Risk Factors Comparison 2025-03-17 to 2024-03-29 Form: 10-K

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Investing in our securities involves a high degree of risk. Set forth below are certain material risks and uncertainties known to us that could adversely affect our business, financial condition, or results of operations or could cause our actual results to differ materially from our expectations expressed in our filings with the SEC and other public statements. The occurrence of the events contemplated by one or more of the factors we describe below could cause the market price of our securities to decline, resulting in the loss of all or part of any investment in our common stock. Furthermore, other risks that are currently unknown to us or that we currently believe to be immaterial may also, nevertheless, adversely affect our business, financial condition, or results of operations in a way that is material. You should carefully consider the risk factors set forth below as may updated by our subsequent filings under the Exchange Act together with all the other information in this Annual Report, including our consolidated financial statements and the related notes included in Part II, Item 8 – Financial Statements and Supplementary Data of this Annual Report and the information set forth in Part II, Item 7A-- Management' s Discussion and Analysis of Financial Condition and Results of Operations, as well as in our other filings with the SEC, before making any investment decisions. Furthermore, the risks and uncertainties described below and in the other information mentioned above are not the only ones the Company faces. Additional risks and uncertainties not presently known to the Company or that we currently believe to be immaterial could, nevertheless, adversely affect the Company' s business, operating results and financial condition, as well as adversely affect the value of an investment in the Company' s securities, and the occurrence of any of these risks might cause you to lose all or part of your investment. Summary of Risk Factors ● The Company is a clinical stage biopharmaceutical company and has incurred significant losses since its inception. The Company expects its net losses to continue for the foreseeable future. The Company is not currently profitable and may never achieve or sustain profitability. The Company is unable to predict the extent of future losses or when it might become profitable, if ever. ● The Company will require additional capital to fund its operations **, including any Phase 3 trial evaluating neflamapimod in patients with DLB** . If the Company fails to obtain necessary financing on acceptable terms, or at all, it may not be able to complete the development and commercialization of neflamapimod. ● The Company currently does not have, and may never have, any products that generate significant revenues. ● The Company is heavily dependent on the success of its lead product candidate, neflamapimod, which is still under clinical development. If neflamapimod does not receive regulatory approval or is not successfully commercialized, the Company' s business will be materially harmed. ● The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming, and inherently unpredictable. There is no guarantee that the Company' s planned clinical trials for neflamapimod to treat patients with DLB, or in any other indications that the Company may pursue, will be successful. If the Company is ultimately unable to obtain regulatory approval for neflamapimod on a timely basis, or at all, its business will be substantially harmed. ● Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of neflamapimod or any other product candidates the Company may develop or acquire. ● The Company has concentrated its research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. The ability to successfully develop drugs for DLB and other age- related neurologic disorders is extremely difficult and is subject to a number of unique challenges. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong. ● Enrollment and retention of participants in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside the Company' s control. ● Results of preclinical studies and early clinical trials may not be indicative of results obtained in later trials. In addition, preliminary, topline and interim data from the Company' s clinical trials that the Company may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. **In addition, conclusions based on data from analyses of open- label results, including the 16- week Extension Phase results from the RewinD- LB Trial, may not be reproduced when implemented in large, well- controlled, randomized clinical trials.** ● If the Company does not adequately protect its proprietary rights, the Company may not be able to compete effectively. ● The Company has no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for its future viability. ● Even if neflamapimod or any other product candidate the Company develops receives marketing approval, it may fail to achieve the level of acceptance necessary for commercial success. ● The Company' s future success depends in large part on the Company' s ability to retain its key employees, as well as its ability to attract, train and motivate additional qualified personnel. The Company may also encounter difficulties in managing its growth, which could disrupt its operations. ● The Company has identified **a** material ~~weaknesses~~ -- **weakness** in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company' s financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financial reporting which it may not be able to remedy in a timely manner. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired. Risks Related to the Company' s Limited Operating History, Financial Condition and Need for Additional Capital Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially viable. The Company has

incurred net losses **in each fiscal year** since its inception, and as of December 31, ~~2023~~ **2024** , it had an accumulated deficit of approximately $ ~~54~~ **70** . ~~4~~ **7** million. The Company expects to incur net losses for the foreseeable future as it incurs significant clinical development costs related to the advancement of neflamapimod. The Company has not commercialized any products and has never generated revenue from neflamapimod or any other product. In order to obtain revenues from any product candidate, the Company must succeed, either alone or in collaboration with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. The Company may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability. The Company expects to incur significant additional operating losses for at least the next several years as it advances neflamapimod through clinical development, conducts clinical trials, seeks regulatory approval and commercializes neflamapimod, if it is ultimately approved for marketing. The costs of advancing product candidates into each successive clinical phase of the clinical development process tend to increase substantially. Therefore, the total costs to advance neflamapimod to marketing approval in even a single jurisdiction will be substantial. Due to the numerous risks and uncertainties associated with pharmaceutical product development, the Company is unable to accurately predict the timing or amount of increased expenses, or when or if it will be able to begin generating revenue from the commercialization of neflamapimod, let alone achieve or maintain profitability. The amount of the Company' s future net losses will depend, in part, on the rate of future growth of its expenses, if and when neflamapimod is approved for marketing in various jurisdictions and its ability to generate revenues from any drug candidate that may ultimately be approved. If the Company is unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, it will not achieve profitability. Even if the Company does achieve profitability, it may not be able to sustain it, which could materially and adversely affect its business. The Company **will require additional capital to fund its operations. If the Company fails to obtain necessary financing on acceptable terms, or at all, it may not be able to complete the development and commercialization of neflamapimod. The Company** expects to spend substantial amounts to complete the development of, seek regulatory approvals for, and commercialize neflamapimod, if it is ultimately approved for marketing. These expenditures will include costs related to **its planned clinical trials** ~~the RewinD- LB Trial~~ and costs associated with its license agreement with Vertex, under which the Company is obligated to make certain payments in connection with the achievement of specified events. Until such time, if ever, that the Company can generate sufficient product revenue and achieve profitability, it expects to seek to finance future cash needs through equity or debt financings and / or corporate collaboration, licensing arrangements and grants. Based upon the Company' s current operating plan, the Company believes that the Company' s cash and cash equivalents as of December 31, ~~2023~~ **2024** , will ~~not~~ be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements for a period of at least 12 months following the issuance of the financial statements included elsewhere in this Annual Report without an additional equity or debt financing. **However** ~~On March 28~~ , ~~2024,~~ the ~~Company entered into a securities purchase agreement with certain purchasers named therein related to the private placement of an aggregate of 2, 532, 285 units, each comprised of (i) (A) one share of common stock or (B) one Pre- Funded Warrant and (ii) one Series A Warrant. The 2024 Private Placement is expected to close on or about April 1, 2024, subject to customary closing conditions. The aggregate upfront gross proceeds from the 2024 Private Placement are expected to be approximately $ 50 million, before deducting offering fees and expenses, and additional gross proceeds of up to approximately $ 99. 4 million may be received if the Series A Warrants are exercised in full for cash. The foregoing estimate does not reflect the Company' s expected receipt of proceeds from the 2024 Private Placement. The~~ Company' s estimates and expectations regarding its cash runway are based on assumptions that may prove to be incorrect, and changing circumstances could cause it to consume capital faster or in different ways than the Company currently expects. For example, the ~~RewinD- LB Trial~~ **Company' s planned clinical trials** may be more expensive, time- consuming, or difficult to implement than the Company currently anticipates. Because the length of time and activities associated with the successful development of neflamapimod are highly uncertain, the Company is unable to estimate the actual funds it will require to complete research and development and ultimately commercialize its drug candidate for one or more indications. The Company' s future capital requirements will depend on, and could increase significantly as a result of, many factors, including: ● the enrollment, progress, timing, costs and results of **its ongoing** ~~the RewinD- LB Trial~~ and ~~any~~ future **clinical** ~~phase 3 trial~~ **trials** evaluating neflamapimod in DLB ~~, as well as if~~ and ~~when it pursues additional development plans for neflamapimod in~~ other ~~disease~~ indications ~~, such as recovery after anterior circulation ischemic stroke or EOAD~~ ; ● the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities; ● its ability to reach certain milestone events set forth in its collaboration agreements and the timing of such achievements, triggering obligations to make applicable payments; ● the hiring of additional clinical, scientific and commercial personnel to pursue the Company' s development plans, as well the increased costs of internal and external resources as to support the Company' s operations as a public reporting company; ● the cost and timing of securing manufacturing arrangements for clinical or commercial production; ● the cost of establishing, either internally or in collaboration with others, sales, marketing and distribution capabilities to commercialize neflamapimod, if approved; ● the cost of filing, prosecuting, enforcing, and defending its patent claims and other intellectual property rights, including defending against any patent infringement actions brought by third parties against the Company; ● the ability to receive additional non- dilutive funding, including the Company' s **remaining** ~~pending request for additional~~ funding **expected** under the NIA Grant and other grants from organizations and foundations; ● the Company' s ability to establish strategic collaborations, licensing or other arrangements with other parties on favorable terms, if at all; and ● the extent to which the Company may in- license or acquire other product candidates or technologies. The Company may raise additional capital in the future through a variety of sources, including public or private equity offerings, debt financings, grant funding, or strategic collaborations and licensing arrangements. However, adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company' s failure to raise capital as and when needed would have a negative effect on its

financial condition and its ability to pursue its business strategy. If the Company is unable to secure additional capital in sufficient amounts or on terms acceptable to the Company, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod. Further, to the extent that the Company raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, current stockholder' s ownership interest in the Company will be diluted. In addition, any debt financing may subject the Company to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises additional capital through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Even if the Company were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to the Company or its stockholders. The Company is a clinical- stage biopharmaceutical company focused on developing treatments for age- related neurologic disorders, currently has no products that are approved for commercial sale, and it is possible it may never be able to develop a marketable product. To date, the Company has not generated any revenues from its lead product candidate, neflamapimod, or from any other product candidate. The Company cannot guarantee that neflamapimod, or any other product candidate that it may develop or acquire in the future, will ever become a marketable product. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation in the U. S. and in other countries. Before the FDA and other regulatory authorities in the European Union and elsewhere will approve neflamapimod (or any other drug candidate) for commercialization, the Company must demonstrate that it satisfies rigorous standards of safety and efficacy for each of its intended uses. If approved, in order to compete effectively in the commercial marketplace, drugs must be easy to administer, cost- effective and economical to manufacture on a commercial scale. The Company may not achieve any of these objectives. The Company ~~initiated its RewinD- LB Trial in the second quarter of 2023 and anticipates completing enrollment in the study in the second quarter of 2024. The Company~~ cannot be certain that **its ongoing trials** ~~the RewinD- LB Trial~~ or any future clinical development of neflamapimod will be successful, or that it will receive the regulatory approvals required to commercialize neflamapimod for any intended use, or that any future research and drug discovery programs undertaken by the Company will yield a drug candidate suitable for investigation through clinical trials. Even if the Company is able to successfully develop neflamapimod through approval and commercialization, any revenues from sales of the drug may not materialize for several years, if at all. The ~~Company has a history of operating losses and expect to continue to incur losses in the foreseeable future, which raises substantial doubt about its ability to continue as a going concern. As discussed further in Note 2 to the Company' s consolidated financial statements included elsewhere in this Annual Report, the Company has a history of operating losses and expects to continue to incur losses in the foreseeable future, which raises substantial doubt regarding the Company' s ability to continue as a going concern. As described in further detail above, the Company currently has no sources of revenue and its ability to continue as a going concern is dependent on its ability to raise capital to fund operations and future business plans. Additionally, volatility in the capital markets and general economic and geopolitical conditions in the U. S. and globally may be a significant obstacle to raising the required funds as and when needed. The Company' s consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. If the going concern basis were not appropriate for these financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses and the balance sheet classifications used. If the Company is unable to continue as a going concern, its stockholders could suffer the loss of all or a substantial portion of their investment in us. The~~ RewinD- LB Trial is funded **primarily** by a non- dilutive grant that is subject to certain conditions for funding in subsequent years. **Funding of the remaining proceeds under the Company' s NIA Grant is also subject to uncertainty as a result of ongoing political uncertainty.** The Company' s RewinD- LB Trial is funded **primarily** by a grant from the NIA, the funds from which ~~will~~ **are scheduled to** be disbursed over the course of the study as costs are incurred. The Company' s receipt of the funds awarded to support future year costs are subject to both the availability of funds (i. e., the NIA is funded by Congress in subsequent fiscal years) and the Company' s demonstration of progress in the project that is in line with the timelines provided in the grant. If such funds are no longer available, including due to a government shutdown **or executive order** that prohibits the disbursal of such funds, or the Company fails to demonstrate such progress, the Company' s ability to continue its clinical programs may be impaired and delayed, and the Company may otherwise need to seek additional financing. For example, **in March 2025,** the Company was granted access to ~~$ 7. 3 million under the NIA Grant in February 2024,~~ 90 % of the full amount of the ~~second~~ **third** year of funding provided for in the NIA Grant, due to current NIA policy as a result of the U. S. government currently being funded on the basis of a continuing resolution. The timing of the Company' s receipt of the remaining 10 % of the grant ~~, or $ 0. 8 million,~~ of current year funding is dependent upon and subject to U. S. congressional approval of a final appropriations bill. In addition, ~~in December~~ **on January 20, ~~2023~~ 2025** , ~~we submitted a request~~ **President Trump was inaugurated and signed Executive Order 14158 – Establishing and Implementing the President' s " Department of Government Efficiency ". In the weeks that have followed, media has reported widely on extensive government- wide cuts enacted under the purported authority of the Department of Government Efficiency resulting in speculation regarding if and to what extent existing contractual and payment obligations will continue to be honored by certain U. S. federal agencies, including the NIA. In particular, the Trump administration has attempted to prevent the NIH from effectively reviewing and awarding grants, or paying out funds under already awarded grants. If this hold on government grants continues, or if the U. S. government takes any other actions to limit funds available** for **life science** ~~supplemental funds in the amount of $ 4. 0 million, of which, if approved, $ 3. 9 million would be received in the current year and the remainder would be received in next the funding year. The request for~~ **or healthcare research** ~~supplemental funds was initially reviewed by the NIA in January 2024 but, due to the NIA currently working under the Continuing Resolution, completion of the review was delayed and the request is currently~~

