | 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). |
| 10.14          | 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).   |
| 10.15          | 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).   |
| 10.16          | 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).  |
| 10.17          | 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).   |
| 10.18          | 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).   |
| 10.19          | 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 June 23, 2020).   |
| 10.20          | 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).  |
| 10.21**        | 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).  |
| 10.22          | 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).  |
| 10.23          | Amendment, dated February 10, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on February 14, 2023).                            |
| 10.24          | Amendment, dated December 21, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.30 to Registrant's annual report on Form 10-K filed with the SEC on December 22, 2023).                                  |
| 10.25          | Third Amendment, dated January 22, 2024, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.6 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024).                           |

| Exhibit Number | Description   |
|----------------|---|
| 10.26          | 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).  |
| 10.27          | At-the-market Sales Agreement between the Company and BTIG, LLC dated May 16, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 16, 2023).                                     |
| 10.28          | Form of Registration Rights Agreement, dated January 22, 2024, between the Company and the investors party thereto (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024). |
| 10.29          | Registration Rights Agreement, dated January 22, 2024, between the Company and Syntone (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024).                             |
| 10.30          | 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 January 24, 2024).   |
| 10.31          | Form of Syntone Common 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 January 24, 2024).   |
| 10.32          | Amendment, dated April 12, 2024, to Sales Agreement, dated May 16, 2023, by and between the Company and BTIG (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 12, 2024).         |
| 19.1           | Insider Trading Policy, as amended and restated.  |
| 21.1           | Subsidiaries of the Registrant.   |
| 23.1           | Consent of independent registered public accounting firm.   |
| 31.1           | Certification of Principal Executive Officer and 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.  |
| 97             | Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrant's annual report on Form 10-K filed with the SEC on December 22, 2023).  |
| 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 27, 2024

By: /s/ Lawrence A. Kenyon

Name: Lawrence A. Kenyon

Title: Chief Financial Officer and Interim 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.

|   |   |                   |
|---|---|-------------------|
| <u>/s/ Ralph H. Thurman</u><br>Ralph H. Thurman     | Executive Chairman  | December 27, 2024 |
| <u>/s/ Lawrence A. Kenyon</u><br>Lawrence A. Kenyon | Chief Financial Officer, Interim Chief<br>Executive Officer,<br>Treasurer, Secretary and Director<br>( <i>Principal Executive, Financial and<br/>Accounting Officer</i> ) | December 27, 2024 |
| <u>/s/ Yezan Haddadin</u><br>Yezan Haddadin         | Director  | December 27, 2024 |
| <u>/s/ Kurt J. Hilzinger</u><br>Kurt J. Hilzinger   | Director  | December 27, 2024 |
| <u>/s/ Julia A. Haller</u><br>Julia A. Haller       | Director  | December 27, 2024 |
| <u>/s/ Faisal G. Sukhtian</u><br>Faisal G. Sukhtian | Director  | December 27, 2024 |
| <u>/s/ Julian Gangolli</u><br>Julian Gangolli       | Director  | December 27, 2024 |
| <u>/s/ Gerd Auffarth</u><br>Gerd Auffarth           | Director  | December 27, 2024 |
| <u>/s/ Andong Huang</u><br>Andong Huang             | Director  | December 27, 2024 |

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2024

or

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

For the transition period from to

COMMISSION FILE NUMBER 001-37759

OUTLOOK THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of Incorporation)

38-3982704

(I.R.S. Employer Identification No.)

111 S. Wood Avenue, Unit #100  
Iselin, New Jersey

(Address of principal executive offices)

08830

(Zip Code)

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

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 that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

|                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                                     | Emerging growth company   | <input type="checkbox"/>            |

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

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

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

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

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of March 31, 2024 (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 \$180.4 million.

As of January 21, 2025, the registrant had outstanding 31,980,072 shares of common stock, par value \$0.01 per share.

Auditor Firm ID: 185

Auditor Name: KPMG LLP

Auditor Location: Philadelphia, Pennsylvania

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## EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A, or this Form 10-K/A, to the Annual Report on Form 10-K of Outlook Therapeutics, Inc., or Outlook Therapeutics, Outlook, the Company, we, us, our and similar references, for the fiscal year ended September 30, 2024, filed with the Securities and Exchange Commission, or the SEC, on December 27, 2024, or the Original Form 10-K, is being filed solely for the purpose of including the information required by Part III of Form 10-K. This information was previously omitted from the Original Form 10-K in reliance on General Instruction G(3) to Form 10-K, which permits the information in the above referenced items to be incorporated in the Form 10-K by reference from our definitive proxy statement if such statement is filed no later than 120 days after our fiscal year-end. We are filing this Form 10-K/A to include Part III information in our Form 10-K because we will not file a definitive proxy statement containing such information within 120 days after the end of the fiscal year covered by the Original Form 10-K. In addition, this Form 10-K/A deletes the reference on the cover of the Original Form 10-K to the incorporation by reference of portions of our proxy statement into Part III of the Original Form 10-K.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, this Form 10-K/A also contains certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which are attached hereto. Because no financial statements have been included in this Form 10-K/A and this Form 10-K/A does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4, and 5 of the certifications have been omitted, as required by Question 161.01 of the Compliance and Disclosure Interpretations of the Division of Corporation Finance of the SEC.

Except as described above, this Form 10-K/A does not modify or update disclosure in, or exhibits to, the Original Form 10-K. Furthermore, this Form 10-K/A does not change any previously reported financial results. Information not affected by this Form 10-K/A remains unchanged and reflects the disclosures made at the time the Original Form 10-K was filed.

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## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### Directors and Executive Officers

The following table sets forth information concerning our current executive officers and directors as of January 15, 2025. There are no family relationships among any of our directors or executive officers.

| NAME                          | AGE | POSITION HELD WITH THE COMPANY   |
|-------------------------------|-----|--|
| <b>Executive Officers</b>     |     |  |
| Lawrence A. Kenyon            | 59  | Interim Chief Executive Officer, Chief Financial Officer, Executive Vice President, Treasurer, Secretary, Director |
| Jeff Evanson                  | 56  | Chief Commercial Officer   |
| <b>Non-Employee Directors</b> |     |  |
| Ralph H. “Randy” Thurman      | 75  | Executive Chairman of the Board, Director  |
| Gerd Auffarth                 | 60  | Director   |
| Julian Gangolli               | 67  | Director   |
| Yezan Haddadin                | 49  | Director   |
| Julia A. Haller               | 70  | Director   |
| Kurt J. Hilzinger             | 64  | Director   |
| Andong Huang                  | 27  | Director   |
| Faisal G. Sukhtian            | 40  | Director   |

#### Executive Officers

**Lawrence A. Kenyon.** Mr. Kenyon has served as our Interim Chief Executive Officer since December 2024, a member of our Board since August 2018, as Chief Executive Officer and President from August 2018 to July 2021, as Interim Chief Executive Officer from June 2018 to August 2018, and as our Chief Financial Officer, Treasurer and Corporate Secretary since September 2015. Prior to that, from February 2014 to September 2015, Mr. Kenyon served as the Chief Financial Officer of Arno Therapeutics, Inc., a biopharmaceutical company focused on the development of therapeutics for cancer and other life-threatening diseases, and also as Chief Operating Officer from July 2014 to September 2015. From December 2011 to March 2013, Mr. Kenyon served as the Interim President & Chief Executive Officer, Chief Financial Officer and Secretary of Tamir Biotechnology, Inc., a publicly held biopharmaceutical company engaged in the development of oncology and anti-infective therapeutics. Prior to that, from December 2008 to July 2010, Mr. Kenyon was the Executive Vice President, Finance and, commencing in March 2009, the Chief Financial Officer of, Par Pharmaceutical Companies, Inc., a publicly held generic and branded specialty pharmaceutical company. Prior to March 2009, Mr. Kenyon was the Chief Financial Officer and Secretary of Alfacell Corporation, from January 2007 through February 2009 and also served at various times during this period as Alfacell’s Executive Vice President, Chief Operating Officer and President, and was a member of Alfacell’s board of directors from November 2007 to April 2009. Prior to joining Alfacell, Mr. Kenyon served as the Executive Vice President, Chief Financial Officer and Corporate Secretary at NeoPharm, Inc., a publicly traded biopharmaceutical company, from 2000 to 2006. Mr. Kenyon received a B.A. in Accounting from the University of Wisconsin — Whitewater and is a Certified Public Accountant in Illinois.

The Board believes Mr. Kenyon’s experience with the Company, combined with his experience in the biopharmaceutical industry, qualifies him to serve on the Board.

**Jeff Evanson.** Mr. Evanson has served as our Chief Commercial Officer since November 2018. Mr. Evanson has led Scott Three Consulting, LLC as Founder and President since April 2018, and from September 2014 through April 2018, served as a Managing Director in the Life Science Practice of Navigant. Prior to joining Navigant, Mr. Evanson was the Vice President and Global Commercial Head of the

Pharmaceutical Franchise at Alcon, a Novartis Company from April 2010 to September 2014. Mr. Evanson serves on the board of directors of Children's HeartLink and was formerly a two-term board member of Gillette Children's Hospital in St. Paul, Minnesota, from 2008 to 2014. Mr. Evanson received his M.B.A. from the University of Minnesota, and a B.A. in Chemistry from the University of St. Thomas in St. Paul Minnesota.

