Risk Factors Comparison 2024-12-27 to 2023-12-22 Form: 10-K

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You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be adversely affected. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition, results of operations and / or prospects. Risks Related to Our Financial Condition and Capital Requirements We have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months. We ~~are a clinical stage biopharmaceutical company and 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 and $ 66. 1~~ million for the years ended September 30, **2024 and** 2023 ~~and 2022~~, 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** ~~none~~ **one** of our product candidates ~~have~~ **, 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: ● ~~conduct an additional clinical trial of ONS- 5010 for the treatment of wet AMD, as required by the FDA;~~ ● prepare to launch and market ONS- 5010 ~~(~~ / LYTENAVA **in the EU and UK** ~~(bevacizumab- vikg))~~, **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 ~~no~~ **one** ~~products~~ **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 ~~late~~ **the first half of calendar** 2025, but this depends heavily on our success in many areas, including but not limited to: ● ~~completing clinical development of~~ **Securing capital sufficient to fund our commercialization efforts; ● launching and commercializing** ONS- 5010 **/ LYTENAVA** ~~for the treatment of wet AMD and the other targeted indications,~~ and any other product candidates **for which** we ~~may develop in the future~~ **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; ● ~~launching~~ **obtaining third- party coverage** and ~~commercializing~~ **adequate reimbursements of** ONS- 5010 **/ LYTENAVA** and any other product candidates **, if** ~~for which we or our partners obtain regulatory and marketing approval~~ **approved** ; ~~● obtaining third- party coverage and adequate reimbursements for our products~~ ; ● obtaining market acceptance of ONS- 5010 **/ LYTENAVA** and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options; **28 ● 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; ~~23~~ ● maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know- how; ~~and~~ ● attracting, hiring and retaining qualified personnel ~~. Even if~~ **; and ● completing clinical development of** ONS- 5010 **/ LYTENAVA** ~~or~~ **for the treatment** ~~one or more~~ of ~~our~~ **wet AMD in the United States and the other targeted indications, and any** other product candidates ~~is approved for commercialization,~~ we **may develop in the future. We** anticipate incurring significant costs to commercialize **ONS- 5010 / LYTENAVA and** any ~~such~~ **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** ~~the EMA,~~ other regulatory ~~agencies~~ **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. ~~In cases~~ **Our ability to generate revenue from the sales of ONS- 5010 / LYTENAVA in the EU, UK or in any other country** where **the** ~~we are successful in obtaining regulatory approvals to market one or more of our~~ product **is approved, or in relation to any other product** ~~candidates~~ **candidate that may be approved** , ~~our revenue~~ 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 ~~our~~ **ONS- 5010 / LYTENAVA and any other** ~~products~~ **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** ~~the~~ **other** product **candidate that may be approved** ; ● the quality and performance of ~~our~~ **ONS- 5010 / LYTENAVA and any other** ~~products~~ **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~~ **29There** 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** ~~(bevacizumab- vikg))~~ 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, ~~2023~~ **2024** , our cash and cash equivalents balance was $ ~~23~~ **14** . ~~4~~ **9** million. We **do not** believe **that** our ~~current~~ **existing** cash ~~resources~~ **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** ~~June 2024 without giving effect to~~ the **Form 10- K filing date** ~~costs associated with initiating the planned NORSE EIGHT clinical trial and excluding repayment of our outstanding convertible promissory note. We are currently assessing the costs to conduct NORSE EIGHT and will need to secure additional funding to complete the study~~ . 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 ~~December~~ **March** ~~2023~~ **2024** , the Lender agreed to extend the maturity of the December 2022 Note from ~~January~~ **April** 1, 2024 until ~~April~~ **July** 1, ~~2024~~ **2025** to provide us time to negotiate the terms to further extend the maturity of ~~the December 2022 Note. However, there can be no assurance that we will be successful in further extending the maturity date. The terms of a further extension 24could include additional interest or other fees, or a change in the conversion price that could increase the number of shares that need to be issued to satisfy a conversion of the December 2022 Note. If we are unable to further extend the maturity of the December 2022 Note and cannot repay the December 2022 Note at maturity, that would constitute an event of default under~~ 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~~ **30our** 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. ~~25In~~ **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~~ **under** the December 2022 Note, " Conversion Price " ~~means~~ **meant** , prior to a Major Trigger Event, $ ~~2~~ **40** . 00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $ ~~2~~ **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 $ ~~0~~ **3** . ~~1756~~ **51** per share, **we** ~~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. ~~In December~~ **On January 22,** ~~2023~~ **2024** , we **entered into an** ~~amended~~ **amendment to** the December 2022 Note **with** ~~to change~~ 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 ~~date~~ of