~~scheduled to be reviewed for~~ **or** ~~approval in May 2024. We currently expect to receive the~~ **other projects** ~~remaining 10 %~~, **it may have** ~~or $ 0. 8 million, of the previously approved year 2 funding upon U. S. congressional approval of~~ a **material and adverse impact on** ~~final appropriations bill, the supplemental amount of $ 4. 0 million following NIA review of~~ our **revenue** ~~supplement request~~, **business** ~~and the year 3 funding of $ 6. 2 million in February 2025. However~~, **financial condition** ~~there can be no guarantee that the NIA will approve this supplement request~~ and **results** ~~that any such amounts will be received. If the Company is unable to secure additional capital through approval~~ of **operations** ~~the supplemental request or other means, it may have to delay, scale back or discontinue its development or commercialization activities for neflamapimod~~. The Company could be subject to audit and repayment of the NIA Grant. In connection with the NIA Grant, the Company may be subject to routine audits by certain government agencies. As part of an audit, these agencies may review the Company' s performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the applicable NIA Grant. If any of the Company' s expenditures are found to be unallowable or allocated improperly or if the Company has otherwise violated terms of the NIA Grant, the expenditures may not be reimbursed and / or it may be required to repay funds already disbursed. Any such audit may result in a material adjustment to the Company' s results of operations and financial condition and harm the Company' s ability to operate in accordance with its business plan. The Company may be required to make significant payments to Vertex in connection with the Company' s license agreement. Pursuant to the Vertex Agreement, the Company previously acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of AD and other CNS disorders. Under the Vertex Agreement, the Company is subject to significant potential future obligations, including payment of development milestones and royalties on net product sales, as well as other material obligations. The Vertex Agreement sets forth specific regulatory and product approval events and the related payments that the Company would be obligated to make to Vertex, if and when such events occur. Among other obligations, the Vertex Agreement provides that the Company will make royalty payments to Vertex in the event aggregate net sales for a commercialized licensed product meet specified thresholds, subject to adjustment in the event of certain events, such as the absence of a valid patent claim or if fees are due to a third party for a license necessary for the development, manufacture, sale or use of a licensed product. Such royalties will be on a sliding scale as a percentage of net sales, depending on the amount of net sales in the applicable years. The Company is also obligated to make a milestone payment to Vertex upon net sales reaching a certain specified amount in any 12- month period. The first expected milestone events concern filing of an NDA with the FDA for marketing approval of a licensed product in the U. S., or a similar filing for a non- U. S. major market. Thus, although the Company does not expect any milestone or royalty payments to be due until such time, these potential obligations represent significant cash amounts that it may ultimately be obligated to pay. The Company cannot guarantee that it will have sufficient funds available to meet its obligations if and when these payments become due. The obligation to pay some or all of these milestone and royalty amounts may materially harm the Company' s development efforts, as well as its overall financial condition. The Company may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. The Company intends to focus its limited financial and other resources on developing neflamapimod and future product candidates for specific indications that the Company identifies as most likely to succeed, in terms of both regulatory approval and commercialization. As a result, the Company may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. The Company' s resource allocation decisions may cause the Company to fail to capitalize on viable commercial products or profitable market opportunities. Spending on current and future research and development programs and on product candidates for specific indications may not yield any commercially viable products. If the Company does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for the Company to retain sole development and commercialization rights to such product candidate **. The Company' s business may be impacted by macroeconomic conditions, including fears concerning the financial services industry, inflation, volatility in interest rates and volatile market conditions, and other uncertainties beyond the Company' s control. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. The Company' s ability to effectively run its business could be adversely affected by general conditions in the global economy and in the financial services industry. Various macroeconomic factors could adversely affect the Company' s business, including fears concerning the banking sector, volatility in inflation and interest rates and overall changes in economic conditions and uncertainties. A severe or prolonged economic downturn could result in a variety of risks, including the Company' s ability to raise additional funding on a timely basis or on acceptable terms, or at all. A weak or declining economy could also impact third parties upon whom the Company depends to run its business. Concerns over bank failures and bailouts and their potential broader effects and potential systemic risk on the banking sector generally and on the biotechnology industry and its participants may adversely affect the Company' s access to capital and its business and operations more generally. Although the Company assesses its banking relationships as it believes necessary or appropriate, its access to funding sources in amounts adequate to finance or capitalize the Company' s current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has arrangements directly, or the financial services industry or economy in general. Certain regulatory limitations may affect our ability to consummate future financings. If the Company' s public float as measured pursuant to General Instruction I. B. 6 to Form S- 3 falls below $ 75 million, the Company will be subject to the restrictions set forth in General Instruction I. B. 6 to Form S- 3 that limit**

its ability to conduct primary offerings under a Form S- 3 registration statement to one- third of the Company' s public float in any 12 calendar months – often referred to as the " baby shelf rules. " As of March 14, 2025, the Company' s public float calculated in accordance with General Instruction I. B. 6 of Form S- 3 was approximately $ 37. 3 million and, accordingly, we will be limited by the " baby shelf rules " unless and until its public float as measured pursuant to General Instruction I. B. 6 to Form S- 3 exceeds $ 75 million . Risks Related to the Company' s Product Development and Regulatory Approval The Company has invested almost all of its efforts and financial resources to date in the development of neflamapimod. To date, the Company has not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product or arranged for a third party to do so on its behalf, or conducted sales and marketing activities necessary for successful product commercialization. The Company' s future success is substantially dependent on its ability to successfully complete clinical development of, obtain regulatory approval for, and successfully commercialize neflamapimod as a treatment for DLB and additional indications, which may never occur. The Company expects a substantial portion of its efforts and expenditures over the next few years will be devoted to the advancement of neflamapimod' s clinical development. In order to be successful, the Company will need to successfully manage clinical and manufacturing activities, the pursuit of regulatory approval in multiple jurisdictions, securing manufacturing supply, building a commercial organization, and significant marketing efforts, among other requirements, before it can generate any revenues from commercial sales. The Company cannot be certain that it will be able to successfully complete any or all of these activities. Furthermore, the Company has not submitted an NDA to the FDA or comparable applications to other regulatory authorities for neflamapimod, and it does not expect to be in a position to do so in the near future, if ever. Significant additional clinical testing and research will be required before it can file an NDA or any other application seeking approval of neflamapimod for the treatment of DLB, or any other indication. If the Company is unable to obtain the necessary regulatory approvals for and commercialize neflamapimod, it would materially adversely affect the Company' s financial position, and the Company may not be able to generate sufficient revenue to continue its business. Clinical trials are expensive and can be difficult to design and implement. Such trials can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any stage during the clinical development process. The Company may experience difficulties in initiating and completing the clinical trials that it intends to conduct, and the Company does not know whether such trials will enroll patients on time, need to be redesigned, or be completed on schedule, if at all. In connection with designing and conducting its clinical trials, the Company faces significant risks, including that its product candidate may not prove to be efficacious, patients may suffer adverse effects for reasons that may or may not be related to the product candidate being tested, the results may not confirm the positive results of its earlier preclinical studies and clinical trials, **the FDA may disagree with the Company' s interpretation of the clinical trial data or how those data inform the design of future clinical trials,** and the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to support approval ~~. For example, in the Company' s AscenD- LB Trial, neflamapimod demonstrated improvement versus placebo in dementia severity and motor function. Although the Company' s ongoing RewinD- LB Trial was designed as a confirmatory, hypothesis- testing, randomized, double- blind placebo- controlled clinical study of neflamapimod in subjects with DLB, the RewinD- LB Trial may not be successful, or the FDA may disagree with the Company' s interpretation of the clinical trial data or how those data inform the design of a potentially pivotal Phase 3 clinical trial for the Company' s lead indication. In addition, even if the AscenD- LB Trial results are confirmed in the RewinD- LB Trial, the Company will still need to successfully complete additional clinical trials, including a Phase 3 trial, before it is prepared to submit an NDA for regulatory approval of neflamapimod in patients with DLB, assuming that the data collected from the Company' s clinical trials are deemed sufficient to support the submission of an NDA~~ . The Company cannot predict with any certainty if or when it might complete its development efforts and submit an NDA for regulatory approval of neflamapimod, or whether any such NDA will be approved by the FDA. An NDA or comparable foreign submission seeking marketing approval for neflamapimod also may not be accepted by FDA or foreign regulatory authorities due to, among other reasons, the content or formatting of the submission. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in the Company' s failure to obtain regulatory approval to market neflamapimod as a treatment for DLB or any other indication, which would significantly harm the Company' s business, results of operations, and prospects. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process ~~,~~ and determining when or whether regulatory approval will be obtained for any new product candidate. Accordingly, even if the Company believes the data collected from its clinical trials are promising, such data may not be sufficient to support approval by the FDA or any comparable foreign regulatory authority. As a result, the Company may be required to conduct additional nonclinical studies, alter its proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which it hopes to conduct clinical trials and develop and market neflamapimod or any of other product candidates, if approved. The Company is also generally required to register certain clinical trials and post the results of completed clinical trials on a government- sponsored database, such as ClinicalTrials. gov in the U. S., within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. The risk of failure in drug development is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, a company must complete nonclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical trials are expensive, difficult to design and implement and can take several years to complete, and their outcomes are inherently uncertain with the potential for failure at any time during the clinical development process. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and early- stage clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if neflamapimod will receive marketing approval. The Company may experience numerous unforeseen events during, or as a result of, its clinical trials that could delay or prevent its ability to receive marketing approval

or commercialize neflamapimod for DLB or any other indication. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than the Company anticipates or for a variety of other reasons, such as: ● delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that the Company is able to execute; ● delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB or ethics committee at each clinical site to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial; ● delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs; ● inability, delay or failure in identifying, recruiting, and training suitable clinical investigators; ● delay or failure in recruiting, screening, and enrolling suitable subjects to participate in a trial; ● delay or failure in having subjects complete a trial or return for post-treatment follow- up; ● delays caused by operational issues at clinical trial sites, including insufficient staffing; ● changes to the clinical trial protocols and / or changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; ● clinical sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with **GCP** ~~Good Clinical Practices~~ or other regulatory requirements, or dropping out of a trial; ● failure to initiate or delay of or inability to complete a clinical trial as a result of the authorizing IND or foreign clinical trial application being placed on temporary or permanent clinical hold by the FDA or comparable foreign regulatory authority; ● lack of adequate funding to continue a clinical trial, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of the Company' s CROs and other third parties, or the cost of clinical trials being greater than the Company anticipated; ● delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of drug product for use in clinical trials or the inability to do any of the foregoing; ● developments on trials conducted by competitors for related technology that raise FDA or foreign regulatory authority concerns about risk to patients of a technology or in any indication more broadly; ● clinical trials of the Company' s product candidates may produce negative or inconclusive results, and the Company may decide, or regulators may require the Company, to conduct additional nonclinical studies, clinical trials or abandon product development programs; ● the number of patients required for clinical trials of the Company' s product candidates may be larger than the Company anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of these clinical trials at a higher rate than it anticipates; ● the Company' s third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to the Company in a timely manner, or at all; ● regulators, the IRB or a Data Safety Monitoring Board if one is used for the Company' s clinical trials, may require that the Company suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, or a finding that the participants are being exposed to unacceptable health risks; ● the supply or quality of the Company' s product candidates or other materials necessary to conduct clinical trials of the Company' s product candidates may be insufficient or inadequate; ● transfer of manufacturing processes to larger- scale facilities operated by a CMO, and delays or failure by the Company' s CMOs or the Company to make any necessary changes to such manufacturing process; ● the FDA or comparable foreign regulatory authorities may require the Company to submit additional data or impose other requirements before permitting it to initiate a clinical trial; or ● changes in governmental regulations or administrative actions. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for neflamapimod or any other future product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with the Company' s clinical trial design and the Company' s interpretation of data from clinical trials or may change the requirements for approval even after the FDA has reviewed and commented on the design for the Company' s clinical trials. If the Company is required to conduct additional clinical trials or other preclinical studies of neflamapimod in various disease conditions beyond those that the Company currently contemplates, if it is unable to successfully complete clinical trials of the Company' s product candidates or other studies, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, the Company may: ● be delayed in obtaining marketing approval for its product candidates; ● not obtain marketing approval for its product candidates at all; ● obtain approval for indications or patient populations that are not as broad as intended or desired; ● obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for its products or inhibit its ability to successfully commercialize the Company' s products; ● be subject to additional post- marketing restrictions or requirements, including post- marketing testing; or ● have the product removed from the market after obtaining marketing approval. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for neflamapimod would delay the Company' s commercialization prospects, substantially increase the costs of commercializing neflamapimod, and severely harm the Company' s business and financial condition. **The Company has concentrated its recent research and development efforts on the treatment of DLB, a disease that has seen limited success in drug development. The ability to successfully develop drugs for DLB and other age- related neurologic disorders is extremely difficult and is subject to a number of unique challenges. In addition, its rationale for neflamapimod in the treatment of DLB is based on a scientific understanding of the disease that may be wrong.** Drug development in the field of brain diseases, including age- related neurologic disorders and other neurodegenerative diseases in particular, has seen very limited success historically. There have been limited efforts by biopharmaceutical and pharmaceutical companies to develop treatments for DLB and there are no therapies available for patients that have been approved with a specific indication to treat DLB. Only symptomatic therapies that are approved for other diseases, generally either AD or **PD** ~~Parkinson' s disease~~, are currently utilized to manage patients with DLB. In addition, many potential disease- modifying therapies have been evaluated in other neurodegenerative diseases, particularly in AD, and these have encountered challenges in their development and, as a result, only recently two disease-