### **Non-Employee Directors**

**Ralph H. "Randy" Thurman.** Mr. Thurman has served as the Executive Chairman of the Board since June 2018 and has served as a member of the Board since April 2018. He also currently serves as a director of uMethod Inc, and as an Advisory Board Director for the Villanova Law School Scarpa Center for Law and Entrepreneurialism and is engaged as an independent advisor/operating executive in the private equity industry. Mr. Thurman was previously a member of the board of directors of Allscripts, Inc. and the Executive Chairman of Presbia PLC (an Orchard Capital Corporation company), a publicly-traded medical device company. From 2008 to 2011, Mr. Thurman served as Executive Chairman of CardioNet Inc. (now known as BioTelemetry, Inc.), and as its interim Chief Executive Officer from 2008 until 2010. From 2001 until 2007, Mr. Thurman was Founder, Chairman and Chief Executive Officer of VIASYS Healthcare Inc., a diversified healthcare technology company, which was acquired by Cardinal Healthcare Inc. in 2007. Mr. Thurman served as a consultant to Cardinal Healthcare Inc. from the date of acquisition until 2008. From 1997 until 2001, Mr. Thurman served as Chairman and Chief Executive Officer of Strategic Reserves LLC, which provided advisory services to biopharmaceutical, genomic and medical device companies. From 1993 until 1997, Mr. Thurman was Chairman and Chief Executive Officer of Corning Life Sciences, Inc., and from 1984 until 1993, Mr. Thurman held various positions at Rhone-Poulenc Rorer Pharmaceuticals, Inc., a global pharmaceutical company, ultimately as its President. Mr. Thurman served as a fighter pilot in the United States Air Force, is a member of the Distinguished Flying Cross Society of America and graduated from the USAF Air Command and Staff College. Mr. Thurman holds a B.S. in Economics from Virginia Polytechnic Institute and an M.A. in Management from Webster University.

The Board believes Mr. Thurman's expertise in corporate governance, operating and investing as well as extensive expertise in the healthcare industry qualify him to serve on the Board.

**Gerd Auffarth, M.D.** Prof. Dr. Auffarth has served as a member of the Board since April 2020. Prof. Dr. Auffarth is an internationally recognized ophthalmologist in the area of research and development as well as clinical care for patients. He currently serves as the Medical Director of Heidelberg University Eye Clinic. Prior to his appointment as Medical Director in 2011, he worked as a senior physician at the University Eye Clinic. He currently serves as the Director of the International Vision Correction Research Center (IVCRC) and the David J. Apple Laboratory for Ocular Pathology. He is a board member of the German and the European Society for Cataract and Refractive Surgery. In 2004 he was appointed Vice Chairman and Deputy Director of the Heidelberg Department of Ophthalmology; he was awarded Extraordinary Professorship in the Medical Faculty of the University of Heidelberg in May 2005. Prof. Dr. Auffarth holds an M.D. from RWTH Aachen University and a Ph.D. in Ocular Pathology from the Ruprecht-Karls University of Heidelberg.

The Board believes Prof. Dr. Auffarth's experience and expertise in ophthalmology qualify him to serve on the Board.

**Julian Gangolli.** Mr. Gangolli has served as a member of the Board since April 2020. From May 2015 to April 2019, he served as President, North America of GW Pharmaceuticals Inc., and President of Greenwich Biosciences, Inc., the U.S. subsidiary of GW Pharmaceuticals Inc., where he was responsible for building out the U.S. commercial infrastructure. Mr. Gangolli also served as a member of the board of directors of GW Pharmaceuticals Inc. from July 2015 to March 2017. Prior to joining GW Pharmaceuticals Inc., Mr. Gangolli served as President of the North American Pharmaceutical division of Allergan Inc. for 11 years. Prior to that, he served as Senior Vice President, U.S. Eye Care at Allergan Inc. Prior to Allergan Inc., Mr. Gangolli served in sales and marketing positions at VIVUS, Inc., Syntex Pharmaceuticals, Inc., and Ortho-Cilag Pharmaceuticals Ltd in the United Kingdom. Mr. Gangolli currently serves as a member of the board of directors of Krystal Biotech, Inc. and Revance Therapeutics. Mr. Gangolli holds a B.S. in Applied Chemistry from Kingston University.

The Board believes that Mr. Gangolli's operating experience in the biopharmaceutical industry, experience at multiple public pharmaceutical companies and his expertise in the development and commercialization of specialty pharmaceutical products qualify him to serve on the Board.

**Yezan Haddadin.** Mr. Haddadin has served as a member of the Board since October 2017. Since July 2017, Mr. Haddadin has served as chief executive officer of GMS Capital Partners LLC, an investment company focused on making direct private equity investments in North America. GMS Capital Partners LLC is a subsidiary of GMS Holdings. From 2014 to 2017, Mr. Haddadin served as the Chief Executive Officer and a member of the board of directors of a regional investment bank based in Amman, Jordan and Dubai, United Arab Emirates. From 2013 to 2014, Mr. Haddadin served as an Advisor at Ripplewood Holdings LLC, a New York-based private equity firm. Mr. Haddadin also served as a Managing Director at Perella Weinberg Partners in New York from 2007 to 2013 and an Executive Director with J.P. Morgan in its mergers and acquisitions group from 2000 to 2007. Mr. Haddadin is member of the board of directors of Jordan Ahli Bank. Mr. Haddadin previously served as a member of the board of directors at Sixth of October Development & Investment Company, a publicly listed Egyptian real estate development company. Mr. Haddadin holds a J.D. from Northwestern University Law School and a B.S. in Foreign Service from Georgetown University. Mr. Haddadin is designated to the Board by GMS Ventures & Investments, or GMS Ventures, pursuant to the Amended and Restated Investor Rights Agreement by and between the Company and GMS Ventures dated April 21, 2022.

The Board believes Mr. Haddadin's managerial and capital raising experience qualifies him to serve on the Board.

**Julia A. Haller, M.D.** Dr. Haller has served as a member of the Board since August 2022. Dr. Haller has served as the Ophthalmologist-in-Chief of Wills Eye Hospital since November 2007, where she holds the William Tasman, M.D. Endowed Chair and is Professor and Chair of the Department of Ophthalmology at Sidney Kimmel Medical College at Thomas Jefferson University and Thomas Jefferson University Hospitals. Prior to her current positions, Dr. Haller trained at the Wilmer Eye Institute at Johns Hopkins where she served as the first female Chief Resident. She then joined the Johns Hopkins faculty where she directed the retina fellowship program and held the Katharine Graham Chair in Ophthalmology. Dr. Haller currently serves on the board of directors at Bristol Myers Squibb Co. and Opthea Limited and previously served on the board of directors at Eyenovia, Inc. and Celgene. Dr. Haller currently serves on the board of The Philadelphia Orchestra Association, is vice chair of the Board of Trustees of The College of Physicians of Philadelphia, chairs the Heed Ophthalmic Foundation, and is president of the council for the Johns Hopkins Medicine Alumni Association. Dr. Haller received a A.B. in Philosophy from Princeton University and her M.D. from Harvard University Medical School.

The Board believes Dr. Haller's experience in ophthalmology, as well as her service on the board of directors for companies in the life sciences industry, qualify her to serve on the Board.

**Kurt J. Hilzinger.** Mr. Hilzinger has served as a member of the Board since December 2015. Since 2007, Mr. Hilzinger has served as a partner at Court Square Capital Partners L.P., an independent private equity firm, where he is responsible for investing in the healthcare sector. Since July 2003, Mr. Hilzinger also has served in various capacities as a member of the board of directors at Humana, Inc., a managed care company, including serving as Lead Director from August 2010 to January 2014, and as Chairman since January 2014. In addition, Mr. Hilzinger also has served in several roles at Cencora, Inc. (formerly AmerisourceBergen Corporation), a healthcare company, including as a member of the board of directors from March 2004 to November 2007, as the President and Chief Operating Officer from October 2002 to November 2007 and as the Executive Vice President and Chief Operating Officer from August 2001 to October 2002. Mr. Hilzinger also serves on the Visiting Committee at the Ross School of Business at the University of Michigan. Mr. Hilzinger received a B.B.A. in Accounting from the University of Michigan and is a Certified Public Accountant in Michigan.

The Board believes Mr. Hilzinger's experience and financial expertise in the healthcare sector qualify him to serve on our Board.

**Andong Huang.** Mr. Huang has served as a member of the Board since June 2020. Mr. Huang has been Vice President, Business Development for Syntone Technologies Group (China) since 2017, focusing

on strategic partnerships and international business relationships. Mr. Huang received his Honours Bachelor of Arts from the University of Toronto with majors in Economics and East Asian Studies and is fluent in Mandarin Chinese and English. Mr. Huang was initially appointed to the Board by Syntone Ventures LLC pursuant to the Stock Purchase Agreement by and between the Company and Syntone Ventures LLC, dated May 22, 2020.

The Board believes Mr. Huang's industry experience and relationship with a significant investor qualify him to serve on the Board.