the December 2022 Note **was extended** to ~~April~~ **July** 1, ~~2024~~ **2025** ~~to allow time to negotiate the terms to further extend the maturity of the December 2022 Note. However, there can be no assurance that we will be successful in further extending the maturity date. The terms of a further extension could include additional interest or other fees, or a change in the conversion price that could increase the number of shares that need to be issued to satisfy a conversion of the December 2022 Note~~ . Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability ~~to~~ **31to** 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** ~~or~~ **for ONS- 5010 / LYTENAVA** ~~grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, terminate product development or future commercialization efforts~~ or to cease operations altogether. ~~26Risks --~~ **Risks** Related to the Discovery and Development of Our Product CandidatesWe are highly dependent on the success of ONS- 5010 **/ LYTENAVA** , our only product ~~candidate~~ **that has been approved** in **the EU** ~~active development,~~ and ~~if~~ **UK. If** ONS- 5010 **/ LYTENAVA** does not ~~successfully~~ receive regulatory approval **outside the EU and UK** , or is not successfully commercialized, our business may be harmed. We currently have ~~no~~ **one** ~~products~~ **product, ONS- 5010 / LYTENAVA,** that ~~are~~ **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** ~~, through clinical trials and the regulatory approval process, and we~~ also expect that we will need to devote significant effort to the commercialization of ONS- 5010 **/ 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 ~~if~~ **in the EU or UK, or any other targeted market in which** we receive regulatory approval ~~in our targeted markets~~ . The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market ONS- 5010 **/ 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; **32** ● 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; ~~or27~~ **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 ~~MAA~~ **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 ~~successfully complete NORSE EIGHT and / or otherwise~~ 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~~ **33Clinical** 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, ~~will require~~ **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** ~~before we are able to re- submit~~ 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 ~~and EIGHT~~) once they are initiated. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to: ● inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials; ● delays in reaching a consensus with regulatory ~~agencies~~ **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** ; ~~28~~ ● imposition of a clinical hold by regulatory ~~agencies~~ **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; **34** ● 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. ~~29The~~ -- **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 ~~agencies~~ **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 ~~agencies~~ **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 ~~agencies~~ **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 ~~agencies~~ **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. ~~However, even if~~ **Although in January 2024** we ~~reach~~ **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. 35We have received marketing authorization for ONS- 5010 / LYTENAVA for the treatment of wet AMD in the EU and UK.** We ~~initially~~ **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. ~~Our~~ **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 ~~our~~ **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 ~~our~~ **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 ~~our~~ **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 ~~30other~~ -- **other** safety issues, and could require us to perform additional studies or halt development or sale of ~~these~~ **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 ~~agencies~~ **authorities** to conduct additional animal or human studies regarding the safety and efficacy of **ONS- 5010 / LYTENAVA** ~~our~~ **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** ~~our~~ **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 ~~agency~~ **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** ~~the~~ **other** ~~particular~~ **future** product candidate ~~, if~~ **that may be** approved, and could significantly harm our business, results of operations and prospects. **We are required by** ~~If we receive approval, regulatory agencies including~~ the FDA, ~~EMA~~ **MHRA, EEA authorities** and other **comparable** foreign regulatory **authorities to** ~~agency regulations require that we~~ report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may ~~also~~ **36also** fail to

appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, ~~EMA~~ **MHRA, the national competent authorities of EEA countries** or other foreign regulatory ~~agencies~~ **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 ~~products~~ **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 ~~31may~~ -- **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** ~~our~~ **or any other** product ~~candidates~~ **candidate** and decreased demand for **ONS- 5010 / LYTENAVA** ~~our~~ **or any other** product ~~candidates~~ **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. ~~Neither we nor any collaboration partners have initiated marketing efforts in any jurisdiction.~~ In order to market our products in Europe, the United States and other jurisdictions, we and any collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. **We have received** ~~The EMA is responsible for the regulation and recommendation for approval of human medicines in the E. U. This procedure results in~~ a ~~single~~ marketing authorization ~~that~~ **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** ~~E. U.