modifying treatments to treat AD have been approved in the U. S. Developing a product candidate for treatment of these brain diseases is extremely difficult and subjects the Company to a number of challenges, including obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on. The Company' s approach to the treatment of DLB focuses in large part on neflamapimod' s ability to inhibit the intra- cellular enzyme p38α. The expression of p38α is considered to be a critical contributor in the toxicity of inflammation, alpha- synuclein, amyloid- beta and tau to neurons and synapses, which the Company and other scientific experts believe leads to synaptic dysfunction. Synaptic dysfunction, specifically impaired synaptic plasticity, leads to disruption of episodic memory and is a significant event in the development and symptomatology of DLB. However, the Company cannot be certain that its approach will lead to the development of approvable or marketable products. To date **,** the only drugs approved by the FDA to treat DLB have addressed the disease' s symptoms. In addition, there has never been an approval of a drug in DLB and therefore, there are no regulatory precedents for endpoints in that indication. Consequently, the FDA has a limited set of products to rely upon in evaluating neflamapimod. This could result in a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of neflamapimod for the treatment of DLB. Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by the Company or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the Company' s business and the market price of its common stock **. Clinical results observed in the Company' s Phase 1, Phase 2 and open- label clinical trials, including the 16- week Extension phase data from the RewinD- LB Trial, evaluating neflamapimod are not regulatory evidence of drug safety or efficacy. Data results from the Company' s non- Phase 3 studies do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for neflamapimod in DLB or any other indication. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized, placebo- controlled studies. The size and open- label design of portions of the Company' s non- Phase 3 studies may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. Different methods of statistical analysis on clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our non- Phase 3 studies add complexity or limitations to the scope of data interpretation. In addition, conclusions based on data from analyses of Phase 1 and Phase 2 clinical studies and open- label results may not be reproduced when implemented in large, well- controlled, randomized clinical trials. Particular caution should be exercised when interpreting preliminary data, data relating to a small number of patients and data from open- label uncontrolled studies, which are generally not capable of providing interpretable evidence of efficacy. There can be no assurance that future large, well- controlled, multi- dose studies will demonstrate the safety, tolerability or efficacy of neflamapimod to treat patients with any indication, including DLB. Even if our clinical trials for neflamapimod are completed as planned, we cannot be certain that their results will support the substantial evidence of safety and efficacy needed to obtain regulatory approval. The failure of neflamapimod to show safety, tolerability or efficacy in any future clinical studies would significantly harm the Company' s business** . The timely completion of clinical trials in accordance with their protocols depends on, among other things, the Company' s ability to enroll a sufficient number of research participants who remain in the study until its conclusion. The Company may encounter delays in enrolling, or be unable to enroll, a sufficient number of individuals to complete any of its clinical trials, and even once enrolled the Company may be unable to retain a sufficient number of participants to complete any of its trials. Subject enrollment and retention in clinical trials depends on many factors, including: ● the eligibility criteria defined in the protocol; ● the size of the patient population required for analysis of the trial' s primary endpoints; ● the nature of the trial protocol; ● the proximity of potential subjects to clinical sites; ● the existing body of safety and efficacy data with respect to the product candidate; ● the Company' s ability to recruit clinical trial investigators with the appropriate competencies and experience; ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies; ● competing clinical trials being conducted by other companies or institutions; ● the risk that participants enrolled in clinical trials will drop out of the trials before completion; and ● the operational efficiency of trial sites, including sufficient staffing. In addition, the U. S. Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial ~~,~~ or other " pivotal study " of a new drug or biologic to support **MA** ~~marketing authorization~~ , to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we or our licensing partners must submit a diversity action plan to the FDA by the time a Phase 3 trial, or pivotal study, protocol is submitted to the agency for review, unless we or our licensing partners are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates **but** ~~or what specific information FDA will expect in such plans. However~~ , initiation of such trials may be delayed if the FDA objects to a proposed diversity action plans for any future Phase 3 trial of our product candidates **. We** ~~, and we~~ or our licensing partners may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan. Furthermore, any negative results the Company may report in clinical trials may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same product candidate. Delays or failures in planned enrollment or retention of clinical trial subjects ~~, including in the Company' s ongoing RewinD- LB Trial,~~ may result in increased costs or program delays, which could have a harmful effect on the Company' s ability to develop a product candidate or could render further development impossible. The results of preclinical studies and early clinical trials of a product candidate, including neflamapimod, may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry, both generally and in the DLB treatment space in particular, have suffered significant setbacks in advanced clinical

trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if the Company' s clinical trials for neflamapimod are completed as planned, including ~~a~~ **any** future Phase 3 trial, the Company cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval, and the Company may decide, or regulators may require it, to conduct additional clinical trials. In addition, from time- to- time, the Company may announce or publish preliminary, topline, or interim data from its clinical trials, which are based on a preliminary analysis of then- available data. Such results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. The Company also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, which may prove to be incomplete or flawed, and it may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary and interim data 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 interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data the Company previously published. As a result, preliminary and interim data are not necessarily predictive of final results and should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm the Company' s business prospects. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain approval from the FDA, the EMA or other regulatory agencies for their products. Others, including regulatory agencies, may not accept or agree with the Company' s assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and the Company in general. In addition, the information the Company chooses to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Others may not agree with what the Company determines is the material or otherwise appropriate information to include in its disclosure, and any information the Company determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding neflamapimod, a future product candidate, or the Company' s business. If the interim, preliminary, or topline data that the Company reports differ from later, final or actual results, or if others, including the FDA and comparable foreign regulatory authorities, disagree with the conclusions reached, the Company' s ability to obtain approval for and, if approved, commercialize its product candidates may be harmed, which could harm its business, financial condition, results of operations and prospects. Regulatory authorities, including the FDA, may not accept data from clinical trials conducted outside of their jurisdiction. The Company has in the past and may in the future conduct additional clinical trials evaluating its product candidates, including neflamapimod, outside the U. S. The acceptance of trial data from clinical trials conducted outside the U. S. by the FDA may be subject to certain conditions or may not be accepted at all, and other comparable non- U. S. regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their jurisdiction. In cases where data from non- U. S. clinical trials are intended to serve as the basis for marketing approval in the U. S. **and the trial is not conducted under the IND** , the FDA will generally not accept such foreign trial data unless: (i) the data are determined to be applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the FDA is able to validate the data through an onsite inspection, if necessary. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many comparable non- U. S. regulatory authorities have similar approval requirements. There can be no assurance that the FDA will accept data from trials conducted outside of the U. S. or that any comparable non- U. S. regulatory authority will accept data form trials conducted outside of the applicable jurisdiction. If the FDA or any comparable non- U. S. regulatory authority does not accept such data or believes that additional data is necessary to supplement such data, it would result in the need for additional trials, which would be costly and time-consuming, could delay a product candidate' s development plan, and which may result in product candidates not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the U. S. may also expose the Company to additional risks, including risks associated with the following, among other things: additional foreign regulatory requirements; foreign exchange fluctuations; compliance with foreign manufacturing, customs, shipment and storage requirements; the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in standard- of- care; cultural differences in medical practice and clinical research; diminished protection of intellectual property rights; and compliance with general local legal requirements. **In August 2024, we initiated a Phase 2a study in Strasbourg, France, to evaluate a twice daily regimen (80mg BID) of neflamapimod in up to 25 patients with DLB with MCI (MoCA score > = 18 during screening). The primary objective of the study is to obtain additional PK data on a dosing regimen not previously used in any of our clinical trials (80mg BID) that is above the maximum dosage currently permitted by the FDA' s partial clinical hold on neflamapimod. If it is determined that the 80mg BID dosing regimen is safe and tolerable, we may in the future seek to use data from this trial to support an application to increase neflamapimod' s no adverse event level and remove the existing partial clinical hold. However, because this data is being obtained from a trial conducted outside of the U. S., it is possible the FDA will not accept such data.** Safety issues with neflamapimod or with any other product candidate the Company may develop or acquire in the future, or with product candidates or approved products of third parties that are similar to the Company' s product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval, if any, or may otherwise cause the Company to modify or supplement its clinical development program. Results of any clinical trial the Company conducts could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. **SAEs** ~~Serious adverse events~~ or undesirable side effects caused by neflamapimod, or any other product candidates the Company may develop or acquire, could cause it 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 comparable foreign authorities. Many compounds that have initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Further, problems with product candidates or approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as neflamapimod or any future product candidates of the Company could adversely affect the development, regulatory approval and commercialization of the Company' s product candidates. For example, to date, neflamapimod has been evaluated in over ~~200 patients~~ **500 participants** , at doses up to ~~750~~ **750mg** ~~mg~~ twice a day, and up to ~~24~~ **32** weeks of treatment. The adverse effects ~~(side effects)~~ seen in more than 5 % of neflamapimod- treated ~~patients~~ **participants in completed trials, which** include headache ~~(10 % in neflamapimod- treated patients vs. 5 % in placebo recipients)~~ , diarrhea ~~(10 % vs. 5 %)~~ , abdominal pain ~~(6 % vs. 5 %)~~ , respiratory infection ~~(5 % vs. 5 %)~~ , and falls ~~(5 % vs. 5 %). In each case~~ , ~~these events~~ were generally mild ~~and in all but one case (a case of diarrhea and abdominal pain) did not lead to treatment discontinuation~~ . In addition, increased levels of certain " liver enzymes " in the blood are a well- known dose- dependent side effect of p38 MAPK inhibitors. These liver enzymes, aspartate aminotransferase and alanine aminotransferase, are proteins ~~are~~ commonly produced in the liver, the measurements of which can help doctors evaluate liver function. In an early 2000s study of neflamapimod conducted by Vertex, during 12 weeks of dosing at 250mg BID (i. e., four- fold higher daily dosing than the dose in the RewinD- LB Trial) in 44 subjects with **RA** ~~rheumatoid arthritis~~ , elevations in such liver enzymes levels were noted in six subjects (14 %). After the Company acquired an exclusive license from Vertex to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders, the Company submitted an IND application to the DNP in February 2015. The DNP cleared the Company' s clinical trial application in March 2015. However, in August 2015, following a standard review of the long- term animal toxicity studies, the DNP placed a partial clinical hold on the Company' s then ongoing Phase 2a study in AD and any subsequent studies proposed under the IND. A partial clinical hold means that the FDA suspends part of the clinical work requested under the IND (e. g., a specific protocol or part of a protocol is not allowed to proceed); however, all other protocols and / or remaining parts of the protocol are allowed to proceed under the IND. Under DNP' s partial clinical hold that remains in effect for the neflamapimod IND, the agency limited administration of neflamapimod to doses that lead to plasma drug levels that provide a ten- fold safety margin to human subjects, based on the plasma drug levels in animals that had previously led to minimal or equivocal toxicity findings. The Company' s current understanding of plasma drug levels achieved with neflamapimod in humans means that its investigational dosing in the U. S. is limited by this partial clinical hold to no more than **40mg TID** ~~40 mg three times daily~~ in patients weighing 50 kg (110 lbs.) or more. ~~The~~ **Accordingly, the** Company' s ongoing RewinD- LB Trial is being conducted at 40mg **TID** ~~three times daily~~ (limited to patients weighing 50 kg (110 pounds) or more within the U. S., and not so limited outside the U. S.) ~~and the Company does not expect this partial clinical hold to impact its ongoing and planned clinical trials or its current development plan for neflamapimod.~~ With respect to the adverse effects discussed above, the ~~patients~~ **participants** were asymptomatic, there were no associated increases in bilirubin, and the elevations resolved with treatment discontinuation. Furthermore, no liver enzyme abnormalities were observed in the AscenD- LB Trial. However, as the Company continues the development and clinical trials of neflamapimod, treatment- related SAEs may arise in the future. Side effects that are deemed to be drug- related could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects in one of the Company' s clinical trials for neflamapimod in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of the Company' s product candidate in other indications. These side effects may not be appropriately recognized or managed by the treating medical staff. In addition, discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval **. On the other hand, many drugs provide superior efficacy at higher doses and, if determined to be safe and tolerable, higher doses of neflamapimod may be desirable for a variety of reasons. Accordingly, the Company is currently undertaking a number of studies, including our Phase 2a DLB trial in Strasbourg, France, and several preclinical studies, to further evaluate the safety and tolerability profile of higher doses of neflamapimod, including 80mg BID** . If the Company or others identify undesirable side effects caused by the mechanisms of action of a product candidate or a class of product candidates, the FDA may require the Company to conduct additional clinical trials, or to implement a REMS program prior to commercial approval. Alternatively, regulatory authorities may not approve the product candidate or, as a condition of approval, may require specific warnings and contraindications or place certain limitations on how the Company can promote the drug. Following a potential future drug product approval, regulatory authorities might also withdraw such approval due to the discovery of previously unknown safety issues relating to the product and require the Company to take its drug off the market. Any of these occurrences may harm the Company' s business, financial condition and prospects significantly. Further, clinical trials, by their nature, utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of neflamapimod or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If neflamapimod, or any other product candidates the Company may develop or acquire, receives marketing approval and the Company or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw or limit their approval of such product candidates; ● regulatory authorities may require the addition of labeling statements, such as a " Boxed " Warning or a contraindication; ● the Company may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates; ● the FDA may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, and regulatory authorities in other jurisdictions may require comparable risk mitigation plans; ● the Company may be subject to regulatory investigations and government enforcement actions; ● the FDA or a comparable foreign

regulatory authority may require the Company to conduct additional clinical trials or costly post- marketing testing and surveillance to monitor the safety and efficacy of the product; ● the Company may decide to recall such product candidates from the marketplace after they are approved; ● the Company could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and ● the Company' s reputation may suffer. The Company may be unable to obtain regulatory approval in the U. S. or foreign jurisdictions and, as a result, be unable to commercialize its product candidates and its ability to generate revenue will be materially impaired. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating companies such as ours are not always applied predictably or uniformly and can change. Any analysis we perform of data from **CMC** ~~chemistry, manufacturing and controls~~, preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the ~~United States~~ **U. S.** , including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the ~~United States~~ **U. S.** , a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If the Company seeks to enter into collaborative arrangements or strategic alliances for its drug candidates, but fails to enter into and maintain successful relationships, it may have to reduce or delay its drug development activities or increase its expenditures. An important element of a biotechnology company' s strategy for developing, manufacturing and commercializing its drug candidates may be to enter into strategic alliances with pharmaceutical companies or other industry participants to advance its programs and enable it to maintain its financial and operational capacity. Biotechnology companies at the Company' s stage of development sometimes rely upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing. To date, the Company has not entered into any collaborative arrangements or strategic alliances, and it may face significant competition in seeking such relationships. In addition, such arrangements may place the development of the Company' s drug candidates outside its control, require the Company to relinquish important rights, or may otherwise be on terms unfavorable to the Company. The Company may not be able to negotiate collaborations and alliances on acceptable terms, if at all. If the Company enters a collaborative arrangement and it proves to be unsuccessful, the Company may have to delay, or limit the size or scope of, certain of its drug development activities. Alternatively, if the Company elects to fund drug development or research programs on its own, it will have to increase its expenditures and will need to obtain additional funding, which may not be available to the Company on acceptable terms, if at all. If the Company is unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, its development programs may be adversely impacted. There are a number of programs administered by the FDA and other regulatory bodies to facilitate and expedite development of drugs in areas of unmet medical need. For example, neflamapimod received a fast track designation in October 2019 from the FDA for investigation as a treatment of DLB. Fast track designation is granted by FDA, in response to a sponsor' s request, upon a determination that the product candidate is intended to treat a serious or life- threatening disease or condition and has the potential to address an unmet medical need, meaning it could provide a therapeutic option for patients where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation does not ensure that neflamapimod will receive marketing approval or that approval will be granted within any particular timeframe. Although fast track designation and other available FDA programs may expedite the development or approval process for certain drug candidates, such programs do not change the standards for approval, and the Company may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation for neflamapimod if it believes that the designation is no longer supported by data from the Company' s clinical development program. Neflamapimod may not qualify for or maintain designations under this or other programs under any of the FDA' s existing or future programs to expedite drug development in areas of unmet medical need. The Company' s inability to fully take advantage of these programs may require the Company to run larger trials, incur delays, lose opportunities that may not otherwise be available to it, and incur greater expense in the development of its product candidates. The **FDA granted orphan drug designation for neflamapimod for certain indications, which might not provide the intended benefit thereof. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug product if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the U. S. In November 2024, the Company received orphan designation from the FDA for neflamapimod for**