**Faisal G. Sukhtian.** Mr. Sukhtian has served as a member of the Board since September 2017. Mr. Sukhtian is the Executive Director at GMS Holdings, a privately owned diversified investment company. Mr. Sukhtian oversees a number of investments within the GMS Holdings portfolio and has served as a director on the company's board since 2008. Mr. Sukhtian has extensive experience in operations, strategy development and mergers and acquisitions in the biopharma and life sciences space. He has been the chairman of the board of Genepharma, a leading European B2B pharmaceutical company, since 2019. Mr. Sukhtian served as a member of the board of MS Pharma, a leading regional pharmaceutical company focused on the MENA region, since 2011. Mr. Sukhtian has served as Vice Chairman of the board of Agri Sciences, an international crop protection company headquartered in Jordan, since 2010. Mr. Sukhtian previously served on the boards of Stelis Biopharma, a biotech company based in India, from 2015 to 2021, as well as Alvogen, a global generics company, from 2008 to 2014. From 2008 to 2011, Mr. Sukhtian served as Executive Director of Munir Sukhtian International. Mr. Sukhtian has served as a member of the board of directors of Expert Petroleum, an oilfield services company based in Romania, since 2008, and Waterloo Industries, Inc., a manufacturer of tool storage based in the United States, from 2015 to 2017. Prior to joining GMS Holdings, Mr. Sukhtian worked at J.P. Morgan, in New York, where he worked primarily on mergers and acquisitions, debt and equity transactions serving clients in the industrials and transportation industries. Mr. Sukhtian received an M.B.A. from Columbia Business School and a B.S. in International Economics from Georgetown University's School of Foreign Service. Mr. Sukhtian is designated to the Board by GMS Ventures pursuant to the Amended and Restated Investor Rights Agreement by and between the Company and GMS Ventures dated April 21, 2022.

The Board believes Mr. Sukhtian's managerial and pharmaceutical industry experience qualifies him to serve on the Board.

### **Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Business Conduct and Ethics is publicly available on our website under the Investors & Media section at [ir.outlooktherapeutics.com](http://ir.outlooktherapeutics.com). This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this Form 10-K/A. We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

### **Insider Trading Policy**

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees and by us. A copy of the Insider Trading Policy is filed as an exhibit to this Form 10-K/A.

## Audit Committee Members and Financial Expert

The Audit Committee of the Board, or the Audit Committee, was established by the Board to oversee our corporate accounting and financial reporting processes and audits of our financial statements. The Audit Committee is currently composed of three directors: Mr. Gangolli, Mr. Thurman and Mr. Hilzinger, with Mr. Hilzinger serving as Chair. The Audit Committee met four times during the fiscal year. The Board has adopted a written Audit Committee charter that is available to stockholders on our website at <https://ir.outlooktherapeutics.com/corporate-governance/governance-highlights>. Information contained on, or that can be accessed through, our website is not incorporated by reference into and does not form a part of this Form 10-K/A.

The Board reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards). The Board has determined that each of the members of the Audit Committee satisfies the independence requirements under Rule 10A-3(b)(1) of the Exchange Act. The Board has also determined that Mr. Hilzinger qualifies as an “audit committee financial expert,” as defined in applicable SEC rules.

## ITEM 11. EXECUTIVE COMPENSATION

### Executive Compensation

For the year ended September 30, 2024, our named executive officers are:

- Lawrence A. Kenyon, our Chief Financial Officer and Interim Chief Executive Officer;
- Jeff Evanson, our Chief Commercial Officer; and
- C. Russell Trenary III, our former President and Chief Executive Officer.

As previously disclosed, on December 3, 2024, Mr. Trenary stepped down as President and Chief Executive Officer of the Company and as a member of the Board, and Mr. Kenyon was appointed to serve as Interim Chief Executive Officer. Mr. Kenyon also continues to serve as Chief Financial Officer of the Company.

### Summary Compensation Table

The following table sets forth the information as to compensation awarded to, paid to or earned by our named executive officers. We did not pay any non-equity incentive plan compensation or have any non-qualified deferred compensation earnings and have omitted those columns from the table. On March 14, 2024, we effected a reverse stock split, or the Reverse Split. All equity-related information presented in the footnotes below gives retroactive effect to the Reverse Split.

| Name and Principal Position                                    | Year | Salary<br>(\$) | Bonus<br>(\$) | Option<br>Awards<br>(\$) <sup>(1)</sup> | All Other<br>Compensation<br>(\$) <sup>(2)</sup> | Total<br>(\$) |
|--|------|----------------|---------------|---|--|---------------|
| Lawrence A. Kenyon <sup>(3)</sup> . . . . .                    | 2024 | 475,000        | —             | 158,427                                 | 1,170  | 634,597       |
| Chief Financial Officer and Interim Chief<br>Executive Officer |      |                |               |   |  |               |
| Jeff Evanson . . . . .   | 2024 | 450,000        | —             | 316,859                                 | 1,170  | 768,029       |
| Chief Commercial Officer                                       | 2023 | 450,000        | —             | 267,025                                 | 1,170  | 718,195       |
| C. Russell Trenary III <sup>(4)</sup> . . . . .                | 2024 | 600,000        | —             | 5,766,842                               | 11,111   | 6,377,953     |
| Former President and Chief Executive Officer                   | 2023 | 600,000        | —             | 1,147,963                               | 10,899   | 1,758,862     |

- (1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock option awards granted computed in accordance with ASC 718, for stock-based compensation transactions. These amounts do not reflect the actual economic value that would be realized by the named executive officer upon the exercise of the stock options. For a discussion of the assumptions used

in determining the fair value of stock option awards in the above table and other additional information on the stock options granted, refer to Note 11 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K filed with the SEC on December 27, 2024.

- (2) Amounts in this column consist of the payment of term life insurance premiums, along with 401(k) matching contributions, where applicable. These benefits are provided to the named executive officers on the same terms as provided to all of our regular full-time employees.
- (3) Mr. Kenyon was not a named executive officer in 2023 and thus, only 2024 compensation information is shown for him in this table. Mr. Kenyon commenced service as Interim Chief Executive Officer on December 3, 2024 and has continued to serve as Chief Financial Officer thereafter.
- (4) Mr. Trenary ceased serving as President and Chief Executive Officer on December 3, 2024.

## **Narrative to Summary Compensation Table**

### ***Retirement Benefits***

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax, after-tax, or Roth basis, up to the statutorily prescribed annual limits on contributions under the Internal Revenue Code of 1986, as amended, or the Code. We may make matching contributions for the plan year ending December 31, based on employee deferrals for the plan year, in an amount equal to up to 3% of compensation deferred. For the 2023 plan year, we made company matching contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

### ***Agreements with our Named Executive Officers***

Below are written descriptions of our compensation arrangements with our named executive officers. All equity-related information presented in this narrative gives retroactive effect to the Reverse Split.

**Mr. Kenyon.** On June 2, 2022, we entered into an amended and restated executive employment agreement with Mr. Kenyon providing for, among other things, Mr. Kenyon's employment as Executive Vice President and Chief Financial Officer of the Company for a term of 12 months. Mr. Kenyon receives a base salary of \$475,000, as well as an annual cash bonus with a target amount equal to 50% of his base salary, which is payable if the Company meets or exceeds certain financial and other business milestone objectives as determined and approved by the board of directors and the Chief Executive Officer of the Company. Under his employment agreement, Mr. Kenyon is entitled to certain severance and change in control benefits, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

**Mr. Evanson.** On December 21, 2021, we entered into an employment agreement with Mr. Evanson. Pursuant to his employment agreement, Mr. Evanson receives a base salary of \$450,000 and a discretionary annual cash bonus with a target amount equal to 50% of his base salary. In connection with his entry into the employment agreement, Mr. Evanson received an option to purchase 40,000 shares of common stock, one quarter of which vested on the first anniversary of the date of grant and the remainder of which vests in monthly installments over the succeeding three years, subject to his continued service through each vesting date. Under his employment agreement, Mr. Evanson is entitled to certain severance and change in control benefits, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

**Mr. Trenary.** In July 2021, in connection with his appointment as President and Chief Executive Officer of the Company, we entered into an employment agreement with Mr. Trenary providing for, among other things, an initial base salary of \$600,000 and a discretionary annual cash bonus with a target amount equal to 70% of his base salary. Mr. Trenary received an initial option to purchase 200,000 shares of common stock, one quarter of which vested on the first anniversary of the date of grant and the remainder of

which was subject to vesting in monthly installments over the next three years, subject to Mr. Trenary's continued service through each vesting date. In fiscal year 2024, Mr. Trenary was entitled to certain severance and change in control benefits pursuant to his employment agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

### **Potential Payments Upon Termination or Change of Control**

Regardless of the manner in which the service of one of our named executive officers terminates, each is generally entitled to receive amounts earned during his term of service, including salary and unused vacation pay. The terms of each named executive officer's potential payments upon termination or change of control are summarized below. In addition, in June 2022, our Compensation Committee approved an extension of the post-termination exercise period applicable to each outstanding stock option held by our executive officers (and our non-employee directors), such that upon a termination of employment for any reason, other than for cause or due to death or disability, each option held by an executive officer will remain exercisable through the end of the term of such option, typically 10 years from the date of grant (referred to in this disclosure as the "PTEP Extension Policy").