~~ countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval ~~abroad~~ **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** ~~Europe~~ **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. ~~If~~ ONS- 5010 **/ LYTENAVA** , or any other product candidates we may pursue ~~,~~ **that** are approved, ~~they~~ will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including ~~both~~ **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~~ **37continue** 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** ~~If our product candidates are approved, 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 ~~agency~~ **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, ~~32marketing~~ -- **marketing** or labeling of a product, such regulatory ~~agency~~ **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 ~~agency~~ **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~~ **38The** 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 ~~of the~~ **other** indications for which we plan to develop ~~it~~ **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. ~~33The~~ -- **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~~ **or39** ● 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** ~~an additional adequate and well- controlled clinical trial~~ , 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. ~~34Any~~ -- **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; **40** ● 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; ~~35~~ ● 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~~ **41or** 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 ~~approval~~ **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; ~~36~~ ● 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 ~~, for example, in 2020, the COVID- 19 global pandemic impacted enrollment in our NORSE 2 clinical trial~~ . Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing. ~~37Adverse~~ **42Adverse** 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; **43** ● such product could become less competitive; and ● our reputation may suffer. ~~38Any~~ -- **Any** of these events could prevent us from achieving or maintaining market acceptance of ONS- 5010 **/ LYTENAVA** or any future product candidate ~~, if~~ **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 ~~agencies~~ **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 CandidatesWe 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~~ **44We** have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include, for example, Novartis, which currently markets LUCENTIS and BEOVU, Regeneron, with its product EYLEA, Genentech, the marketer of VABYSMO, ~~and~~ both Biogen and Coherus with their biosimilar formulations of LUCENTIS **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 ~~39approved~~ -- **approved** for use in these patients. ~~Our~~ ONS- 5010 **/ LYTENAVA** is ~~being developed as~~ 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, ~~EMA~~ **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 ~~, if approved~~ , 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; **45** ● 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; ~~40~~ ● 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 ~~, if~~ **that may be** approved; ● our ability to maintain compliance with regulatory

requirements; and ● labeling or naming imposed by FDA or other regulatory ~~agencies~~ **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** ~~the~~ **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** ~~our~~ **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 ~~but~~ fail to achieve an adequate level of acceptance by physicians, patients, third- party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable. **Although** ~~Even if~~ 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** ~~Even if~~ 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 ~~do not yet~~ have ~~any~~ **one** ~~products~~ **product** ~~approved~~ **, ONS- 5010 / LYTENAVA,** for **which** ~~sale, and~~ we **received a marketing authorization in the EU and the UK. We** , as a company, have no experience selling and marketing ~~any~~ **46any** 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 ~~ONS- 5010 receives regulatory approval and~~ we are not able to secure a strategic licensing partner who will commercialize ~~such~~ **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 ~~41to~~ **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 ~~are~~ **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. ~~For example, in July 2020, one of our contract counterparties for our former biosimilar program filed a complaint claiming breach, which was subsequently settled in~~

~~March 2021 and dismissed in April 2021.~~ If we are not able to successfully resolve ~~this or any other~~ disagreements with our contract partners, it could negatively impact our business or reputation. Further, if we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business. In addition to commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and even if so, we may underestimate our development costs, and such fund may not be sufficient to develop a particular product candidate internally or to bring it to market. Failure to bring ONS- 5010 **/ 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~~ **47The** 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 ~~, if~~ **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. ~~42There~~ -- **There** is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. In the United States, third- party payors play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end- stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means and / or certain disabilities. The Medicare and Medicaid programs increasingly are used as models for how third- party payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third- party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for seeking favorable coverage determinations often is time- consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Our inability to promptly obtain coverage and profitable reimbursement rates from third- party payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. ~~We~~ **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. 48We** believe the increasing emphasis on cost- containment initiatives in the **EU** ~~E. U.~~, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates ~~. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits~~ . Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United