the treatment of FTD. There is no guarantee that neflamapimod will be successfully approved by the FDA for such indication, neflamapimod will be commercially successful for such indication in the marketplace, if approved, or that another product will not be approved for the same indication ahead of neflamapimod. Even if we obtain orphan product exclusivity for neflamapimod for the treatment of FTD, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug product is approved, the FDA can subsequently approve another drug or biologic for the same disease or condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, orphan product exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The Company relies on third parties to conduct, supervise and monitor its clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, the Company' s business will be harmed. Although the Company designs and manages its nonclinical studies and clinical trials, ~~it~~ **the Company has a limited number of employees and** does not currently have the ability to conduct clinical trials for neflamapimod on its own. The Company has relied, and will continue to rely, on third parties such as CROs, medical institutions, and clinical investigators to ensure the proper and timely conduct of its clinical trials. The Company' s reliance on CROs for clinical development activities limits its control over these activities, but the Company remains responsible for ensuring that each of its trials is conducted in accordance with the applicable protocol, as well as legal and regulatory and scientific standards. The Company has limited control over these third parties, and they may not devote sufficient time and resources to the Company' s projects, or their performance may be substandard, resulting in clinical trial delays or suspensions, delays in submission of marketing applications or failure of a regulatory authority to accept the Company' s applications for filing. There is no assurance that the third parties the Company engages will be able to provide the functions, tests, activities or services as agreed upon, or provide them at the agreed upon price and timeline or to the Company' s requisite quality standards, including due to geopolitical events, natural disasters, public health emergencies or pandemics, or poor workforce relations or human capital management. The Company and its CROs are required to comply with GLP requirements for preclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA and required by comparable foreign regulatory authorities. If the Company or its CROs fail to comply with GCP requirements, the clinical data generated in the Company' s clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require the Company to perform additional clinical trials before approving marketing applications for the Company' s product candidates. There is also no assurance these third parties will not make errors in the design, management or retention of the Company' s data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could also delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the Company' s clinical protocols or regulatory requirements or for any other reason, the Company' s clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that it develops. As a result, the Company' s financial results and the commercial prospects for neflamapimod would be harmed, its costs could increase, and its ability to generate revenue could be delayed, all of which could have a material adverse effect on the Company' s business, financial condition, results of operations and prospects. The Company has employed several different CROs for clinical trial services. Although the Company believes there are numerous alternatives to provide these services, in the event that it seeks a new CRO, the Company may not be able to enter into replacement arrangements without delays or incurring additional expenses. Switching or adding additional CROs involves substantial cost and requires management' s time and focus. In addition, there is a natural transition period when a new CRO commences work. Though the Company intends to carefully manage its relationships with its CROs, there can be no assurance that the Company will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on its business, financial condition and prospects. The Company' s reliance on third parties for the production of neflamapimod may result in delays in the Company' s clinical trials or regulatory approvals and may impair the development and ultimate commercialization of neflamapimod, which would adversely impact the Company' s business and financial position. The Company has no manufacturing facilities and does not have extensive experience in the manufacturing of drugs or in designing drug- manufacturing processes. The Company currently relies on third parties for the manufacture of drug substance, the manufacture of drug product, and the packaging of drug product for clinical use. This reliance on **CMOs** ~~contract manufacturers~~ and suppliers subjects the Company to inherent uncertainties related to product safety, availability, security and cost. Holders of NDAs, or other forms of FDA approvals, or those distributing a regulated product under their own name, are ultimately responsible for compliance with manufacturing obligations even if the manufacturing is conducted by a third party. The Company further intends to rely on third- party CMOs for the production of commercial supply of neflamapimod if it is ultimately approved. If CMOs cannot successfully manufacture drug substance and drug product for the Company' s neflamapimod program, or any other product candidate that the Company may develop or acquire in the future, in conformity to its specifications and the applicable regulatory requirements, the Company will not be able to secure or maintain regulatory approval for the use of that product candidate in clinical trials, or for commercial distribution of that product candidate, if approved. Additionally, any problems the Company experiences with any such CMOs could delay the manufacturing of its product candidates, which could harm its results of operations. All drug manufacturers and packagers are required to operate in accordance with FDA- mandated cGMPs. A failure of any of the Company' s current or future CMOs to establish and follow **adequate procedures to ensure compliance with applicable** ~~cGMPs~~ **cGMP requirements** and to document their adherence

to such practices may lead to significant delays in obtaining regulatory approval of product candidates or the ultimate launch of products based on the Company' s product candidates into the market. In the event of such failure, the Company could also face fines, injunctions, civil penalties, and other sanctions. Further, if the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve a CMO' s facilities for the future commercial manufacture of neflamapimod, or if it withdraws any such approval or finds deficiencies in the future, the Company may need to find alternative manufacturing facilities, which would delay its development program and significantly impact its ability to obtain regulatory approval for or commercialize neflamapimod. In addition, if any facility of the Company' s third- party drug manufacturers or suppliers were to suffer an accident or a force majeure event such as war, missile or terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of its backup generators or similar event, the Company could be materially adversely affected and any of its clinical trials could be materially delayed. An extended shut down may force the Company to procure a new research and development facility or another manufacturer or supplier, which could be time-consuming. The Company' s ongoing RewinD- LB Trial is being conducted with a drug substance (the API) previously manufactured at a third- party CMO. Future supplies of the neflamapimod drug substance could be interrupted from time to time, and the Company cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. During this period, the Company may be unable to receive investigational neflamapimod supplies or any other product candidates it may develop or acquire. In addition, a disruption in the supply of drug substance could delay the commercial launch of the Company' s product candidates, if approved, or result in a shortage in supply, which would impair its ability to generate revenues from the sale of its product candidates. Growth in the costs and expenses of raw materials may also impair the Company' s ability to cost effectively manufacture its product candidates. The Company also currently relies on a third- party CMO (different than that for the API) for the manufacture of neflamapimod drug product. The Company has used the same manufacturer for its neflamapimod drug product in all its clinical trials to date. If neflamapimod is ultimately approved for commercial sale, the Company expects to continue to rely on third- party contractors for manufacturing the drug product. Although the Company intends to do so prior to any commercial launch, it has not yet entered into long- term agreements for the commercial supply of either drug substance or drug product with its current manufacturing providers, or with any alternate manufacturers. While the Company believes that there are multiple alternative sources available for manufacturing of both drug substance and drug product in its neflamapimod program, the Company may not be able to enter into replacement arrangements, on acceptable terms or at all, without delays or additional expenditures. It cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in the Company' s development and commercialization efforts. Although the Company generally has not, and does not intend to, begin a clinical trial unless it believes it has on hand, or will be able to obtain, a sufficient supply of neflamapimod to complete the clinical trial, any significant delay in the supply of neflamapimod drug substance or drug product could considerably delay conducting the Company' s clinical trials and potential regulatory approval of its product candidates. Further, third- party suppliers, manufacturers, or distributors may not perform as agreed or may terminate their agreements with the Company, including due to the effects related to geopolitical events, natural disasters, public health emergencies or pandemics, ~~such as the COVID- 19 pandemic,~~ or force majeure events that affect their facilities or ability to perform. Any significant problem that the Company' s suppliers, manufacturers, distributors or regulatory service providers experience could delay or interrupt supply of materials necessary to produce the Company' s product candidates. Failure to obtain the needed quantities of the Company' s product candidates could have a material and adverse effect on its business, financial condition, results of operations and prospects. If the Company changes the manufacturers of its product candidates, it may be required to conduct comparability studies evaluating the manufacturing processes of the product candidates **and incur other costs related to the technology transfer** . The FDA and other regulatory agencies maintain strict requirements governing the manufacturing process for prescription drug products that would apply to the Company' s product candidates, if approved. For example, when a manufacturer seeks to make any change to the manufacturing process, the FDA typically requires the applicant to conduct nonclinical and, depending on the magnitude of the changes, potentially clinical comparability studies that evaluate the potential differences in the product candidates resulting from the change in the manufacturing process. If the Company were to change manufacturers of its drug substance or drug product during or after the clinical trials and regulatory approval process for neflamapimod or any of its other product candidates, the Company will be required to conduct comparability studies assessing product candidates manufactured at the new manufacturing facility. Further, manufacturing changes are generally categorized as having either a substantial, moderate, or minimal potential to adversely affect the identity, strength or quality of the drug product as they may relate to the safety or effectiveness of the product, and if a change has a substantial potential to have an adverse effect on the drug product, an applicant must submit and receive FDA approval of a prior approval supplemental application before the product made with the manufacturing change is distributed. Other forms of notice to the FDA are also required for manufacturing changes that have a moderate or minimal potential to have an adverse effect on the drug product' s safety or effectiveness. Regardless of the type of manufacturing change, the methods used and the facilities and controls used for the manufacture, processing, packaging, or holding of human drugs must comply with applicable cGMP regulations **. For example, if the Company decides to utilize a different CMO to manufacture future drug substance batches, certain compatibility studies may be required and the Company may incur additional costs related to the technology transfer** . Delays in designing and completing a comparability study to the satisfaction of the FDA or other regulatory agencies could delay or preclude the Company' s development plans and, thereby, delay the Company' s ability to receive marketing approval or limit its revenue and growth, once approved. In addition, in the event that the FDA or other regulatory agencies do not accept nonclinical comparability data, the Company may need to conduct a study involving dosing of patients comparing the two products. That study may result in a delay in the approval or launch of any of its product candidates. Risks Related to the Company' s Intellectual Property The Company relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to neflamapimod. The Company' s

commercial success depends in part on obtaining and maintaining proprietary rights in the U. S. and in international jurisdictions, and successfully defending these rights against third- party challenges if and as they occur. The Company seeks to protect its proprietary position by filing patent applications related to neflamapimod in the U. S. and in other countries. Although the Company has already obtained several issued patents and is working to expand its estate with additional patent applications, third parties may challenge the validity, enforceability, or scope of the Company' s patents, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to the Company could deprive it of rights necessary for the successful commercialization of neflamapimod, or any other product candidates it may develop. Further, if the Company encounters delays in regulatory approvals due to patent- related issues, the period of time during which it could market a product candidate under patent protection could be reduced. The Company' s issued patents and patent applications also remain subject to uncertainty and continued monitoring. The Company' s patent applications may fail to result in issued patents with claims that provide further coverage for neflamapimod in the U. S. or in foreign countries. The patent prosecution process is expensive and time- consuming, and the Company may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The Company may also fail to identify further patentable aspects of its research and development output before it is too late to obtain patent protection, including as a result of the publication of prior art. There is also no assurance that all potentially relevant prior art relating to the Company' s patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. The patent position of life sciences companies can often involve complex legal and factual questions and in recent years has been the subject of significant litigation. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, the Company cannot know with certainty whether it was the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. Further, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and the Company' s patents may be challenged in the courts or patent offices in the U. S. or other jurisdictions. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit the Company' s ability to prevent others from using or commercializing similar or identical technology and products. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of the Company' s patents, requiring it to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may also develop, seek approval for and launch generic versions of the Company' s products. Without patent protection for the Company' s current or future product candidates, these candidates may be open to competition from other products. As a result, the Company' s patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing products similar or identical to the Company' s. The Company may also seek to rely on regulatory exclusivity for protection of its product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or to maintain the extent or duration of such protections that the Company expects for its product candidates, if approved, could affect the Company' s decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on its revenue or results of operations. There is currently no composition of matter patent protection that covers neflamapimod. EIP acquired an exclusive license from Vertex in 2014 to develop and commercialize neflamapimod for the treatment of AD and other CNS disorders. This license covers know- how, preclinical and clinical data, and certain specified Vertex patent rights, including a composition of matter patent for neflamapimod that expired in 2017. EIP has thus focused its efforts on discoveries related to neflamapimod that are reflected in issued patents and patent applications covering a range of subjects, including: methods of treating patients suffering from DLB or AD, as well as methods of reducing amyloid plaque burden; methods of improving cognition and treating neurologic disorders; methods for promoting recovery of function in patients who have suffered acute neurologic injuries, including those resulting from various forms of stroke; and methods of treating patients suffering from dementia. In addition, EIP has filed patents related to formulations of neflamapimod, including pharmaceutical compositions for oral administration exhibiting desirable ~~pharmacokinetics~~ **PK** and processes for the manufacture thereof. In the U. S., the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent is limited. Accordingly, there is currently no composition matter patent protection that covers neflamapimod. Rather, the Company' s patents provide protection around either the use of neflamapimod for specific or medical indication (so called " use patents ") or the administration of neflamapimod in specific manner (e. g., at a specific dose or in a specific formulation). Patents that are not around composition of matter are narrower in scope (i. e., they do not protect against development of neflamapimod in an indication other than that the patent defines), may be more difficult to defend against challenges against validity, and may be more difficult to enforce against infringement. For these reasons, some pharmaceutical companies choose not to develop and / or license compounds that are not covered by a composition of matter patent. The Company owns a patent that is issued in the U. S. around co- crystals of neflamapimod, any of which if they were successfully developed would be afforded composition of matter patent protection under this patent. Accordingly, the lack of composition of matter patent protection that covers neflamapimod may subject the Company to increased risk of third- party litigation and / or reduce third party collaborators' interest in or valuation of neflamapimod, any of which could have an adverse effect on the Company' s business, financial condition or results of operations. If the Company fails to comply with its obligations under its existing license agreement with Vertex, or with any future intellectual property licenses with third parties, the Company could lose license rights that are important to its business. The Company is party to the Vertex Agreement pursuant to which it acquired an exclusive license to develop and commercialize neflamapimod for the diagnosis, treatment, and prevention of AD and other CNS disorders. Under the terms of the Vertex Agreement, the Company must use commercially