**Mr. Kenyon.** Pursuant to Mr. Kenyon's current executive employment agreement, if he is terminated without cause or if he resigns for good reason, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the Company's proprietary information, inventions, non-competition and non-solicitation agreement, or PIIA, he is entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then unvested time-vesting equity awards, and reimbursement of expenses owed to him through the date of his termination.

If Mr. Kenyon's employment is terminated by us or any successor entity (provided such successor entity either assumes Mr. Kenyon's equity awards or substitutes similar equity awards) without cause or if he resigns for good reason within two months prior to or within 12 months following a change in control (as defined in the Company's 2024 Equity Incentive Plan (formerly known as the 2015 Equity Incentive Plan), or the 2024 Plan), subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he is entitled to continued payment of his base salary for 18 months, 150% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 18 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, (i) if the termination occurs within six months prior to a change in control, 100% of Mr. Kenyon's then-unvested time-vesting equity awards shall become fully vested as of the date of his termination, and (ii) if the termination occurs within 12 months following a change in control and the outstanding time-vesting equity awards are assumed or substituted with similar equity awards by the acquiring company, 100% of Mr. Kenyon's then-unvested time-vesting equity awards shall become fully vested as of the date of termination.

For purposes of Mr. Kenyon's employment agreement:

- "Cause" for termination means that the Company has determined in its sole discretion that Mr. Kenyon has engaged in any of the following: (i) a material breach of any covenant or condition under his employment agreement or any other agreement between Mr. Kenyon and the Company; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) material violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of the Company; (vi) negligence or incompetence in the performance of his duties or failure to perform such duties in a manner satisfactory to the Company after the expiration of 10 days without cure after written notice of such failure; or (vii) breach of fiduciary duty.
- "Good reason" means the occurrence of any of the following events without Mr. Kenyon's consent: (i) a material reduction in his base salary of at least 25%; (ii) a material breach of the employment agreement by us; (iii) a material reduction in Mr. Kenyon's duties, authority and responsibilities relative to his duties, authority, and responsibilities in effect immediately prior to such reduction; or

(iv) the relocation of Mr. Kenyon's principal place of employment in a manner that lengthens his one-way commute distance by 50 or more miles from his then-current principal place of employment immediately prior to such relocation; provided, however, that none of the events described in this sentence will constitute good reason unless and until (x) Mr. Kenyon first notifies us in writing describing in reasonable detail the condition(s) that constitutes good reason within 30 days of its occurrence, (y) we fail to cure the condition(s) within 30 days after our receipt of written notice, and (z) Mr. Kenyon voluntarily terminates his employment within 30 days after the end of 30-day cure period.

**Mr. Evanson.** Pursuant to Mr. Evanson's current executive employment agreement, if he is terminated without cause or if he resigns for good reason, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the Company's PIIA, he is entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then-unvested time-vesting equity awards, and reimbursement of expenses owed to him through the date of his termination.

If Mr. Evanson's employment is terminated by us or any successor entity without cause or if Mr. Evanson terminates his employment for good reason within two months prior to or within 12 months following a change in control, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he would be entitled to receive an amount equal to 12 months of his base salary plus a bonus equal to 150% of his full target amount and employee benefit coverage for up to 12 months. Additionally, (i) if the termination occurs within six months prior to a change in control, 100% of Mr. Evanson's then-unvested time-vesting equity awards shall become fully vested as of the date of his termination, and (ii) if the termination occurs within 12 months following a change in control and the outstanding time-vesting equity awards are assumed or substituted with similar equity awards by the acquiring company, 100% of Mr. Evanson's then-unvested time-vesting equity awards would have become fully vested as of the date of termination.

For purposes of Mr. Evanson's employment agreement:

- "Cause" is generally as defined above with respect to Mr. Kenyon's employment agreement.
- "Good reason" generally means the occurrence of any of the following events without Mr. Evanson's consent: (i) a material reduction in Mr. Evanson's base salary of at least 25%; (ii) a material breach of the employment agreement by the Company; (iii) a material reduction in Mr. Evanson's duties, authority and responsibilities relative to Mr. Evanson's duties, authority, and responsibilities in effect immediately prior to such reduction; or (iv) the relocation of Mr. Evanson's principal place of employment in a manner that lengthens his one-way commute distance by 50 or more miles from his then-current principal place of employment immediately prior to such relocation, not to include Mr. Evanson's initial relocation to a new headquarters to be established at the direction of the board of directors; provided, however, that none of the events described in this sentence will constitute good reason unless and until (x) Mr. Evanson first notifies us in writing describing in reasonable detail the condition(s) that constitutes good reason within 30 days of its occurrence, (y) we fail to cure the condition(s) within 30 days after our receipt of written notice, and (z) Mr. Evanson voluntarily terminates his employment within 30 days after the end of 30-day cure period.

**Mr. Trenary.** Pursuant to Mr. Trenary's executive employment agreement that was in effect in fiscal year 2024, if he had been terminated without cause or if he resigned for good reason, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he would have been entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then-unvested time-vesting equity awards, and reimbursement of expenses owed to him through the date of his termination.

If Mr. Trenary's employment had been terminated by us or any successor entity without cause or if he resigned for good reason within two months prior to or within 12 months following a change in control (as defined in the 2024 Plan), subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he would have been entitled to continued payment of his base salary for 18 months, 150% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 18 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, (i) if the termination had occurred within two months prior to a change in control, 100% of Mr. Trenary's then-unvested time-vesting equity awards would have become fully vested as of the date of his termination, and (ii) if the termination had occurred within 12 months following a change in control and the outstanding time-vesting equity awards had been assumed or substituted with similar equity awards by the acquiring company, 100% of Mr. Trenary's then-unvested time-vesting equity awards would have become fully vested as of the date of termination.

For purposes of Mr. Trenary's employment agreement:

- "Cause" is generally as defined above with respect to Mr. Kenyon's employment agreement.
- "Good reason" is generally as defined above with respect to Mr. Kenyon's employment agreement.

As noted above, on December 3, 2024, Mr. Trenary stepped down as President and Chief Executive Officer of the Company and as a member of the Board. Mr. Trenary's departure constituted a termination without cause for purposes of his employment agreement. In consideration of his execution of a separation agreement and release of claims, Mr. Trenary received the severance benefits described above for a termination without cause not in connection with a change in control. In addition, the outstanding options held by Mr. Trenary at his departure remain exercisable through the end of the term of such options (typically 10 years from the date of grant) pursuant to the PTEP Extension Policy described above.

### Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information regarding equity awards granted to our named executive officers that remain outstanding as of September 30, 2024. Pursuant to the Reverse Split, every twenty shares of our issued and outstanding common stock were automatically combined into one issued share of common stock, with corresponding adjustments to all issued and outstanding options. All equity-related information presented in the table below gives retroactive effect to Reverse Split.

| Name                         | Grant date | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Option awards <sup>(1)</sup>   |                            |                        |
|------------------------------|------------|---|---|--|----------------------------|------------------------|
|                              |            |   |   | Equity incentive plan awards: Number of securities underlying unexercised unearned options (#) | Option exercise price (\$) | Option expiration date |
| Lawrence A. Kenyon . . . . . | 8/1/2018   | 3,125   | — <sup>(2)</sup>  | —  | 137.60                     | 8/1/2028               |
|                              | 2/19/2019  | 5,000   | — <sup>(2)</sup>  | —  | 211.20                     | 2/19/2029              |
|                              | 9/12/2019  | 22,500  | — <sup>(2)</sup>  | —  | 35.00                      | 9/12/2029              |
|                              | 3/19/2020  | 10,821  | — <sup>(2)</sup>  | —  | 10.80                      | 3/19/2030              |
|                              | 7/17/2020  | 22,500  | — <sup>(2)</sup>  | —  | 31.60                      | 7/17/2030              |
|                              | 10/1/2020  | 137,586   | 45,863 <sup>(2)</sup>   | —  | 14.20                      | 10/1/2030              |
|                              | 3/20/2024  | —   | 12,500 <sup>(3)</sup>   | —  | 6.78                       | 3/20/2034              |
|                              | 3/20/2024  | —   | —   | 12,500 <sup>(4)</sup>  | 6.78                       | 3/20/2034              |

| Name                             | Grant date | Option awards <sup>(1)</sup>  |   |  |                            |                        |
|----------------------------------|------------|---|---|--|----------------------------|------------------------|
|                                  |            | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Equity incentive plan awards: Number of securities underlying unexercised unearned options (#) | Option exercise price (\$) | Option expiration date |
| Jeff Evanson. . . . .            | 12/21/2021 | 27,500  | 12,500  | —  | 28.80                      | 12/21/2031             |
|                                  | 12/21/2021 | 5,000   | — <sup>(3)</sup>  | —  | 28.80                      | 12/21/2031             |
|                                  | 4/17/2023  | 3,402   | 6,205 <sup>(3)</sup>  | —  | 21.60                      | 4/17/2033              |
|                                  | 3/20/2024  | —   | 25,000 <sup>(3)</sup>   | —  | 6.78                       | 3/20/2034              |
|                                  | 3/20/2024  | —   | —   | 25,000 <sup>(4)</sup>  | 6.78                       | 3/20/2034              |
| C. Russell Trenary III . . . . . | 7/6/2021   | 158,331   | 41,669 <sup>(3)</sup>   | —  | 48.40                      | 7/6/2031               |
|                                  | 12/21/2021 | 25,000  | —   | —  | 28.80                      | 12/21/2031             |
|                                  | 4/17/2023  | 4,553   | 8,304 <sup>(3)</sup>  | —  | 21.60                      | 4/17/2033              |
|                                  | 3/20/2024  | —   | 455,000 <sup>(3)</sup>  | —  | 6.78                       | 3/20/2034              |
|                                  | 3/20/2024  | —   | —   | 455,000 <sup>(4)</sup>   | 6.78                       | 3/20/2034              |