States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for ONS- 5010 **/ 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. ~~If~~ **We may only promote or market ONS-5010 / LYTENAVA in the EEA and the UK, or any other of** our product candidates ~~are~~ **that may be** approved ~~by the FDA~~ , ~~we may only promote or market our product candidates~~ for their specifically approved indications. We will train our ~~future~~ marketing and sales force against promoting **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** ~~our~~ **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 ~~bodies~~ **authorities** . Any actual or alleged ~~43failure~~ -- **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** ~~our~~ **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~~ **49knowledge** and understanding of these diseases. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the ~~European Union~~ **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 ~~clinical~~ **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. ~~44Risks~~ **50Risks** Related to Our Reliance on Third PartiesWe 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** ~~the Member States of the European Economic Area~~ 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** ~~Previously,~~ we **may rely on third parties, some of which are or may be sole source vendors for** ~~manufactured~~ **manufacturing** ~~bulk~~ **and supply of our** drug ~~substance~~ **candidates** for preclinical and clinical **development materials and commercial** supplies ~~of~~ **, our supply may become limited** ~~our~~ **or interrupted** ~~product candidates in our~~ **or** ~~in- house facility~~ **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** ~~no~~ **not** ~~longer~~ 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~~ **51efforts** 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 ~~45delay~~ -- **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** ~~If ONS- 5010 or any of our product candidates are approved, we~~ may need to enter into agreements with another third party for contract manufacturing **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 ~~or market them~~ **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~~ **and52** ● 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. ~~46Any~~ -- **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 ~~may~~ 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~~ **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 ~~, Inc., or Cencora,~~ in preparation for the anticipated commercial launch **of ONS- 5010 / LYTENAVA in the EEA, UK, and** in the United States ~~of ONS- 5010 (LYTENAVA (bevacizumab- vikg))~~, 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, **andmedical information,** as well as **other regions outside** ~~medical information and pharmacovigilance services in~~ the United States ~~. If required, Cencora can provide similar services in Europe to support the commercialization of ONS- 5010~~ . 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~~ **53product** candidates, we must, at times, share trade secrets with them ~~. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our collaboration or similar agreements. For example, under our joint participation arrangement with Huahai, we are obligated to share with Huahai certain information relating to the development of ONS- 3010, including reports from nonclinical studies and clinical trials~~ . We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, CROs, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third- party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our ~~47technological~~ **technological** achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time- consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business ~~. We are required to co- fund the development of, and proportionately share in the revenue from, the commercialization of ONS- 3010 in the United States, Canada, E. U., Japan, Australia and New Zealand under a joint participation agreement with Huahai. We may also be required to form a joint venture to further co- develop and commercialize ONS- 3010 with Huahai in the agreed countries, if so requested by Huahai. We currently have a joint participation arrangement with Huahai that provides for the co- funding of the development of ONS- 3010 in the United States, Canada, E. U., Japan, Australia and New Zealand and the proportionate sharing of the revenue from commercialization of ONS- 3010 in such countries. In the event we were to restart the active development of this program, we could also be required to further co- develop and commercialize ONS- 3010 with Huahai in the agreed countries pursuant to a joint venture, if so requested by Huahai, as contemplated by our joint participation agreement. Under the joint participation agreement, assuming Huahai funds its proportionate share of development costs incurred after completion of the " Phase- 3 Ready Package " for ONS- 3010, we will have a 49 % value ownership interest with Huahai having a 51 % value ownership interest in ONS- 3010. Accordingly, our share of any potential revenues from the successful commercialization of ONS- 3010 in the agreed countries, including major markets such as the United States and E. U., would also be in proportion to such ownership interests. While we anticipate that we will each act in accordance with the terms of our agreement for the joint development and commercialization of ONS- 3010, we cannot control Huahai, nor can we predict with any certainty that our interests will be aligned and that we will successfully collaborate~~ . We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill- finish manufacturing and product testing of ONS- 5010 **/ LYTENAVA** . The loss of any of these suppliers, or any future single source suppliers, could harm our business. ~~Our~~ ONS- 5010 ~~product candidate~~ **/ 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. ~~48Risks~~ -- **Risks** Related to Intellectual PropertyIf 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~~ **54Our** 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** ~~E. U.