reasonable efforts during the license term to develop and obtain regulatory approval for a licensed product in specified major markets, and to promptly and effectively commercialize the licensed product once such approval is obtained. The Vertex Agreement also contains certain specified minimum diligence requirements, including making annual expenditures set forth in a development plan, and commencing a Phase 2 clinical trial of the licensed product within a specified time period. The Vertex Agreement provides that either party may terminate the agreement if the other party is in material breach of its obligations thereunder, following a 60- day notice and cure period, or if the other party files for bankruptcy, reorganization, liquidation, receivership, or an assignment of a substantial portion of assets to creditors. The Vertex Agreement also provides that in the event the Company materially breaches any of certain specified diligence obligations as to a specific major market, Vertex' s sole remedy for such breach, following the applicable notice and cure period, would be to terminate the license as to such specific major market country. Accordingly, any uncured, material breach under the Vertex Agreement could result in the loss of certain of its rights to neflamapimod and could compromise the Company' s development and commercialization efforts. This in turn would have an adverse effect on the Company' s business, which could be material. The Company may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or the Company may need to become involved in lawsuits to protect or enforce its patents, either of which could be costly and time consuming, potentially delay or prevent the development and commercialization of the Company' s product candidates, or put its patents and other proprietary rights at risk. The Company' s commercial success depends, in part, upon the Company' s ability to develop, manufacture, market and sell its lead product candidate, neflamapimod, without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. While the Company is not currently subject to any pending intellectual property litigation, and is not aware of any such threatened litigation, the Company may be exposed to future litigation by third parties based on claims that its product candidates, technologies or activities infringe the intellectual property rights of others. Some claimants may have substantially greater resources than the Company does and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than the Company. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target the Company in the future. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the Company' s product candidates may be subject to claims of infringement of the intellectual property rights of third parties. The Company may be subject to third- party claims including infringement, interference or derivation proceedings, reexamination proceedings, post- grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if the Company believes such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block the Company' s ability to commercialize its applicable product candidate unless the Company obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. These proceedings may also result in the Company' s patent claims being invalidated or narrowed in scope. In addition, a court may hold that a third- party is entitled to certain patent ownership rights instead of the Company. As a result of patent infringement claims, or in order to avoid potential infringement claims, the Company may choose to seek, or be required to seek, a license from the third party, which may require it to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give the Company' s competitors access to the same intellectual property rights. If the Company is unable to enter into a license on acceptable terms, it could be prevented from commercializing one or more of its product candidates, forced to modify such product candidates, or to cease some aspect of the Company' s business operations, which could harm the Company' s business significantly. In addition, if the breadth or strength of protection provided by the Company' s patents and patent applications is threatened, it could dissuade companies from collaborating with the Company to license, develop or commercialize current or future product candidates. If the Company were to initiate legal proceedings against a third party to enforce a patent covering one of its product candidates, the defendant could counterclaim that the Company' s patent is invalid or unenforceable. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, the Company cannot be certain that there is no invalidating prior art of which the Company and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, the Company would lose at least part, and perhaps all, of the corresponding patent protection on its product candidates. Furthermore, the Company' s patents and other intellectual property rights also will not protect its technology if competitors design around the Company' s protected technology without infringing its patents or other intellectual property rights. Finally, even if resolved in the Company' s favor, litigation or other legal proceedings relating to intellectual property claims may cause the Company to incur significant expenses and could distract its technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, which could damage the Company' s reputation, harm its business, and the price of its common stock could be adversely affected. The Company may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect the Company' s ability to develop, manufacture and market its product candidates. From time to time, the Company may identify patents or applications in the same general area as its products and product candidates. The Company may determine these third- party patents are irrelevant to its business based on various factors including its interpretation of the scope of the patent claims and its interpretation of when the patent expires. If the patents are asserted against the Company, however, a court may disagree with the Company' s determinations. Further, while the Company may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, the Company' s determination may be incorrect, and the issuing patent may be asserted against the Company. The Company cannot guarantee that it will be able to successfully settle or otherwise resolve such infringement claims. If the

Company fails in any such dispute, in addition to being forced to pay monetary damages, it may be temporarily or permanently prohibited from commercializing certain product candidates. The Company might also be forced to redesign its product candidates so that it no longer infringes the third- party intellectual property rights, if such redesign is even possible. Any of these events, even if the Company were ultimately to prevail, could require it to divert substantial financial and management resources that it would otherwise be able to devote to its business. The Company may be involved in lawsuits to protect or enforce its patents or other intellectual property or the intellectual property of its licensors, which could be expensive, time-consuming, and unsuccessful. Competitors may infringe the Company' s patents or other intellectual property or the intellectual property of its licensors. To cease such infringement or unauthorized use, the Company may be required to file patent infringement claims, which can be expensive and time- consuming and divert the time and attention of the Company' s management and scientific personnel. The Company' s pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues therefrom. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of the Company' s patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the Company' s patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of the Company' s patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put the Company' s patent applications at risk of not issuing. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may be a substantial diversion of employee resources from the Company' s business. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, the Company' s patents or patent applications. An unfavorable outcome could result in a loss of the Company' s current patent rights and could require the Company to cease using the related technology or to attempt to license rights to it from the prevailing party. The Company' s business could be harmed if the prevailing party does not offer it a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to the Company' s interests and, even if the Company is successful, may result in substantial costs and distract the Company' s management and other employees. Even if the Company establishes infringement, a 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. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of the Company' s confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of the Company' s common stock. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing the Company' s ability to protect its product candidates. The Company' s success is heavily dependent on intellectual property, particularly patents, and obtaining and enforcing patents in its industry involves both technological and legal complexity. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of the Company' s patents or narrow the scope of its patent protection. For example, the AIA, which was passed in September 2011, resulted in significant changes to the U. S. patent system. Pursuant to the AIA, the U. S. transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before the Company could therefore be awarded a patent covering an invention of the Company' s even if the Company made the invention before it was made by the third party. This requires the Company to be cognizant going forward of the time from invention to filing of a patent application. The AIA also introduced changes that provide opportunities for third parties to challenge any issued patent with the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Such changes could increase the uncertainties and costs surrounding the prosecution of the Company' s patent applications and the enforcement or defense of its issued patents. In addition, the laws of other countries may not protect the Company' s rights to the same extent as the laws of the U. S. The complexity and uncertainty of European patent laws has increased in recent years, and the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit the Company' s ability to obtain new patents in the future that may be important for its business. The Company enjoys only limited geographical protection with respect to certain patents, and it may not be able to protect its intellectual property rights throughout the world. Filing, prosecuting and defending patents covering the Company' s product candidates in all countries throughout the world would be prohibitively expensive and time- consuming with diminishing marginal returns. Competitors may use the Company' s technologies in jurisdictions where it has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection, but enforcement is not as strong as that in the U. S. or the European Union. These products may compete with the Company' s product candidates, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Although the Company intends to seek protection of its intellectual property rights in its expected significant markets, the Company cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which the Company may wish to market its product candidates. The Company may also decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding, which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for the Company to stop the infringement of its patents or marketing of

competing products in violation of the Company' s proprietary rights generally. Proceedings to enforce its patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert its efforts and attention from other aspects of the Company' s business, could put the Company' s patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing, and could provoke third parties to assert claims against the Company. The Company may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If the Company is forced to grant a license to any third parties with respect to any patents relevant to the Company' s business, its competitive position may be impaired. The lives of the Company' s patents may not be sufficient to effectively protect the Company' s products and business. Patents have a limited lifespan. For example, in the U. S., if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering the Company' s product candidates are obtained, once the patent life has expired for a product, the Company may be open to competition from biosimilar or generic medications. The launch of a generic version of one of the Company' s products, in particular, would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on the Company' s business, financial condition, results of operations and prospects. As a result, the Company' s patent portfolio may not provide it with sufficient rights to exclude others from commercializing product candidates similar or identical to the Company' s product candidates. In addition, although upon issuance in the U. S. a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the U. S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, the Company may not receive an extension if the Company fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If the Company is unable to obtain patent term extension or restoration, or the term of any such extension is less than the Company requests, the period during which the Company will have the right to exclusively market the Company' s product will be shortened and the Company' s competitors may obtain approval of competing products following the Company' s patent expiration and may take advantage of the Company' s investment in development and clinical trials by referencing the Company' s clinical and preclinical data to launch their product earlier than might otherwise be the case, and the Company' s revenue could be reduced, possibly materially. If the Company does not have sufficient patent life to protect the Company' s products, the Company' s business and results of operations will be adversely affected. Intellectual property discovered or developed through government funded programs may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a manufacturing preference for U. S.- based companies. Compliance with such regulations may limit the Company' s exclusive rights and limit its ability to contract with non- U. S. manufacturers. The Company received the NIA Grant to support its ongoing RewinD- LB Trial. Pursuant to the Bayh- Dole Act, the U. S. government may have certain rights in any invention developed or reduced to practice with this funding. In addition, in the future the Company may discover, develop, acquire, or license intellectual property that has been generated through the use of U. S. government funding or grants in which the U. S. government may have certain rights pursuant to the Bayh- Dole Act. These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right, under certain limited circumstances, to require the Company to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). Such " march- in " rights would apply to new subject matter arising from the use of such government funding or grants and would not extend to pre- existing subject matter or subject matter arising from funds unrelated to the government funding or grants. If the U. S. government exercises its march- in rights in the Company' s intellectual property rights that are generated through the use of U. S. government funding or grants, the Company could be required to license or sublicense intellectual property discovered or developed by it or that it licenses on terms unfavorable to the Company, and there can be no assurance that the Company would receive compensation from the U. S. government for the exercise of such rights. The U. S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require the Company to expend substantial resources. Should any of these events occur, it could significantly harm the Company' s business, results of operations and prospects. In addition, the U. S. government requires that, in certain circumstances, any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the U. S. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U. S. or that under the circumstances domestic

manufacture is not commercially feasible. This preference for U. S. industry may limit the Company' s ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. The Company' s reliance on third parties requires the Company to share its trade secrets, which increases the possibility that its trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. The Company may rely on trade secrets or confidential know- how to protect various aspects of its business, especially where patent protection is believed by the Company to be of limited value. Due to its reliance on third parties in various aspects of its business, including CMC, ~~R & D~~ **research and development,** and collaborations, the Company must, at times, share trade secrets with such parties. The Company may also conduct joint research and development programs that require it to share trade secrets under the terms of the Company' s research and development partnerships or similar agreements. Such trade secrets or confidential know- how can be difficult to protect as confidential. To protect this type of information against disclosure or appropriation by competitors, the Company' s policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with the Company prior to beginning research or disclosing proprietary information. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose the Company' s confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know- how is expensive, time- consuming and unpredictable. In addition, the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Despite the Company' s efforts to protect its trade secrets, the Company' s competitors may discover the Company' s trade secrets, either through breach of the Company' s agreements with third parties, independent development or publication of information by any of its third- party collaborators. A competitor' s discovery of the Company' s trade secrets could impair its competitive position and have an adverse impact on its business. Intellectual property rights do not necessarily address all potential threats to the Company' s competitive advantage. The degree of future protection afforded by the Company' s intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect the Company' s business or permit the Company to maintain its competitive advantage. For example: ● others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that the Company owns or has exclusively licensed; ● others may independently develop similar or alternative technologies or duplicate any of the Company' s technologies without infringing the Company' s intellectual property rights; ● it is possible that the Company' s pending patent applications will not lead to issued patents; ● the Company may not develop additional proprietary technologies that are patentable; ● the Company may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property; ● the Company may fail to adequately protect and police the Company' s trademarks and trade secrets; and ● the patents of others may have an adverse effect on the Company' s business, including if others obtain patents claiming subject matter similar to or improving that covered by the Company' s patents and patent applications. Should any of these events occur, they could significantly harm the Company' s business, results of operations and prospects. Obtaining and maintaining the Company' s patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and the Company' s patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. In any such event, the Company' s competitors might be able to enter the market, which would have a material adverse effect on the Company' s business. Risks Related to Commercialization The Company has not yet demonstrated, either on its own or through collaboration with third parties, an ability to successfully complete a large- scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about its future success or viability may not be as accurate as they may be if the Company had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. In addition, as a business with a limited operating history, the Company may encounter unforeseen expenses, complications, delays and other known and unknown factors. If it is able to successfully develop neflamapimod, the Company may eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. The Company may not be successful in such a transition and, as a result, its business may be adversely affected. As the Company continues to build its business, the Company expects that its financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond its control. Accordingly, investors should not rely upon the results of any particular quarterly or annual period as indications of the Company' s future operating performance. The Company' s business operations are subject to applicable healthcare laws and regulations. If neflamapimod is approved, the Company will also be subject to stringent regulation and ongoing regulatory obligations and restrictions, which could delay its marketing and commercialization activities and also expose it to penalties if the Company fails to comply with applicable regulations. Although the Company does not currently have any products on the market, once it begins commercializing neflamapimod or any other future product candidates, it will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments as well as foreign governments