- (1) The outstanding equity awards as of September 30, 2024 are stock options that were granted under and subject to the terms of the 2024 Plan. Except as otherwise indicated, each stock option is subject to vesting, subject to the executive's continuous service with us through the vesting dates (or satisfaction of the vesting conditions) and the potential vesting acceleration of the time-based vesting conditions upon a change in control and certain terminations of employment.
- (2) The shares underlying each option vested or will vest annually in four equal installments starting from the applicable grant date, subject to continuous service with the Company on each such date. The option is also subject to acceleration under certain circumstances.
- (3) Twenty-five percent of the shares subject to the option vested or will vest on the first anniversary of the grant date, with the remaining shares vesting in equal monthly installments over the following three years thereafter, subject to continuous service with the Company on each such date. The option is also subject to acceleration under certain circumstances.
- (4) Shares subject to the option will vest 25% upon the Company's achievement of a specified milestone and the remainder in equal monthly installments over the three years following achievement of the milestone, subject to the individual's continued employment with the Company at each applicable vesting date.

### ***March 2024 Option Awards***

On March 20, 2024, the Board awarded options to purchase common stock pursuant to the 2024 Plan to each of: Mr. Kenyon (12,500 options), Mr. Evanson (50,000 options) and Mr. Trenary (910,000 options). Half of each individual's award comprised time-based options, which vest as follows: 25% of the shares subject to the option vest on March 20, 2025, with the remaining shares vesting in equal monthly installments over the following three years thereafter, subject to the individual's continued employment with the Company at each vesting date. The remaining half of each individual's award comprised performance-based options, which will vest 25% upon the Company's achievement of a specified milestone and the remainder in equal monthly installments over the three years following achievement of the milestone, subject to the individual's continued employment with the Company at each applicable vesting date.

### **Clawback Policy**

The SEC adopted final rules implementing the incentive-based compensation recovery provisions of the Dodd-Frank Act, and Nasdaq has adopted listing standards consistent with the SEC rules. In compliance with those standards, we have adopted an incentive compensation recoupment policy, or "clawback"

policy, which applies to our executive officers, within the meaning of Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, who were employed by the Company or a subsidiary of the Company during the applicable recovery period. Under the policy, in the event that the financial results upon which a cash or equity-based incentive award was predicated become the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate payout gives retroactive effect to the financial results as restated. The policy covers any cash or equity-based incentive compensation award that was paid, earned or granted to a covered officer during the last completed three fiscal years immediately preceding the date on which the Company is required to prepare the accounting restatement.

## **Policies and Practices Related to the Grant of Certain Equity Awards**

From time to time, the Company awards stock options to its employees, including the named executive officers. Historically, the Company has awarded new-hire option grants on or soon after a new hire's employment start date and periodic annual refresh employee option grants, which refresh grants are typically approved at a meeting of the Compensation Committee. Non-employee directors receive automatic initial and annual stock option grants, at the time of a director's appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, and, at their election, may receive automatic option grants in lieu of annual cash compensation. For additional information on our non-employee director compensation policy see below under the heading, "Director Compensation — Non-Employee Director Compensation Policy." Starting in fiscal year 2025, annual director option grants are made automatically on the first day of the fiscal year. The Company does not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. The Compensation Committee considers whether there is any material nonpublic information ("MNPI") about the Company when determining the timing and terms of stock option awards and generally does not time the grant of stock options in relation to the Company's public disclosure of MNPI. The Company has not timed the release of MNPI for the purpose of affecting the value of executive compensation.

## **Director Compensation**

The following table sets forth information concerning the compensation earned for service on the Board during the year ended September 30, 2024. Mr. Kenyon's and Mr. Trenary's respective compensation as named executive officers is set forth under "— Summary Compensation Table." Mr. Kenyon and Mr. Trenary did not receive any additional compensation for service as a director. None of our directors earned any compensation other than cash fees or stock option awards under the 2024 Plan during the fiscal year ended September 30, 2024. Accordingly, we have omitted all other columns from the table below. All equity-related information presented in the footnotes below gives retroactive effect to the Reverse Split.

| <b>Name</b>                  | <b>Fees Earned or Paid in Cash<sup>(1)</sup><br/>(\$)</b> | <b>Option Awards<sup>(2)(3)</sup><br/>(\$)</b> | <b>Total<br/>(\$)</b> |
|------------------------------|---|--|-----------------------|
| Randy Thurman . . . . .      | 207,500   | 35,000   | 242,500               |
| Gerd Auffarth . . . . .      | 44,000  | 35,000   | 79,000                |
| Julian Gangolli . . . . .    | 77,500  | 35,000   | 112,500               |
| Yezan Haddadin . . . . .     | 75,000  | 35,000   | 110,000               |
| Julia A. Haller . . . . .    | 44,000  | 35,000   | 79,000                |
| Kurt Hilzinger . . . . .     | 60,000  | 35,000   | 95,000                |
| Andong Huang . . . . .       | 40,000  | 35,000   | 75,000                |
| Faisal G. Sukhtian . . . . . | 78,000  | 35,000   | 113,000               |

- (1) All non-employee directors, except Randy Thurman, elected to receive annual cash fees pursuant to our non-employee director compensation policy as in effect during fiscal 2024 in the form of stock options. See discussion below under "— Non-Employee Director Compensation Policy" for cash

retainers, as well as discussion of stock options in lieu of fees below under “— Non-Employee Director Compensation Policy — Option Awards in Lieu of Cash Fees.”

- (2) Reflects the aggregate grant date fair value of the stock option awards granted computed in accordance with ASC 718, for stock-based compensation transactions. These amounts do not reflect the actual economic value that would be realized by the director upon exercise of the stock options. For a discussion of the assumptions used in determining the fair value of awards of stock options in the above table and other additional information on stock options granted, refer to Note 11 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K filed with the SEC on December 27, 2024. Amounts exclude stock options granted in lieu of cash fees in addition to annual grants. See discussion of stock options in lieu of cash fees below under “— Non-Employee Director Compensation Policy — Option Awards in Lieu of Cash Fees.”
- (3) As of September 30, 2024, the following non-employee directors held options to purchase the following number of shares of our common stock: Randy Thurman (214,899), Gerd Auffarth (133,778), Julian Gangolli (177,959), Yezan Haddadin (276,590), Julia Haller (136,597), Kurt Hilzinger (241,522), Andong Huang (124,619) and Faisal Sukhtian (279,352).

### **Non-Employee Director Compensation Policy**

We have adopted a non-employee director compensation policy, pursuant to which our non-employee directors are eligible to receive compensation for service on the Board and committees of the Board.

For the year ended September 30, 2024, each non-employee director received the compensation described below. All equity-related information presented in the narrative below gives retroactive effect to the Reverse Split.

#### ***Equity Compensation***

##### ***Initial Grant***

Each new non-employee director who joins the Board is granted a non-statutory stock option to purchase 25,000 shares of common stock under the 2024 Plan, which options vest annually over the three years from the grant date, subject to continued service as a director through the applicable vesting date.

##### ***Annual Grant***

On the date of each annual meeting of our stockholders, each non-employee director also receives an annual non-statutory stock option grant under the 2024 Plan with respect to a number of shares of our common stock having an aggregate “fair value” of \$35,000 as of the annual meeting date, determined using a Black-Scholes or binominal valuation model regularly used by us on the grant date. These options vest on the earlier of the first anniversary of the grant date or the date of the next annual meeting of our stockholders, subject to continued service as a director through the applicable vesting date.

Pursuant to our PTEP Extension Policy, upon a termination of service for any reason other than for cause or due to death or disability, each outstanding stock option held by a non-employee director will remain exercisable through the end of the term of such option, typically 10 years from the date of grant.

#### ***Cash Compensation***

Each non-employee director receives an annual cash retainer of \$40,000 for serving on the Board. The chairperson of the Board also receives an additional annual cash retainer of \$30,000. In the event that the chairperson is an employee and the Board appoints a Lead Independent Director, that person will receive the additional annual cash retainer otherwise payable to the chairperson.

In addition, as Executive Chairman, Mr. Thurman is entitled to an additional annual retainer of \$120,000 payable in equal monthly installments.