~~, the burden of proving invalidity of a patent also usually rests on the party alleging invalidity. Even if we are successful in litigation, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could harm our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable ~~49terms~~ -- **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~~ **55foreign** 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** ~~E. U.~~ states (including Switzerland) seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. So called " submarine " patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether. The term " submarine " patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from a U. S. application with an effective filing date prior to June 8, 1995 that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may be issued to our competitors covering our product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and / or commercialization of a product candidate. The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a candidate into the U. S. market. We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. ~~50The~~ -- **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~~ **56Our** 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. ~~51We~~ **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~~ **57unsuccessful** in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. If we are unable to obtain and maintain effective patent rights for ~~our product candidates~~ **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** ~~our~~ **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 ~~52prevent~~ -- **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~~ **58typically** 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 ® (AbbVie and Genentech, respectively) own patents directed to formulations for these products. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products that we believe are not covered by valid claims of third- party patents, including AbbVie or Genentech' s formulation patents; and we have filed patent applications directed to our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third- party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of adalimumab (Humira) and bevacizumab (Avastin ®) would cover the formulations of any competitors. For example, we are aware that Sandoz is developing biosimilar versions of adalimumab (Humira) and has filed patent applications directed to formulations of adalimumab (Humira). We are also aware that Boehringer is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have patents and patent applications directed to aspects of our downstream manufacturing processes for various biosimilars, including ONS- 3010. In contrast to our patent applications directed to formulations of ONS- 3010, the proprietary technologies embodied in our process- related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third- party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties. ~~53Obtaining~~ -- **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~~ **59We** 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 ~~54other~~ -- **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~~ **60our** 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 ~~55employees~~ -- **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~~ **61we** 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 ~~56by~~ **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~~ **62If** 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 OperationsOur 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. ~~57Unfavorable~~ -- **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; **63** ● 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. ~~58We 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 **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~~ **64We** and certain of our officers have been named as defendants in a pending securities class action lawsuit. ~~This~~ **Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These** ~~lawsuit~~ **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. ~~This~~ **These** ~~lawsuit~~ **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 ~~lawsuit~~ **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 ~~lawsuit~~ **lawsuits** ~~is~~ **are** currently at an early stage, and we cannot be certain how long it may take to resolve the pending ~~lawsuit~~ **lawsuits** or the possible amount of any damages that we may be required to pay. Monitoring, initiating and ~~59defending~~ -- **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 ~~lawsuit~~ **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 ~~lawsuit~~ **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 ~~lawsuit~~ **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~~ **65Healthcare** 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. ~~While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or~~ **For example** ~~delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act' s individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act- mandated fees, and increasing the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally~~ , on June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. Accordingly, we continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, led to aggregate reductions of Medicare payments to providers up to 2 % per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments will stay in effect until ~~2031~~ **2032** unless additional Congressional action is taken ~~from May 1, 2020 through March 31, 2022, due to the COVID- 19 pandemic~~ . Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which ~~eliminates~~ **eliminated** the statutory Medicaid drug rebate cap, ~~currently~~ **previously** set at 100 % of a drug' s average manufacturer price, for single ~~60source~~ -- **source** and innovator multiple source drugs, ~~beginning~~ **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~~ **66fiscal** 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 ~~they~~ - **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. **HHS** ~~It is currently unclear how the IRA~~ will **select up** ~~be effectuated but is likely~~ to ~~have a significant impact on~~ **fifteen additional drugs covered under Part D for negotiation in 2025. HHS has and will continue to issue and update guidance as** ~~the~~ **these** ~~pharmaceutical industry~~ **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~~ **67patient** 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; ~~61~~ ● 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 ~~federal~~ 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~~ **68If** 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. ~~62The~~ -- **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~~ **69regulations** 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 ~~63stringent~~ -- **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~~ **70We** 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 ~~64things~~ -- **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~~ **71Our** 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 ~~65our~~ -- **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 ~~and~~ operations ~~would suffer~~ **; 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 72provides 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 thePIPL impose strict requirements for processing personal data. For example, under the GDPR, in the event of ~~computer system failures~~ **any non- compliance** , ~~cyberattacks~~ **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** ~~or~~ **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 ~~deficiency in~~ **legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption** ~~our~~ **or** ~~cybersecurity. Despite~~ **degradation of our operations, the need to relocate part of or all of our business or data processing activities to** ~~the~~ **other** ~~implementation~~ **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 ~~measures~~ **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** ~~our~~ **or** ~~internal computer~~ **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. 73Obligations 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 74affected** by **vulnerabilities present in acquired** ~~computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber- intrusions over the Internet, attachments to emails, persons inside our~~ **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** ~~organization~~ **organizations** , ~~or persons~~ **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** ~~access to systems inside our organization and vulnerable to damage therefrom. The risk of~~ a security ~~breach~~ **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** ~~or~~ **our** ~~disruption~~ **damages** , ~~particularly through cyberattacks~~ or ~~cyber intrusion~~ **we may be unable to recover such award. In addition** , **supply- chain** ~~including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted~~ attacks ~~and intrusions from around the world~~ have increased **in frequency** . ~~If such an~~ **and severity** ~~event were to interrupt our operations~~ , ~~it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts~~ and **we cannot guarantee** ~~significantly increase our costs to recover or reproduce the data. To the extent~~ that ~~any disruption~~ **third parties' infrastructure in** ~~or~~ **our supply chain or our third- party partners' supply chains have not been compromised. While we have implemented** security ~~breach was~~ **measures designed** to **protect against security incidents** ~~result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed. Risks Related to Ownership of Our SecuritiesOur common stock may be delisted from The Nasdaq Capital Market and begin trading in the over- the- counter markets if we are not successful in regaining compliance with Nasdaq' s continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets. On October 16, 2023, we received a letter from the Listing Qualifications Staff, or the Nasdaq Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that for the last 32 consecutive business days, the bid price of our common stock had closed below $ 1. 00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550 (a) (2). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we have a period of 180 calendar days, or until April 15, 2024, or the Compliance Date, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must be at least $ 1. 00 per share for a minimum of ten consecutive business days before the Compliance Date. If we do not achieve compliance by~~

~~the Compliance Date, we may be eligible for an additional 180- day period to regain compliance if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible for the additional compliance period, and we do not regain compliance by the Compliance Date, The Nasdaq Capital Market will provide written notification to us that our common stock is subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq listing rules. However~~ , there can be no assurance that ~~, if we do appeal the~~ **these** ~~delisting determination by Nasdaq~~ **measures will be effective. We take steps designed** to **detect** ~~the panel~~ , **mitigate, and remediate vulnerabilities in our information systems (** such **as our hardware and /** ~~appeal would be successful. 