in the jurisdictions in which the Company conducts its business. Physicians, other healthcare providers and third party payors will play a primary role in the recommendation, prescription and use of any product candidates for which the Company obtains marketing approval. The Company' s future arrangements with such third parties may expose the Company to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells and distributes any products for which the Company obtains marketing approval. Among others, restrictions under applicable domestic and foreign healthcare laws and regulations include: ● the U. S. federal AKS, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; ● U. S. federal false claims, false statements and civil monetary penalties laws, including the **FCA** ~~U. S. federal False Claims Act~~, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● HIPAA, which imposes (i) criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services and (ii) obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● analogous state and foreign laws and regulations relating to healthcare fraud and abuse, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; ● the U. S. federal " Physician Payments Sunshine Act ", which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report to CMS information related to physician payments and other transfers of value to physicians, certain advanced non- physician health care practitioners, and teaching hospitals, as well as the ownership and investment interests of physicians and their immediate family members; ● analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other healthcare providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the healthcare industry; ● U. S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs; and ● state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business. Efforts to ensure that the Company' s business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, including due to lack of applicable precedent and regulations. Any action against the Company for violation of these laws, even if the Company successfully defends against it, could cause the Company to incur significant legal expenses and divert its management' s attention from the operation of its business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. If the FDA or a comparable foreign regulatory authority approves any of the Company' s product candidates, the Company will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that the Company' s business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, resulting in government enforcement actions. If the Company' s operations are found to be in violation of any of these laws or any other governmental regulations that may apply to the Company, it may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of the Company' s operations. If any of the physicians or other healthcare providers or entities with whom the Company expects to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal healthcare programs. If neflamapimod, or any other product candidate the Company may develop or acquire in the future, receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, health care professionals, patients, third-party payors and others in the medical community. If the Company' s drug does not achieve an adequate level of acceptance, the Company may not generate significant product revenues or become profitable. The degree of market acceptance will depend on a number of factors, including but not limited to: ● the ability to provide acceptable evidence of efficacy and potential advantages compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the Company' s ability to offer its drug for sale at competitive prices, which may be subject to regulatory control; ● the availability of third- party insurance coverage and adequate reimbursement; ● the

availability of alternative treatments and the cost of a new treatment in relation to those alternatives, including any similar generic treatments; ● the relative convenience and ease of administration of a new treatment compared to alternatives, and the prevalence and severity of any side effects of a new treatment; ● the strength and effectiveness of the Company' s sales, marketing and distribution capabilities, either internally or in collaboration with others; ● any restrictions on the use of the Company' s product together with other medications; and ● any restrictions on the distribution of the Company' s product such as those imposed under a mandatory REMS program. If neflamapimod or any other product candidate that the Company may develop in the future does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance, and the Company will not generate sufficient revenues to achieve profitability. Because the Company expects sales of its product candidates, if approved, to generate substantially all of its revenues for the foreseeable future, the failure of the Company' s product candidates to find market acceptance would materially harm its business. If the market opportunity for any product candidate that the Company develops is smaller than it believes, its revenue may be adversely affected and its business may suffer. The Company intends to initially focus its product candidate development on treatments for various CNS and neurodegenerative indications, in particular DLB. The addressable patient populations that may benefit from treatment with the Company' s product candidates, if approved, are based on its estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these CNS and neurodegenerative diseases. Any regulatory approval of the Company' s product candidates would be limited to the therapeutic indications examined in the Company' s clinical trials and as determined by the FDA, which would not permit the Company to market its products for any other therapeutic indications not expressly reviewed and approved as safe and effective. **In DLB, in particular, prevalence estimates among experts and practitioners vary greatly, as do estimates of the percentage of DLB patients that have AD co- pathology.** Additionally, the potentially addressable patient population for the Company' s product candidates may not ultimately be amenable to treatment with the Company' s product candidates. Even if the Company receives regulatory approval for any of its product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. The Company' s market opportunity may also be limited by future competitor treatments that enter the market. If any of the Company' s estimates prove to be inaccurate, the market opportunity for any product candidate that the Company or its strategic partners develop could be significantly diminished and have an adverse material impact on its business. The Company faces substantial competition from other biotechnology and pharmaceutical companies, and its operating results will suffer if it fails to compete effectively. The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. If neflamapimod is approved, it will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies, biopharmaceutical companies in the U. S. and other jurisdictions, academic institutions and governmental agencies and public and private research institutions. These organizations may have significantly greater resources than the Company does. They may also conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with neflamapimod. Currently, there are a limited number of companies **developing treatments specifically** ~~and disease modifying approaches~~ for DLB. However, given the potential market opportunity for the treatment of DLB and other neurodegenerative diseases, an increasing number of established pharmaceutical firms and smaller biotechnology / biopharmaceutical companies are pursuing a range of potential therapies for these diseases in various stages of clinical development. In addition to these current and potential competitors, the Company anticipates that more companies will enter the DLB market in the future. The Company' s potential competitors could have significantly greater financial resources, as well as drug development, manufacturing, marketing, and sales expertise. They may also be able to develop and commercialize products that are safer, more effective, less expensive, more convenient, easier to administer, or have fewer severe effects, than existing treatments or, if it is ultimately approved, neflamapimod. Competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than the Company may obtain approval for neflamapimod, which could result in their establishing or strengthening a commercial position before the Company is able to enter the market. The highly competitive nature of the biotechnology and pharmaceutical industries, as well as the rapid technological changes in those fields, could limit The Company' s ability to advance neflamapimod commercially. If the Company is unable to compete effectively, this could have a material adverse effect on its business and results of operations. The successful commercialization of neflamapimod, or any other product candidate the Company may develop or acquire, will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Enacted and future healthcare legislation may increase the difficulty and cost for the Company to obtain marketing approval of and commercialize its product candidates, if approved, and also affect the prices it may set. Failure to obtain or maintain coverage and adequate reimbursement for the Company' s product candidates, if approved, could limit its ability to market those products and decrease its ability to generate revenue. There have been, and the Company expects will continue to be, a number of legislative and regulatory proposals and changes to the healthcare systems in the U. S. and other jurisdictions that could affect the Company' s future results of operations. In particular, a number of initiatives at the U. S. federal and state levels have aimed to reduce healthcare costs and improve the quality of healthcare. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of neflamapimod or any future product candidates the Company may develop or acquire. The Company cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, the Company may lose any marketing approval that it may have obtained, and it may not achieve or sustain profitability. In the U. S., the availability and adequacy of coverage and reimbursement by

governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third- party payors are essential for most patients to be able to afford prescription medications such as neflamapimod, if it is approved. The Company' s ability to achieve acceptable levels of coverage, payment, and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on the Company' s ability to successfully commercialize neflamapimod and any other potential future product candidates. Assuming the Company obtains coverage for neflamapimod by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. ~~the~~ **The** Company cannot be sure that coverage, payment, and reimbursement in the U. S. or elsewhere will be available for ~~or~~ any drug product that the Company may develop, and any reimbursement that may become available may be decreased or eliminated in the future. There have recently been and may continue to be a number of significant legislative initiatives in the U. S. to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U. S. Congress enacted the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the ~~United States~~ **U. S** . In August 2022, ~~President Biden~~ **the IRA was** signed into law ~~the IRA~~ , which, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. In addition, multiple large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. For these and other reasons, the implementation of the IRA and its impact on the Company' s business is currently unclear. 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. In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that may lead to appears to be leading to further and more aggressive efforts by states in this area. The **FTC** ~~Federal Trade Commission~~ in mid- 2022 also launched sweeping investigations into the practices of the PBM industry, and members of Congress continue to propose reforms for the PBM industry, all or each of which could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. In addition, in the last few years, several states have formed PDABs with the authority to implement UPLs on drugs sold in their respective jurisdictions. There are several pending federal lawsuits challenging the authority of states to impose UPLs, however. Further, if neflamapimod is approved in any jurisdictions outside of the U. S., the Company may also be subject to extensive governmental price controls and other market regulations in those countries. Governments outside of the U. S., particularly the countries of the European Union, tend to impose strict price controls on prescription pharmaceutical products. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, the Company may be required to conduct a clinical trial that compares the cost- effectiveness of its product candidate to other available therapies. If reimbursement of the Company' s products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the Company' s business could be harmed, possibly materially. As a result, the Company might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product and negatively impact the revenue the Company is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder the Company' s ability to recoup its investment in its product candidates, even after obtaining regulatory approval. The Company cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the U. S. or any other jurisdiction. In the U. S., future laws and regulation may result in more rigorous coverage criteria and increased downward pressure on the price pharmaceutical companies may receive for any approved product. Reductions in reimbursement from Medicare or other government programs may result in similar reductions in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the Company from being able to generate revenue, attain profitability or commercialize its product candidates. Further, if the Company or any third parties with whom it engages in the future are slow or unable to adapt to changes in existing requirements or policies, or if the Company is not able to maintain regulatory compliance, its ability to generate revenue, attain profitability, or commercialize neflamapimod or any other products for which it receives regulatory approval may be materially and adversely affected. If the Company is unable to obtain adequate coverage and payment levels for its products from third- party payors, physicians may limit how much or under what circumstances they will prescribe or administer them, and patients may decline to purchase them. This in turn would affect the Company' s ability to successfully commercialize any approved products and thereby adversely impact its profitability, results of operations, and financial condition. If the Company is unable to establish sales, marketing and distribution capabilities either on its own or in collaboration with third parties, it may not be successful in commercializing neflamapimod, if approved. The Company does not currently have any infrastructure for the sales, marketing or distribution of an approved drug product, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market and successfully commercialize neflamapimod, if approved, the Company must build its sales, distribution, marketing, managerial

and other non- technical capabilities, or make arrangements with third parties to perform these services. There are significant expenses and risks involved in establishing the Company' s own sales, marketing and distribution functions, including the Company' s ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Alternatively, to the extent that the Company depends on third parties for such services, any revenues it receives will depend upon the efforts of those third parties, and there can be no assurance that such efforts will be successful. If the Company is unable to establish adequate sales, marketing and distribution capabilities, either on its own or in collaboration with others, the Company will not be successful in commercializing neflamapimod, if it is ultimately approved, and it may never become profitable. The Company will be competing with companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, the Company may be unable to compete successfully against these more established companies. Consumers may sue the Company for product liability, which could result in substantial liabilities that exceed its available resources and damage its reputation. Researching, developing, and commercializing drug products entail significant product liability risks. The use of neflamapimod or any other product candidates the Company may develop in clinical trials and the sale of any products for which it obtains marketing approval exposes it to the risk of product liability claims. Product liability claims might be brought against the Company by clinical trial participants, patients, healthcare providers, pharmaceutical distributors or others selling or otherwise coming into contact with its product candidates or future commercial products. The Company has obtained limited product liability insurance coverage for its clinical trials, which the Company believes to be reasonable given its current operations. However, the Company' s insurance coverage may not reimburse the Company or may not be sufficient to reimburse it for any expenses or losses it may suffer. Although the Company currently has limited product liability insurance that covers its clinical trials, it will need to increase and expand this coverage as it commences larger scale trials, as well as if neflamapimod is ultimately approved for commercial sale. This insurance may be extremely expensive or may not fully cover the Company' s potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of neflamapimod, if it is approved. Product liability claims could have a material adverse effect on the Company' s business and results of operations. Any product candidate for which the Company obtains marketing approval will be subject to extensive post- marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and the Company may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its products, when and if any of them are approved. If the FDA or a comparable foreign regulatory authority approves neflamapimod or any of the Company' s future product candidates for marketing, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post- marketing nonclinical studies or clinical trials (often called " Phase 4 trials ") and post- marketing surveillance to monitor the safety or efficacy of the product. If the Company or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not- compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or the Company. If the Company or its third party providers, including the Company' s CMOs, fail to comply fully with applicable regulations, then the Company may be required to initiate a recall or withdrawal of its products. The Company must also comply with requirements concerning advertising and promotion for any of its product candidates for which it obtains marketing approval. 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 labeling. Thus, the Company will not be able to promote any products it develops for indications or uses for which they are not approved. The FDA and other agencies closely oversee the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if the Company promotes its products beyond their approved indications, it may be subject to enforcement actions or prosecution arising from that off- label promotion. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Accordingly, to the extent the Company receives marketing approval for neflamapimod, the Company and its CMOs and other third- party partners will continue to expend time, money and effort in all areas of regulatory compliance, including promotional and labeling compliance, manufacturing, production, product surveillance, and quality control. If the Company is not able to comply with post- approval regulatory requirements, it could have marketing approval for any of its products withdrawn by regulatory authorities and its ability to market any future products could be limited, which could adversely affect its ability to achieve or sustain profitability. Thus, the cost of compliance with post- approval regulations may have a negative effect on the Company' s operating results and financial condition. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of the Company' s product candidates. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained, which would adversely affect the Company' s business, prospects and ability to achieve or sustain profitability. Risks Related to Ownership of the Company' s Securities The Company' s stock price may be volatile, there may be limited liquidity in the trading market for the Company' s common stock, and the market price of its common stock may drop in the future. The market price of the Company' s common stock may be subject to significant fluctuations. Market prices for securities of early- stage pharmaceutical, biotechnology and other life sciences companies have historically been volatile. Some of the factors that may cause the market price of the