The chairperson and members of the four standing committees of the Board are generally entitled to the following annual cash retainers:

| Board Committee   | Chairperson Fee | Member Fee |
|---|-----------------|------------|
| Audit Committee . . . . .                               | \$15,000        | \$ 7,500   |
| Compensation Committee . . . . .                        | 10,000          | 5,000      |
| Nominating and Corporate Governance Committee . . . . . | 8,000           | 4,000      |
| Executive Committee . . . . .                           | —               | 30,000     |

All annual cash compensation amounts are payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, pro-rated based on the days served in the applicable fiscal quarter. As discussed below under “— Option Awards in Lieu of Cash Fees,” with respect to the 2024 fiscal year, Messrs. Gangolli, Haddadin, Hilzinger, Huang and Sukhtian, and Prof. Dr. Auffarth and Dr. Haller elected to receive a one-time equity grant in lieu of cash fees.

### ***Option Awards in Lieu of Cash Fees***

Under the non-employee director compensation policy, for the 2024 fiscal year, each non-employee director had the option to elect to receive either 50% or all annual cash compensation in the form of stock options granted pursuant to the 2024 Plan. This election must be made prior to the beginning for the applicable fiscal year, and each non-employee director must submit a new election for each fiscal year. If a non-employee director elects to receive compensation in the form of stock options, such stock options are automatically be granted on the third business day in October of such fiscal year and 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 the non-employee director is in service as a director on the first day of the fiscal quarter of the applicable scheduled vesting date. Non-employee directors who join the Board mid-fiscal year must make their elections within 30 days following commencement of service, and options are automatically granted on the first day of the fiscal quarter following such election.

In accordance with such election in the fiscal year 2024, our non-employee directors were granted the following option awards. All equity-related information presented in the table below gives retroactive effect to Reverse Split:

| Name                      | Grant date | Option awards             |                            |                            |                        |
|---------------------------|------------|---------------------------|----------------------------|----------------------------|------------------------|
|                           |            | Number of options granted | Grant date fair value (\$) | Option exercise price (\$) | Option expiration date |
| Gerd Auffarth . . . . .   | 10/4/2023  | 10,511                    | 44,000                     | 4.80                       | 10/4/2033              |
| Julian Gangolli . . . . . | 10/4/2023  | 18,514                    | 77,500                     | 4.80                       | 10/4/2033              |
| Yezan Haddadin . . . . .  | 10/4/2023  | 17,916                    | 75,000                     | 4.80                       | 10/4/2033              |
| Julia A. Haller . . . . . | 10/4/2023  | 10,511                    | 44,000                     | 4.80                       | 10/4/2033              |
| Kurt Hilzinger . . . . .  | 10/4/2023  | 14,333                    | 60,000                     | 4.80                       | 10/4/2033              |
| Andong Huang . . . . .    | 10/4/2023  | 9,555                     | 40,000                     | 4.80                       | 10/4/2033              |
| Faisal Sukhtian . . . . . | 10/4/2023  | 18,633                    | 78,000                     | 4.80                       | 10/4/2033              |

### ***Director Compensation Changes for Fiscal Year 2025***

In September 2024, based on recommendations provided by Mercer, the Company’s independent compensation consultant, the Board approved the following changes to our non-employee director compensation policy, effective October 1, 2024:

- The annual cash retainer for Board service was increased from \$40,000 to \$50,000.
- Certain annual committee member and chairperson fees were increased as follows: (i) for the Audit Committee, from \$7,500 to \$12,500 for members and from \$15,000 to \$25,000 for the chairperson;

(ii) for the Compensation Committee, from \$5,000 to \$10,000 for members and from \$10,000 to \$20,000 for the chairperson; and (iii) for the Nominating and Corporate Governance Committee, from \$4,000 to \$5,000 for members and from \$8,000 to \$10,000 for the chairperson.

- Initial stock option grants will now have a grant date fair value equal to \$245,000 instead of being denominated as a fixed number of shares.
- The grant date fair value of annual stock option grants was increased from \$35,000 to \$265,000. In addition, annual stock option grants will now be made on the first day of the Company's fiscal year rather than at the time of the annual meeting of stockholders.

### ***One-Time Director Stock Option Grants in Fiscal Year 2025***

In September 2024, following the Compensation Committee's review and consideration of market data provided by Mercer, the Company's independent compensation consultant, and an analysis of the equity holdings of the non-employee directors serving on the Board following the Company's private placements that closed in March and April 2024, the Compensation Committee recommended, and the Board approved, one-time grants of stock options under the 2024 Plan to the non-employee directors (other than Dr. Haller) in the amounts set forth in the table below. In addition, in September 2024, following the Compensation Committee's review and consideration of market data provided by Mercer, the Compensation Committee recommended, and the Board approved, the one-time stock option grant under the 2024 Plan for Dr. Haller set forth in the table below. When combined with the initial stock option grant Dr. Haller received when she joined the Board in August 2022, the size of Dr. Haller's one-time grant was intended to approximate the value of an initial stock option grant under the non-employee director compensation policy, as amended effective October 1, 2024 (and as described above). Each of the one-time option grants vests 100% on the first anniversary of the grant date, subject to continued service as a director through the applicable vesting date.

| Name                       | Grant date | Option awards             |                            |                            |                        |
|----------------------------|------------|---------------------------|----------------------------|----------------------------|------------------------|
|                            |            | Number of options granted | Grant date fair value (\$) | Option exercise price (\$) | Option expiration date |
| Gerd Auffarth . . . . .    | 10/1/2024  | 29,493                    | 138,000                    | 5.22                       | 10/1/2034              |
| Julian Gangolli . . . . .  | 10/1/2024  | 71,169                    | 333,000                    | 5.22                       | 10/1/2034              |
| Yezan Haddadin . . . . .   | 10/1/2024  | 132,293                   | 619,000                    | 5.22                       | 10/1/2034              |
| Julia A. Haller . . . . .  | 10/1/2024  | 47,232                    | 221,000                    | 5.22                       | 10/1/2034              |
| Kurt Hilzinger . . . . .   | 10/1/2024  | 105,151                   | 492,000                    | 5.22                       | 10/1/2034              |
| Andong Huang . . . . .     | 10/1/2024  | 23,509                    | 110,000                    | 5.22                       | 10/1/2034              |
| Faisal Sukhtian . . . . .  | 10/1/2024  | 134,430                   | 629,000                    | 5.22                       | 10/1/2034              |
| Ralph H. Thurman . . . . . | 10/1/2024  | 89,549                    | 419,000                    | 5.22                       | 10/1/2034              |

### **Hedging Transactions**

Our Insider Trading Policy prohibits officers, directors, employees or our consultants from engaging in short sales, transactions in put or call options, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to our securities at any time.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

### **Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information relating to the beneficial ownership of our common stock as of January 15, 2025, 2025, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;

- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes any shares over which a person exercises sole or shared voting or investment power. Applicable percentage ownership and total voting power are based on 24,905,635 shares of common stock outstanding as of January 15, 2025. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown beneficially owned by them, subject to applicable community property laws. Shares of common stock issuable upon vesting, exercise or conversion of outstanding equity awards or preferred stock that are exercisable, subject to vesting or convertible within 60 days after January 15, 2025 are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the awards, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

As otherwise noted below, the address for persons listed in the table is c/o Outlook Therapeutics, Inc., 111 S. Wood Avenue, Unit #100, Iselin, New Jersey 08830.

| Name of Beneficial Owner   | Common Stock                        |             |
|--|-------------------------------------|-------------|
|  | Number of Shares Beneficially Owned | %           |
| <b>Five Percent Stockholders (other than directors and officers):</b>  |                                     |             |
| GMS Ventures and Investments <sup>(1)</sup>  | 9,266,645                           | 32.7%       |
| Syntone Ventures, LLC <sup>(2)</sup>   | 2,776,867                           | 10.7%       |
| Entities affiliated with Great Point Partners LLC <sup>(3)</sup>   | 2,481,973                           | 10.0%       |
| Tang Capital Partners, LP <sup>(4)</sup>   | 2,215,851                           | 8.9%        |
| Entities affiliated with Sphera <sup>(5)</sup>   | 1,458,192                           | 5.9%        |
| <b>Named Executive Officers and Directors:</b>   |                                     |             |
| Lawrence A. Kenyon, Director, Chief Financial Officer, Interim Chief Executive Officer, Treasurer and Corporate Secretary <sup>(6)</sup> | 253,341                             | 1.0%        |
| Jeff Evanson, Chief Commercial Officer <sup>(7)</sup>  | 78,368                              | *           |
| C. Russell Trenary III, Former Director, President and Chief Executive Officer <sup>(8)</sup>  | 447,551                             | 1.8%        |
| Ralph H. “Randy” Thurman, Executive Chairman <sup>(9)</sup>  | 69,307                              | *           |
| Gerd Auffarth, M.D, Director <sup>(10)</sup>   | 41,607                              | *           |
| Julian Gangolli, Director <sup>(11)</sup>  | 50,154                              | *           |
| Yezan Haddadin, Director <sup>(12)</sup>   | 80,941                              | *           |
| Julia A. Haller, M.D. Director <sup>(13)</sup>   | 26,270                              | *           |
| Kurt J. Hilzinger, Director <sup>(14)</sup>  | 94,054                              | *           |
| Andong Huang, Director <sup>(15)</sup>   | 38,982                              | *           |
| Faisal G. Sukhtian, Director <sup>(16)</sup>   | 81,799                              | *           |
| <b>All executive officers and directors as a group (10 persons)</b>  | <b>1,262,374</b>                    | <b>4.8%</b> |

\* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

† Represents voting power of less than one percent (1%) of the outstanding common stock.