66We intend to actively monitor the closing bid price of our~~ - **or software, including that of third parties** ~~common stock between now and the Compliance Date and will evaluate available options to resolve the deficiency and regain compliance~~ with **whom** ~~the minimum bid price rule. If we are~~ **work). We may** not ~~successful in regaining compliance~~ , **however** ~~we anticipate that our common stock would begin trading on the over- the- counter market. Delisting from Nasdaq and trading on the over- the- counter market could adversely affect the liquidity of our common stock. Stocks traded on the over- the- counter market generally have limited trading volume and exhibit a wider spread between the bid / ask quotation~~ , ~~as compared to securities listed~~ **detect and remediate all such vulnerabilities including** on a **timely basis** ~~national securities exchange~~ . ~~Consequently~~ **Further** , ~~you~~ **we** may ~~not~~ **experience delays in deploying remedial measures or patches designed to address identified vulnerabilities. Vulnerabilities could** be **exploited** ~~able to liquidate your investment in the event of an~~ **and** ~~emergency or~~ **result in a security incident. Any of the previously identified** ~~for~~ - **or** ~~any~~ **similar threats could cause a security incident or** other **interruption that** ~~reason. If our common stock is delisted from the Nasdaq, we~~ could ~~face~~ **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 ~~:- A limited~~ **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** ~~quotations for our common stock; · A reduced amount~~ of **the** ~~news and analyst coverage for our company~~ **Company could be leaked, 75disclosed,** ~~; · A decreased ability to issue additional securities or obtain additional financing in the future; · Reduced liquidity for~~ - **or revealed as a result of** ~~our~~ - **or in connection with our** ~~stockholders; · Potential loss of confidence by partners and~~ employees **'** ~~; and · Loss of institutional investor interest and fewer business development opportunities. Additionally~~ , ~~delisting of~~ **personnel' s,** ~~our~~ - **or vendors'** ~~common stock from the Nasdaq would constitute an event of default under 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~~ **use of generative AI** ~~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~~ . ~~The~~ **Risks Related to Ownership of Our SecuritiesThe** 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; ~~67~~ ● 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; **76** ● 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. ~~68As~~ **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. ~~This~~ **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. ~~This~~ **These** ~~lawsuit~~ **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 ~~lawsuit~~ **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 result in delays of NORSE EIGHT and / or could preclude or delay potential future clinical trials, or~~ 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~~ **77GMS** 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, ~~2023~~ **2024** , GMS Ventures owned ~~70~~ **5** , ~~047~~ **808** , ~~204~~ **074** shares of common stock and a warrant to acquire an additional ~~1~~ **3** , ~~230~~ **458** , ~~315~~ **571** shares of common stock. Accordingly, GMS Ventures beneficially owned approximately ~~27~~ **33** . ~~3~~ **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; ~~69~~ ● 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~~ **78If** 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. ~~70We~~ **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~~ **79could** decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management. Future sales and issuances of our common stock or rights to purchase securities, including pursuant to our equity incentive plans or exercise of warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause the market price of our securities to fall. We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Pursuant to the ~~2015~~ **2024** Equity Incentive Plan, or the ~~2015~~ **2024** Plan, our management is authorized to grant stock options and other equity- based awards to our employees, directors and consultants. Under the ~~2015~~

2024 Plan, the number of shares of our common stock reserved for future issuance as of September 30, ~~2023~~ **2024** was ~~17~~ **4**, ~~414~~ **680**, ~~910~~ **755** shares ~~. The number of shares available for future grant under the 2015 Plan also provides for an " evergreen " increase on an annual basis unless our board of directors determines otherwise~~. In addition, we have reserved shares for issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, which similarly provides for an annual " evergreen " increase unless determined otherwise by our board of directors. If our board of directors does not elect to reduce the annual increases in the number of shares available for future grant under the ~~2015~~ **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 ~~7~~ **14**, ~~328~~ **207**, ~~549~~ **622** shares of our common stock, at prices ranging from $ ~~0~~ **7**. ~~9535~~ **70** to $ ~~12~~ **240**. 00 per share. ~~71Additionally~~ -- **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~~ **80there** may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations. The enactment of proposed or future tax legislation may adversely impact our financial condition and results of operations. ~~On August 16~~ **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, ~~President Biden signed into law~~ the ~~Inflation Reduction~~ **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** ~~or~~ **for research activities conducted in** the ~~IRA~~ **United States and over 15 years for research activities conducted outside the United States**. ~~The IRA contains a number of~~ **In addition, U. S. federal, state and local** tax ~~related provisions including a 15 % minimum corporate~~ **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 ~~on certain large~~ **allocations, which may adversely affect our results of** ~~corporations~~ -- **operations** ~~as well as an~~ **and** ~~excise tax on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA, but do not expect it to have a material impact on our~~ financial ~~statements~~ **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 ~~72dividends~~ -- **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; **81** ● 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 ~~73~~ **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. 82**