Company' s common stock to fluctuate include among others: ● the ability of the Company or its partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective; ● the ability of the Company or its partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals; ● failure of any of the Company' s product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success; ● failure by the Company to maintain its existing third- party license, manufacturing and supply agreements; ● failure by the Company or its licensors to prosecute, maintain, or enforce its intellectual property rights; ● changes in laws or regulations applicable to the Company' s product candidates; ● any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices; ● adverse regulatory authority decisions; ● introduction of new or competing products by the Company' s competitors; ● failure to meet or exceed financial and development projections the Company may provide to the public; ● the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; ● announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by the Company or its competitors; ● disputes or other developments relating to proprietary rights, including patents, litigation matters, and the Company' s ability to obtain intellectual property protection for its technologies; ● additions or departures of key personnel; ● significant lawsuits, including intellectual property or stockholder litigation; ● if securities or industry analysts do not publish research or reports about the Company, or if they issue an adverse or misleading opinions regarding its business and stock; ● changes in the market valuations of similar companies; ● general market or macroeconomic conditions; ● sales of its common stock by the Company or its stockholders in the future; ● the trading volume of the Company' s common stock; ● the limited percentage of the Company' s outstanding shares that are currently freely tradeable as a result of the significant holdings of the Company' s directors and officers; ● adverse publicity relating to the Company' s markets generally, including with respect to other products and potential products in such markets; ● changes in the structure of health care payment systems; and ● period- to- period fluctuations in the Company' s financial results. Accordingly, the market price of **the** Company' s common stock may be highly volatile and could fluctuate widely in price as a result of these or other factors. In particular, the Company has relatively few shares of common stock outstanding in the " public float " as a higher percentage of the Company' s outstanding shares are held by a small number of shareholders. In addition, the shares of common stock may be sporadically or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by shareholders may disproportionately influence the price of those shares in either direction, particularly over short periods of time. The price for such shares could, for example, decline precipitously in the event that a large number of the shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without a material reduction in share price. An active trading market for the Company' s shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. The Company may in the future be the target of similar litigation if its stock continues to experience price volatility. Securities litigation could result in substantial costs and liabilities and could divert management' s attention and resources. The Company has funded its operations to date through the issuance of securities, including common stock, warrants to purchase common stock (including pre- funded warrants), convertible preferred stock, and convertible debt securities, and expects that in the future it will need to raise additional capital through similar means to fund its continued operations and liquidity needs. Assuming funding is available on acceptable terms, any future issuance of common stock or securities convertible for or exchangeable into common stock will result in dilution to the Company' s existing stockholders and could depress the market price of its common stock. Furthermore, the terms of future financing transactions may contain provisions that restrict our operations or require us to relinquish certain rights to our product candidates or other technologies. The Company will likely need to raise additional funds in the future to continue its operations, fund research and development, and, if approved, commercialize its product candidates. The Company currently plans to continue to finance operations with a combination of equity issuances, debt arrangements, and, potentially, licensing, or other partnering relationships. The Board may determine at any time to raise additional capital if it believes the terms are in the best interests of the Company' s stockholders. In addition, the Company may also issue securities to counterparties as part of an acquisition, merger, or similar transaction, including as part of our strategic review process. Any issuance or sale of shares, or the perception in the market of an intent to issue or sell shares in the near- term, by the Company or holders of a large number of shares could reduce the market price of the Company' s common stock, including in connection with the **exercise of any Series A Warrants issued in connection with the** 2024 Private Placement ~~which is expected to close on or about April 1, 2024, subject to customary closing conditions~~ . The Company also cannot assure you that any such sale of common stock or other securities will be at a price per share that is equal to or greater than the price per share paid by you for the Company' s common stock. Furthermore, a depressed stock price could limit the Company' s ability to raise necessary capital through the sale of additional equity securities on terms that are acceptable. ~~In addition, in connection with the 2024 Private Placement, the Company issued the Series A Warrants pursuant to which the holders thereof are entitled to purchase an aggregate of 2, 532, 285 shares of common stock at an exercise price equal to $ 39. 24 per share. The Series A Warrants are exercisable immediately and will expire at the earlier of (i) April 1, 2027 or (ii) 180 days after the date that the Company makes a public announcement of positive top- line data from the RewinD- LB Trial, subject to certain beneficial ownership limitations and other conditions set forth therein. Any future issuance of common stock upon exercise of the Series A Warrants will result in dilution to the Company' s existing stockholders and could depress the market price of its common stock. The Company may become obligated to pay liquidated damages if we fail to file, obtain effectiveness and maintain effectiveness of a registration statement in accordance with the terms of the securities purchase agreement related to its 2024 Private Placement. In connection with the 2024 Private Placement, the Company granted the purchasers of securities in the offering certain resale registration rights pursuant to the terms of the securities purchase agreement. In addition to the registration rights, the purchaser may be~~

~~entitled to receive liquidated damages upon the occurrence, or failure to occur, of a number of events relating to the filing, effectiveness and maintenance of effectiveness of a registration statement related to the common stock sold in the 2024 Private Placement. The liquidated damages will be payable upon the occurrence, or failure to occur, of each of those events and each monthly anniversary thereof until cured. The amount of liquidated damages payable per monthly period would be equal to 1 % of the aggregate purchase price paid by the purchaser, provided, however, the maximum aggregate liquidated damages payable to the purchaser would be 5 % of the aggregate amount paid by such purchaser for the purchaser of such securities in the 2024 Private Placement.~~ Ownership of the Company' s common stock is highly concentrated among its officers and directors, which may prevent the Company' s stockholders from influencing significant corporate decisions and may result in perceived conflicts of interest that could cause the Company stock price to decline. As of March ~~26~~ **15** , ~~2024~~ **2025** , executive officers and directors of the Company owned, directly or indirectly, approximately ~~47~~ **33** . 4 % of the outstanding shares of the Company common stock. Accordingly, these stockholders, in the aggregate, may exercise substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit the other stockholders of the Company. The significant concentration of stock ownership may adversely affect the trading price of the Company' s common stock due to investors' perception that conflicts of interest may exist or arise. Future sales of shares by existing stockholders could cause the Company' s stock price to decline. If existing stockholders of the Company sell, or indicate an intention to sell, substantial amounts of the Company' s common stock in the public market after certain legal and contractual restrictions on resale lapse, the trading price of the common stock of the Company could decline. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, its business, or its market, its stock price and trading volume could decline. The trading market for the Company' s common stock will be influenced by the research and reports that equity research analysts may publish about it and its business from time to time. Equity research analysts may elect not to provide or continue research coverage of the Company' s common stock, which may adversely affect the market price of the stock. In the event the Company does have equity research analyst coverage at any given time, the Company will not have any control over the analysts, or the content and opinions included in their reports. The price of the Company' s common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of the Company or fails to publish reports on the Company regularly, demand for the Company' s common stock could decrease, which in turn could cause its stock price or trading volume to decline. If the Company cannot continue to satisfy the Nasdaq Capital Market continued listing standards and other Nasdaq rules, its common stock could be delisted, which could harm the Company' s business, the trading price of its common stock, the Company' s ability to raise additional capital and the liquidity of the market for its common stock. The Company' s common stock is currently listed on the Nasdaq Capital Market. To maintain this listing, the Company is required to meet certain listing requirements related to, among other things, the trading price of the Company' s common stock, the Company' s market capitalization and certain corporate governance- related requirements. In the event the Company' s common stock is delisted from Nasdaq for a failure to meet such requirements and is not eligible for quotation or listing on another market or exchange, trading of the Company' s common stock could be conducted only in the over- the- counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult for the Company to raise capital and for the Company' s stockholders to dispose of, or obtain accurate price quotations for, the Company' s common stock. There would likely also be a decline in the liquidity of the trading market for the Company' s common stock and a reduction in the Company' s coverage by securities analysts and the news media, which could cause the price of the Company' s common stock to decline further. Provisions in the Company' s corporate charter documents and under Delaware law could make an acquisition of the Company, which may be beneficial to the Company' s stockholders, more difficult and may prevent attempts by the Company' s stockholders to replace or remove its current directors and members of management. Provisions in the Company' s certificate of incorporation, as amended, and its amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which the Company' s stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors are willing to pay in the future for shares of the Company' s common stock, thereby depressing the market price of its common stock. In addition, because the Board is responsible for appointing the members of its management team, these provisions may frustrate or prevent any attempts by the Company' s stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of the Board. Among other things, these provisions: ● allow the authorized number of the Company' s directors to be changed only by resolution of the Board; ● limit the manner in which stockholders can remove directors from the Board; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the Board; ● limit who may call stockholder meetings and the Company stockholders' ability to act by written consent; ● authorize the Board to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the Board; and ● require the approval of the holders of at least 2 / 3 of the votes that all the Company' s stockholders would be entitled to cast to amend or repeal specified provisions of the Company' s certificate of incorporation, as amended, or for stockholders to amend or repeal the Company' s amended and restated bylaws. Moreover, because the Company is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which generally prohibits a person who, together with their affiliates and associates, owns 15 % or more of a company' s outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15 % or more of the company' s outstanding voting stock, unless the merger or

combination is approved in a prescribed manner. The Company' s certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by its stockholders, which could discourage lawsuits against the company and its directors, officers and employees. The Company' s certificate of incorporation provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for certain proceedings, including: (1) any derivative action or proceeding brought on the Company' s behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of the Company' s directors, officers, employees or stockholders to the company or its stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of the Company' s certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction. These exclusive- forum provisions may make it more expensive for Company stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction, and may limit the ability of the Company' s stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with the Company or its directors, officers or employees, which may discourage such lawsuits against the Company and its directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in the Company' s certificate of incorporation to be inapplicable or unenforceable in an action, the Company may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect its business, financial condition and operating results. The Company does not anticipate that it will pay any cash dividends in the foreseeable future. The Company' s current expectation is that it will retain future earnings, if any, to fund the development and growth of the Company' s business. As a result, capital appreciation, if any, will be your sole source of potential gain on an investment in the Company' s common stock for the foreseeable future. General Risks Related to the Company' s Business and Operations The Company has a small number of employees, and it is highly dependent on the principal members of its management team, including its President and Chief Executive Officer, John Alam, M. D. Although the Company has employment agreements or offer letters with its executive officers and certain key employees, these agreements do not prevent them from terminating their services at any time. Competition in the biotechnology industry for skilled and experienced employees is intense, particularly in the greater Boston, Massachusetts area, where the Company' s headquarters is located ~~, and the Philadelphia, Pennsylvania area, where approximately 50 % of the employee' s workforce is located~~ . The Company also faces competition for the hiring of scientific and clinical personnel from universities and research institutions, many of which are near the Company' s headquarters. The loss of the services of any member of the Company' s senior management, clinical development or scientific staff, or any other key employee, may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on the Company' s business, operating results and financial condition. The Company also relies on consultants and advisors to assist it in formulating and executing its business strategy. Many of the Company' s consultants and advisors are either self- employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, which may affect their ability to contribute to the Company. As the Company continues to develop neflamapimod ~~for the treatment of DLB, and also to expand into clinical trials for other CNS disorders~~ , the Company expects to experience significant growth in the number of employees and the scope of its operations. This strategy will require it to recruit additional clinical development, regulatory, scientific, and technical personnel, as well as sales and marketing personnel if neflamapimod is approved. If the Company is unable to attract, retain and motivate a sufficient number of highly qualified personnel to match such growth, its ability to further develop and commercialize neflamapimod, or any future product candidates the Company may develop or acquire, will be limited. The Company may also be required to implement and improve managerial, operational and financial systems to manage its potential growth. Due to its limited financial and personnel resources, the Company may not be able to effectively manage the expansion of its operations or recruit and train a sufficient number of additional qualified personnel. The expansion of the Company' s operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of the Company' s business plans or disrupt its operations **. The Company has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of the Company' s financial statements and have other adverse consequences. The Company may identify additional material weaknesses in its internal controls over financial reporting which it may not be able to remedy in a timely manner. If the Company fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired** . The Company is subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that the Company maintain effective disclosure controls and procedures and internal control over financial reporting. The Company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. This requires that the Company incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. The Company may experience difficulty in meeting these reporting requirements in a timely manner. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company' s consolidated financial statements would not be prevented or detected on a timely basis. The identified material weaknesses, if not corrected, could result in a material misstatement to the Company' s consolidated financial

statements that may not be prevented or detected. The Company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. For example, in connection with the audit of the Company' s financial statements for the years ended December 31, **2024,** 2023 and 2022, material weaknesses in the Company' s internal control over financial reporting were identified related to ~~(i)~~ **the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts, and in the years ended December 31, 2023 and 2022, an additional material weakness related to** the Company' s recording of significant complex transactions **was identified** ~~, and (ii) the absence of effective controls regarding the accurate identification, evaluation and proper recording of various expense accounts~~ . The Company may identify additional material weaknesses in its internal controls over financing reporting in the future which it may not be able to remedy in a timely manner. Any material weaknesses will not be considered remediated until a remediation plan has been fully implemented, the applicable controls operate for a sufficient period of time, and it has been concluded, through testing, that the newly implemented and enhanced controls are operating effectively. If the Company is not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if it is unable to maintain proper and effective internal controls, the Company may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. More generally, any failure by the Company to implement and maintain effective internal control over financial reporting could result in errors in the Company' s financial statements that could result in a restatement of the Company' s financial statements and could cause the Company to fail to meet its reporting obligations, any of which could diminish investor confidence in the Company and cause a decline in the price of the Company' s common stock. The Company' s disclosure controls and procedures may not prevent or detect all errors or acts of fraud. The Company is subject to the periodic reporting requirements of the Exchange Act and its disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by the Company in reports it files or submits under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. The Company believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. The Company' s **IT** ~~information technology~~ systems, or those of its vendors, collaborators or other contractors or consultants, may fail or suffer security incidents, loss of data and other disruptions, which could result in a material disruption of its product development programs, compromise sensitive information related to its business or prevent it from accessing critical information, potentially exposing it to liability or otherwise adversely affecting its business. In the ordinary course of the Company' s business, the Company collects and stores sensitive data, intellectual property, and proprietary business information. This data encompasses a wide variety of business-critical information including research and development information, clinical trial information, commercial information, and business and financial information. The Company faces risks relative to protecting this critical information including loss of access, unauthorized disclosure, unauthorized modification, and inadequate monitoring of its controls over these risks ~~security~~ .The Company **also** relies on **IT** ~~information technology~~ systems and networks,including third- party" cloud- based" service providers,and the Company' s third- party CROs,to process,transmit and store electronic information in connection with the Company' s business activities.This includes crucial systems such as email,other communication tools,electronic document repositories,and archives.As use of digital technologies has increased,cyber incidents,including deliberate attacks and attempts to gain unauthorized access to computer systems and networks,have increased in frequency and sophistication.These threats pose a risk to the security of the Company' s systems and networks and the confidentiality,availability and integrity of the Company' s data.Cyberattacks could include wrongful conduct by hostile foreign governments,industrial espionage,wire fraud and other forms of cyber fraud,the deployment of harmful malware,denial- of- service,social engineering fraud or other means to threaten data security,confidentiality,integrity and availability.Furthermore,because the techniques used to obtain unauthorized access to,or to sabotage,systems change frequently and often are not recognized until launched against a target,the Company may be unable to anticipate these techniques or implement adequate preventative **measures** . Despite the implementation of security measures, the Company' s internal IT systems and those of its current and any future third- party vendors, collaborators and other contractors or consultants are vulnerable to system failures, accidents, security incidents, damage, interruption or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, ransomware, social engineering (including phishing attacks), denial- of- service attacks, sophisticated nation- state and nation- state- supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. **Additionally, developments in artificial intelligence and machine learning provide threat actors with the capability to use more sophisticated means to attack the Company' s systems and may exacerbate cybersecurity risk.** These threats pose a risk to the security of the Company' s IT systems and networks and the confidentiality, availability and integrity of the Company' s data. There can be no assurance that the Company will be successful in **detecting or** preventing cybersecurity incidents **,** or successfully mitigating their effects **. As a result, the Company may experience cybersecurity incidents that may remain undetected for an extended period** . Any such disruption or security incident could cause interruptions to its operations and result in disruption of the Company' s development programs and business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in the Company' s regulatory approval efforts and significantly increase its costs to recover or reproduce the data **. A successful cyberattack**