(1) Based on a Schedule 13D/A filed with the SEC on March 20, 2024 reporting beneficial ownership as of March 18, 2024. Includes 3,458,571 shares of common stock issuable upon exercise of outstanding

warrants. GMS Ventures & Investments, a Cayman Islands exempted company, is a private investment vehicle and wholly owned subsidiary of GMS Holdings. Ghiath M. Sukhtian, or Sukhtian, a natural person, is the holder of a controlling interest in GMS Holdings. The principal office address of Sukhtian is Zahran Street, 7th Circle Zahran Plaza Building, 4th Floor P.O. Box 142904, Amman, Jordan 11844.

- (2) Based on a Schedule 13D/A filed with the SEC on April 17, 2024 reporting beneficial ownership as of April 15, 2024. Includes 1,071,429 shares of common stock issuable upon exercise of outstanding warrants. All shares are held directly by Syntone Ventures LLC, a Delaware limited liability company, or Syntone. Syntone LLC, a Delaware limited liability company, or the Manager, is the manager of Syntone, and is wholly-owned by Syntone Technologies Group Co. Ltd., a company organized in the People's Republic of China, or Syntone Technologies. The principal business address for each of Syntone and the Manager is 1517 Champlain Crest Way, Cary, NC 27513. The principal business address for Syntone Technologies is Beihuan Road East, Renqiu City, Hebei Province, People's Republic of China.
- (3) Based on Schedule 13G filed with the SEC on April 8, 2024 reporting beneficial ownership as of April 1, 2024. The reporting persons hold an aggregate of 2,220,000 shares of common stock issuable upon exercise of outstanding warrants; however, the provisions of such warrants restrict the exercise of such warrants to the extent that, after giving effect to such exercise, the holder of the warrants and its affiliates, together with any other person or entities with which such holder would constitute a group, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. As a result, an aggregate of 751,324 shares underlying such warrants were reported as being beneficially owned by the reporting persons in the Schedule 13G. Consists of (i) 816,960 shares of common stock held by Biomedical Value Fund, L.P., or BVF, and 414,731 shares of common stock underlying warrants held by BVF (of the total warrants to purchase 1,225,440 shares of common stock held by BVF), (ii) 562,400 shares of common stock held by Biomedical Offshore Value Fund, Ltd., or BOVF, and 285,503 shares of common stock underlying warrants held by BOVF (of the total warrants to purchase 843,600 shares of common stock held by BOVF) and (iii) 100,640 shares of common stock held by Cheyne Global Equity Fund (an Open-Ended Fund of Cheyne Select Master Fund ICAV), or CGEF and together with BVF and BMOV, the GPP Entities, and 51,090 shares of common stock underlying warrants held by CGEF (of the total warrants to purchase 150,960 shares of common stock held by CGEF). Great Point Partners LLC, or GPP LLC, is the investment manager of BVF and BOVF and the sub-advisor to CGEF, and by virtue of such status may be deemed to be the beneficial owner of the securities held by the GPP Entities. Each of Dr. Jeffrey R. Jay, M.D., as Senior Managing Member of GPP LLC, and Mr. Ortav Yehudai, as Managing Director of GPP LLC, has voting and investment power with respect to securities held by the GPP Entities, and therefore may be deemed to be the beneficial owner of the securities held by the GPP Entities. Notwithstanding the above, GPP LLC, Dr. Jay and Mr. Yehudai disclaim beneficial ownership of the securities held by the GPP Entities except to the extent of their respective pecuniary interests. The principal business address for the GPP Entities is 165 Mason Street, 3rd Floor, Greenwich, CT 06830.
- (4) Based on Schedule 13G filed with the SEC on March 28, 2024 reporting beneficial ownership as of March 18, 2024. The reporting person holds an aggregate of 1,151,933 shares of common stock issuable upon exercise of outstanding warrants; however, the provisions of such warrants restrict the exercise of such warrants to the extent that, after giving effect to such exercise, the holder of the warrants and its affiliates, together with any other person or entities with which such holder would constitute a group, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. As a result, an aggregate of 596,439 shares underlying such warrants were reported as being beneficially owned by the reporting person in the Schedule 13G. All shares are held directly by Tang Capital Partners, LP. Kevin Tang is the sole manager of Tang Capital Management, LLC, which is the general partner of Tang Capital Partners, LP. Kevin Tang has a pecuniary interest in the shares beneficially held by Tang Capital Partners, LP. The principal business address of the reporting person is 4747 Executive Drive, Suite 210 San Diego, CA 92121.
- (5) This information was obtained from the stockholder in connection with our filing of the Registration Statement on Form S-3 (Registration No. 333- 278209) on March 25, 2024, and reflects beneficial ownership as of March 18, 2024. Consists of (i) 509,412 shares of common stock held by Sphera Biotech Master Fund LP, or Sphera Biotech, and 728,571 shares of common stock underlying warrants held by Sphera Biotech and (ii) 91,638 shares of common stock held by Sphera Global Healthcare Master Fund, or Sphera Global and together with Sphera Biotech, the Sphera Funds, and 128,571 shares of

common stock underlying warrants held by Sphera Global, Sphera Biotech GP LP, or Sphera General Partner, is the general partner of Sphera Biotech. Sphera Global Healthcare Management LP is the general partner of the Sphera General Partner, and acts as the Investment Manager for the Sphera Funds, and holds voting and investment power over the shares held by each of them. Accordingly, Sphera Global Healthcare Management LP may be deemed to have beneficial ownership of the shares held by the Sphera Funds. Sphera Global Healthcare Management LP disclaims beneficial ownership of such shares, except to the extent of its pecuniary interest therein. The shares of common stock issuable upon exercise of the warrants held by each of the Sphera Funds are subject to a beneficial ownership limitation of 9.99%. The principal business address of the reporting persons is 4 Yitzhak Sadeh, Entrance A, 29th Floor, Tel Aviv 6777520, Israel.

- (6) Includes 247,395 shares of common stock issuable under outstanding options held by Mr. Kenyon exercisable within 60 days of January 15, 2025.
- (7) Includes 41,070 shares of common stock issuable under outstanding options held by Mr. Evanson exercisable within 60 days of January 15, 2025.
- (8) Includes 444,805 shares of common stock issuable under outstanding options held by Mr. Trenary exercisable within 60 days of January 15, 2025.
- (9) Includes 69,307 shares of common stock issuable under outstanding options held by Mr. Thurman exercisable within 60 days of January 15, 2025.
- (10) Represents shares of common stock issuable under outstanding options held by Prof. Dr. Auffarth exercisable within 60 days of January 15, 2025.
- (11) Represents shares of common stock issuable under outstanding options held by Mr. Gangolli exercisable within 60 days of January 15, 2025.
- (12) Includes 77,774 shares of common stock issuable under outstanding options held directly by Mr. Haddadin exercisable within 60 days of January 15, 2025.
- (13) Represents shares of common stock issuable under outstanding options held by Dr. Haller exercisable within 60 days of January 15, 2025.
- (14) Includes 70,399 shares of common stock issuable under outstanding options held by Mr. Hilzinger exercisable within 60 days of January 15, 2025.
- (15) Represents shares of common stock issuable under outstanding options held by Mr. Huang exercisable within 60 days of January 15, 2025.
- (16) Includes 78,399 shares of common stock issuable under outstanding options held directly by Mr. Sukhtian exercisable within 60 days of January 15, 2025.

#### **Equity Compensation Plan Information**

The following table provides certain information with respect to all of our equity compensation plans in effect as of September 30, 2024.

| Plan Category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)(#) | Weighted average exercise price of outstanding options, warrants and rights (b)(\$) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)(#) |
|--|--|---|--|
| <b>Equity compensation plans approved by security holders:</b>     |  |   |  |
| 2024 Equity Incentive Plan <sup>(1)</sup> . . . . .                | 2,613,146  | \$16.56   | 4,680,755 <sup>(2)</sup>   |
| 2016 Employee Stock Purchase Plan . . . . .                        | —  | —   | 47,407 <sup>(3)</sup>  |
| <b>Equity compensation plans not approved by security holders:</b> |  |   |  |
| None . . . . .   | —  | —   | —  |
| <b>Total</b> . . . . .   | <u>2,613,146</u>   |   | <u>4,728,162</u>   |

- (1) Upon approval of the 2024 Plan, no additional options or awards were granted under the 2011 Stock Incentive Plan; all outstanding stock awards continue to be governed by their existing terms.
- (2) Number of securities to be issued upon exercise of outstanding options, warrants and rights outstanding at September 30, 2024 under the 2024 Plan comprises option awards only.
- (3) The number of shares of our common stock reserved for issuance under the 2016 Employee Stock Purchase Plan, or ESPP, automatically increases on January 1st each year continuing through January 1, 2026, by the lesser of (i) one percent (1%) of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (ii) 11,000 shares of our common stock and (iii) a number determined by our board of directors. Accordingly, on January 1, 2025, an additional 11,000 shares were automatically added to the ESPP reserve.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

#### Transactions with Related Persons

The following is a summary of transactions since October 1, 2022 to which we have been a party, in which the amount involved exceeded or will exceed the lesser of (x) \$120,000 or (y) 1% of the average of our total assets at September 30, 2023 and 2024, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest other than compensation and other arrangements that are described in the section titled “Executive Compensation.” We also describe below certain other transactions with our directors, former directors, executive officers and stockholders.

#### *Employment and Other Compensation Arrangements, Equity Plan Awards*

We have entered into employment agreements and consulting agreements with certain of our executive officers in connection with their employment or provision of services to us. For more information regarding the executives’ arrangements, see “Executive Compensation — Agreements with Our Named Executive Officers.”

We also have established certain equity plans, pursuant to which we grant equity awards to our employees and directors.

## **GMS Ventures & Investments**

### ***December 2022 Registered Direct Equity Offering***

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, the Company issued 1,423,042 shares of common stock at a purchase price per share of \$17.568 for \$24.0 million in net proceeds after payment of placement agent fees and other estimated offering costs. GMS Ventures purchased an aggregate of 711,521 in the registered direct equity offering.

### ***January 2024 Private Placement***

In January 2024, the Company entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which the Company issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of \$7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for \$55,498,311 in net proceeds after payment of placement agent fees and other offering costs (the “Private Placement”). GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The warrants have an exercise price of \$7.70 per share of common stock and will expire on March 18, 2029.

## ***Syntone Ventures LLC***

### ***January 2024 Private Placement***

In January 2024, the Company entered into a securities purchase agreement with Syntone, pursuant to which the Company issued 714,286 shares of common stock and accompanying warrant to purchase 1,071,429 shares of common stock for \$4,835,371 in net proceeds on substantially the same terms as the Private Placement. The warrants have an exercise price of \$7.70 per share of common stock and will expire on April 15, 2029.

## **Indemnification Agreements**

Our restated certificate of incorporation, as amended, contains provisions limiting the liability of directors, and our amended and restated bylaws, as amended, provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws, each as amended, also provides the Board with discretion to indemnify our employees and other agents when determined appropriate by the Board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers that requires us to indemnify our directors and executive officers.

## **Related-Party Transaction Policy**

In 2016, we adopted a formal written policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related-party transaction with us without the prior consent of our Audit Committee, or other independent members of the Board in the event it is inappropriate for our Audit Committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of their immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee will consider the relevant facts and circumstances available and deemed relevant to our Audit Committee, including, but not limited to, whether the transaction will be on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related party's interest in the transaction.

## **Independence of the Board of Directors**

As required under the listing standards of The Nasdaq Stock Market, LLC, or Nasdaq, a majority of the members of a listed company's board of directors must qualify as “independent,” as affirmatively

determined by the Board. The Board consults with our outside counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of “independent,” including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, our senior management and our independent registered public accounting firm, the Board has affirmatively determined that the following eight directors are independent directors within the meaning of the applicable Nasdaq listing standards: Prof. Dr. Auffarth, Dr. Haller, and Messrs. Gangolli, Haddadin, Hilzinger, Huang, Sukhtian and Thurman. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with the Company.

In making those independence determinations, the Board took into account certain relationships and transactions that occurred in the ordinary course of business between us and entities with which some of our directors are or have been affiliated, including the relationships and transactions described in the section of this Form 10-K/A captioned “Transactions with Related Persons,” and all other facts and circumstances that the Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each director.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table represents aggregate fees billed to the Company for the fiscal years ended September 30, 2024 and 2023 by KPMG LLP, our independent registered public accounting firm.

|                              | Fiscal Year Ended September 30, |                  |
|------------------------------|---------------------------------|------------------|
|                              | 2024                            | 2023             |
| Audit Fees . . . . .         | \$722,000                       | \$752,930        |
| Audit-Related Fees . . . . . | —                               | —                |
| Tax Fees . . . . .           | 80,000                          | 68,000           |
| All Other Fees . . . . .     | —                               | —                |
| Total Fees . . . . .         | <u>\$802,000</u>                | <u>\$820,930</u> |

**Audit Fees.** This category consists of the annual audit of our consolidated financial statements and the interim reviews of the quarterly consolidated financial statements and services rendered in connection with registration statements, including comfort letters and consents.

**Audit-Related Fees.** This category consists of fees billed for professional services provided in connection with assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and that are not reported under Audit Fees.

**Tax Fees.** This category includes all fees associated with tax compliance, tax advice and tax planning work.

**All Other Fees.** This category consists of fees for all other services that are not reported above.

#### Pre-Approval Policies and Procedures

Our Audit Committee of the Board, or the Audit Committee, charter provides that the Audit Committee will approve the fees and other significant compensation to be paid to our independent registered public accounting firm, and pre-approve all audit services and all non-audit services of our independent registered public accounting firm permitted under applicable law. The charter also provides that the Audit Committee may establish other pre-approval policies and procedures for the engagement of our independent registered public accounting firm to render services to us, including without limitation policies that would allow the delegation of pre-approval authority to one or more members of the Audit Committee, provided that any pre-approval decision is reported to the Audit Committee at its next scheduled meeting. The Audit Committee has approved all audit and audit-related work covered by the audit fees and tax fees.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a) The financial statements required by Item 15(a) are filed in Item 8 of our Original Form 10-K.
- (b) 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 our Original Form 10-K.

### EXHIBITS

| Exhibit Number | Description   |
|----------------|---|
| 3.1            | Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on May 15, 2024).  |
| 3.2            | 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 (incorporated by reference to Exhibit 4.1 to the Registrant's annual report on Form 10-K filed with the SEC on December 27, 2024).   |
| 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#          | 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2024).   |
| 10.6#          | Form of Stock Option Grant Notice and Stock Option Agreement under the 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2024).                                  |
| 10.7#          | 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).   |
| 10.8#          | 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 Registrant's current report on Form 8-K filed with the SEC on July 9, 2021).               |
| 10.9#          | 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 Registrant's current report on Form 8-K filed with the SEC on June 7, 2022). |

| Exhibit Number | Description  |
|----------------|--|
| 10.10#         | 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 Registrant's current report on Form 8-K filed with the SEC on December 23, 2021).  |
| 10.11#         | Outlook Therapeutics, Inc. Non-Employee Director Compensation Policy, as amended and restated, effective as of October 1, 2024 (incorporated by reference to Exhibit 10.11 to the Registrant's annual report on Form 10-K filed with the SEC on December 27, 2024).  |
| 10.12#         | 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).  |
| 10.13†         | 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). |
| 10.14          | 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).   |
| 10.15          | 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).   |
| 10.16          | 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).  |
| 10.17          | 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).   |
| 10.18          | 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).   |
| 10.19          | 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 June 23, 2020).   |
| 10.20          | 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).  |
| 10.21**        | 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).  |
| 10.22          | 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).  |
| 10.23          | Amendment, dated February 10, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on February 14, 2023).                            |
| 10.24          | Amendment, dated December 21, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.30 to Registrant's annual report on Form 10-K filed with the SEC on December 22, 2023).                                  |

| Exhibit Number | Description   |
|----------------|---|
| 10.25          | Third Amendment, dated January 22, 2024, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.6 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024).                                |
| 10.26          | 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).  |
| 10.27          | At-the-market Sales Agreement between the Company and BTIG, LLC dated May 16, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 16, 2023).   |
| 10.28          | Form of Registration Rights Agreement, dated January 22, 2024, between the Company and the investors party thereto (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024).   |
| 10.29          | Registration Rights Agreement, dated January 22, 2024, between the Company and Syntone (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on January 24, 2024).   |
| 10.30          | 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 January 24, 2024).   |
| 10.31          | Form of Syntone Common 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 January 24, 2024).   |
| 10.32          | Amendment, dated April 12, 2024, to Sales Agreement, dated May 16, 2023, by and between the Company and BTIG (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 12, 2024).   |
| 19.1           | Insider Trading Policy, as amended and restated (incorporated by reference to Exhibit 19.1 to the Registrant's annual report on Form 10-K filed with the SEC on December 27, 2024).   |
| 21.1           | Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's annual report on Form 10-K filed with the SEC on December 27, 2024).  |
| 23.1           | Consent of independent registered public accounting firm (incorporated by reference to Exhibit 23.1 to the Registrant's annual report on Form 10-K filed with the SEC on December 27, 2024).  |
| 31.1           | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 31.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended September 30, 2024). |
| 31.2           | Certification of Principal Executive Officer and 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 (incorporated by reference to Exhibit 32.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended September 30, 2024).    |
| 97             | Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrant's annual report on Form 10-K filed with the SEC on December 22, 2023).  |

| Exhibit Number | Description  |
|----------------|--|
| 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.

\*\*\* Previously filed with Original Form 10-K.

## ITEM 16. FORM 10-K SUMMARY

None.

## SIGNATURES

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

Date: January 23, 2025

By: /s/ Lawrence A. Kenyon

Name: Lawrence A. Kenyon

Title: Chief Financial Officer and Interim Chief  
Executive Officer