could also cause misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans . If the Company were to experience a significant cybersecurity incident that impacts its information systems or data, the costs associated with the investigation, remediation, and potential notification of the cybersecurity incident to counterparties, regulatory authorities, and data subjects could be material. In addition, the Company' s remediation efforts may not be successful. Cybersecurity incidents could also lead to significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, the Company' s recently- increased remote workforce could increase the Company' s cybersecurity risk, create data accessibility concerns, and make the Company more susceptible to communication disruption. To the extent that any disruption or cybersecurity incident were to result in a loss of, or damage to, the Company' s or its third- party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, the Company could incur liability including litigation exposure, penalties and fines, the Company could become the subject of regulatory actions or investigations, its competitive position could be harmed and the further development and commercialization of its product candidates could be delayed. Any of the above could have a material adverse effect on the Company' s business, financial condition, reputation, competitive advantage, results of operations or prospects. While the Company maintains cyber- liability insurance, such insurance may not be adequate to cover any losses experienced as a result of a cybersecurity incident. The Company' s business may be affected from time- to- time by government investigations and litigation with third parties, including its ongoing matter with Paul Feller. The Company may from time to time receive inquiries and subpoenas and other types of information requests from government authorities and other third parties and may become subject to claims and other actions related to its business activities. While the ultimate outcome of investigations, inquiries, information requests and legal proceedings is difficult to predict, defense of litigation claims (even if ultimately successful) can be expensive, time- consuming and distracting, and adverse resolutions or settlements of those matters may result in, among other things, modifications to business practices, costs and significant payments, any of which could have a material adverse effect on the Company' s business, financial condition, results of operations and prospects. For example, in August 2014, Paul Feller, the former Chief Executive Officer of the Company' s legal predecessor, filed a complaint asserting various causes of action related to his past affiliations with the Company' s legal predecessor. While the Company ~~believes it has meritorious defense to the claims alleged in this matter and~~ is defending itself vigorously **against the claims alleged in this matter** , the Company is unable to predict the outcome and possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company' s financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company' s consolidated financial position, results of operations and cash flows ~~. Now that the Merger has closed, there can be no further recourse by either party or its stockholders for a breach of representation or warranty by any of the parties to the Merger Agreement. The representations and warranties of Diffusion, EIP and Merger Sub contained in the Merger Agreement or any certificate or instrument delivered pursuant to the Merger Agreement terminated at the Effective Time. To the extent that any such party' s breach of any representations and warranties is discovered or occurs in the future, there is no mechanism pursuant to which the other parties can pursue recourse or remedy~~ . The Company' s business is, or may in the future become, subject to complex and evolving U. S. and foreign laws and regulations relating to privacy and data protection. These laws and regulations are subject to change and uncertain interpretation, and the Company' s actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm its business. ~~A~~ **The global data protection landscape is rapidly evolving, and the Company is currently and may become subject to or impacted by a** wide variety of provincial, state, national, and international laws and regulations apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data. These data protection and privacy- related laws and regulations are evolving and may result in increased regulatory and public scrutiny and escalating levels of enforcement and sanctions **. Implementation standards and enforcement practices are likely to remain uncertain and unpredictable for the foreseeable future, which may create uncertainty in the Company' s business, affect the Company' s or the Company' s service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on the Company. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect the Company' s operating results and business** . In the U. S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health- related and other personal information. ~~Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect our operating results and business.~~ For example, ~~California has enacted~~ the CCPA, which **became** ~~went into effect~~ **effective** in ~~January of~~ 2020 ~~. The CCPA~~ **, broadly defines personal information,** gives California residents expanded **individual privacy** rights ~~to access~~ and **protections** ~~require deletion of their personal information, opt out of certain personal information sharing,~~ and ~~receive detailed information about how their personal information is used. The CCPA~~ provides for civil penalties for violations **and** ~~, as well as~~ a private right of action for data breaches ~~that may increase data breach litigation~~ . ~~Although~~ **Further, the CPRA, which became effective in 2023 and amends** the CCPA ~~includes~~ **, creates additional obligations with respect to processing and storing personal information. While there is limited** ~~exemptions~~ -- **exception** for ~~certain clinical trials data, and HIPAA~~ protected health information **that is subject** ~~, the law may increase the Company' s compliance costs and potential liability with respect~~ to **HIPAA and clinical trial regulations,** ~~other~~ -- **the CCPA may regulate or impact the Company' s processing of** personal information **depending on the context. Unlike** ~~the~~ **other** ~~Company~~ **state privacy laws, the CCPA also regulates personal information** ~~collects~~ **collected in a business to business** and

~~processes~~ **in human resources contexts. Further, there continues to be some uncertainty** about **how provisions of** ~~California residents. Additionally in 2020, California voters passed the CPRA, which went into full effect on January 1, 2023. The CPRA significantly amends~~ the CCPA ~~, potentially resulting in further uncertainty, additional costs related to our compliance efforts~~ and ~~additional potential for harm and liability if we fail to comply. Among other~~ -- **the** ~~things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting~~ new regulations ~~under the CPRA and~~ will ~~have expanded enforcement authority~~ **be interpreted and how the law will be enforced** . In addition to California, more U. S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas ~~will~~ **took effect in 2024. Laws in a number of other U. S. states took effect, or are set to** take effect **,** in ~~2024~~ **2025** ~~. In addition~~ , ~~laws~~ in **2026, and** ~~other U. S. states are set to take effect~~ beyond ~~2024~~ , and additional U. S. states have proposals under consideration ~~, all~~ **. The existence** of **differing comprehensive privacy laws in different states in the country may make the Company' s compliance obligations more complex and costly and may require us to modify the Company' s data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. In addition, other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state recently passed the " My Health My Data " Act,** which **came into force in 2024 and regulates " consumer health data, " which is broadly defined as " personal information that is linked or reasonably linkable to a consumer and that identifies a consumer' s past, present, or future physical or mental health. " The " My Health My Data " Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C. F. R. Parts 46, 50 and 56. Notably, the " My Health My Data " Act contains a private right of action. In addition, Nevada recently enacted a consumer health data privacy bill, SB 370, which also took effect in 2024, and regulates " consumer health data. " SB 370 shares many similarities with Washington' s " My Health My Data " Act, and Connecticut recently amended its comprehensive privacy law to include heighted regulation of " consumer health data. " Additional states are considering and may adopt health- specific privacy laws that** could **impact** ~~increase the Company' s regulatory compliance costs and risks, exposure to regulatory enforcement action and other~~ -- **the** ~~liabilities~~ **Company' s business activities and the Company' s collection and handling of health- related data** . Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the GDPR which became fully effective in May 2018 and governs the collection and use of personal data in the European Union, including by companies outside of the European Union., The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the ~~United States~~ **U. S** . The GDPR imposes stringent data protection requirements and provides for penalties for noncompliance of up to the greater of € 20 million or four percent of worldwide annual ~~revenues~~ **turnover** . The GDPR and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. The **GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the Company' s cost of providing the Company' s products and services or even prevent us from offering certain services in jurisdictions that the Company may operate in. The GDPR may increase the Company' s responsibility and liability in relation to personal data that the Company processes where such processing is subject to the GDPR, and the** Company may be required to ~~devote significant~~ **put in place** additional ~~resources~~ **mechanisms** to ~~complying~~ **ensure compliance** with **the GDPR, including as implemented by individual countries. Ensuring the Company' s continued compliance with the GDPR is a rigorous and time- intensive process that may increase the Company' s cost of doing business or require us to change the Company' s business practices, and despite those efforts, there is a risk that the Company may be subject to fines and penalties, litigation, and reputational harm in connection with the Company' s European activities. Many jurisdictions outside of U. S. and Europe are also considering and / or enacting comprehensive data protection legislation that could have an impact on market expansion and clinical trials as well. Additionally, following the United Kingdom' s withdrawal from the European Union (i. e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £ 17. 5 million or 4 % of global turnover. Transfers of personal data to certain countries outside of the EEA and the UK are also highly regulated under the GDPR and UK GDPR. For example, the GDPR only permits exports of personal data outside of the EEA to " non- adequate " countries where there is a suitable data transfer mechanism in place to safeguard personal data (e. g., the EU Commission approved Standard Contractual Clauses or certification under the Data Privacy Framework). On July 16, 2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the U. S. The CJEU is the highest court in Europe and the Schrems II decision heightened the burden to assess U. S. national security laws on their business, and future actions of EEA data protection authorities are difficult to predict at this time. While the Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any data transfers from the EEA being halted. Future actions of European Union data protection authorities are difficult**

to predict. Some customers or other service providers may respond to these **evolving** laws and regulations ~~,~~ **by asking us to make certain privacy or data- related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships. Because the interpretation** and **application of many privacy and data protection laws (including laws in the U. S. and the GDPR), commercial frameworks, and standards are uncertain,** it is possible that ~~the~~ **these** ~~GDPR or other~~ laws **, frameworks,** and **standards** ~~regulations relating to privacy and data protection~~ may be interpreted and applied in a manner that is inconsistent ~~from jurisdiction to jurisdiction or inconsistent~~ with the Company' s ~~current~~ **existing data management practices and** policies **. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, the Company could be required to fundamentally change the Company' s business activities** and practices **or modify the Company' s solutions, which could have an adverse effect on the Company' s business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage the Company' s reputation, inhibit the Company' s ability to conduct trials, and adversely affect the Company' s business** . Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, the Company may find that it is violating the laws or regulations of another jurisdiction. Despite the Company' s efforts, the Company may not have fully complied in the past and may not in the future. That could require the Company to incur significant expenses, which could significantly affect its business. Failure to comply with data protection laws or to protect personal data or other data the Company processes or maintains may expose the Company to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, potential significant fines, penalties and other liabilities if it is found to be non- compliant, and damage to the Company' s reputation, any of which could materially affect its business, financial condition, results of operations and prospects. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm the Company' s business and reputation. Past or future transactions resulting in an ownership change under Section 382 ~~of the Code~~ may subject the Company' s NOL carryforwards and certain other tax attributes to limitation. As of December 31, ~~2023~~ **2024** , the Company had U. S. federal NOL carryforwards of approximately $ 38. ~~9~~ **7** million. Under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an " ownership change " (within the meaning of Section 382), the corporation' s NOL carryforwards and certain other tax attributes (such as research tax credits) arising before the ownership change are subject to limitation on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation' s equity ownership by certain stockholders that exceeds fifty percentage points (by value) over a rolling three- year period. Similar rules may apply under state tax laws. Past or future transactions to which the Company is a party may, alone or in the aggregate, result in such an ownership change and, accordingly, the Company' s NOL carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use in the future. Consequently, even if the Company achieves profitability, it may not be able to utilize a material portion of its NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, the Company' s existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. The Company incurs costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies. The Company incurs significant legal, accounting and other expenses associated with public company reporting requirements. The Company also incurs costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC, as well as the rules and regulations of Nasdaq. These laws, rules and regulations also may make it difficult and expensive for the Company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the Company to attract and retain qualified individuals to serve on the Company' s Board or as executive officers of the Company, which may adversely affect investor confidence in the Company and could cause the Company' s business or stock price to suffer. The Company may fail to comply with evolving privacy..... successfully mitigating their effects. The Company ' s business activities may be subject to the FCPA and similar anti- bribery and anti- corruption laws. The Company' s business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which the Company operates, including the U. K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. 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. The Company' s business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, any Company dealings with these prescribers and purchasers are subject to regulation under the FCPA. ~~The SEC and U. S. Department of Justice have recently increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies.~~ There is no certainty that all the Company' s employees, agents, contractors, or collaborators, or those of the Company' s 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 the Company, its officers, or its employees, the closing down of facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of its business. Any such violations could include prohibitions on the Company' s ability to offer its products in one or more countries and could materially damage the Company' s reputation, its brand, future international expansion efforts, its ability to attract and retain employees, and its business, prospects, operating

results, and financial condition **. However, in February 2025, President Trump issued an executive order directing the Department of Justice to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration U. S. national security and the competitiveness of U. S. companies abroad. It is unclear how, if at all, this presidential directive may affect the pharmaceutical industry as a whole or our business in particular** . The Company' s employees, independent contractors, consultants, vendors and future commercial partners, if any, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. The Company is exposed to the risk of fraud, misconduct or other illegal activity by its employees, independent contractors, consultants, vendors and other third parties. Misconduct by these parties could include intentional, reckless and negligent conduct that may fail to, among other things: comply with the rules and regulations of the FDA, EMA and other comparable foreign regulatory authorities; provide true, complete and accurate information to such authorities; comply with manufacturing standards the Company has established; comply with healthcare fraud and abuse laws; or report financial information or data accurately or to disclose unauthorized activities to the Company. If the Company obtains FDA approval of any of its product candidates and begins commercializing those products, its potential exposure under such laws will increase significantly, and its costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive legal and regulatory requirements designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of subject recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to the Company' s reputation. The Company has adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions the Company takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against the Company, and the Company is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant fines or other sanctions. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of the Company' s business may rely, which could negatively impact the Company' s business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, its ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, the NIA, the SEC and other government agencies on which the Company' s operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. **Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA' s regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the next FDA user fee reauthorization package is expected to enter stakeholder negotiations beginning in mid- 2025, with any agreement sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program would need to be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA' s review goals for NDAs and other activities supported by user fees assessed against industry. In addition,** ~~Disruptions~~ **disruptions** at the FDA and other agencies may ~~also~~ slow the time necessary for clinical trial applications and / or marketing applications for new drugs to be reviewed or approved, which would adversely affect the Company' s business. **For example** ~~Over the last several years~~ , **political disputes in Congress may result in a shutdown of** the U. S. government ~~has shut down several times~~ and **, in such cases,** certain regulatory agencies, such as the FDA and the SEC, **may** have ~~had~~ to furlough critical staff and stop critical activities. If a prolonged government or slowdown shutdown occurs, it could significantly impact the ability of the NIA to disburse funds for the Company' s clinical trial and for the FDA to timely review and process the Company' s regulatory submissions, which could have a material adverse effect on the Company' s business. For example, **in March 2025,** the Company ~~received~~ **was only granted** access to ~~$ 7. 3 million under the NIA Grant in February 2024,~~ 90 % of the full amount of ~~current~~ **the third** year **of** funding provided for in the NIA Grant ~~, due to current NIA policy~~ as a result of the U. S. government ~~currently~~ being funded on the basis of a continuing resolution. The timing of the Company' s receipt of the remaining 10 % ~~, or $ 0. 8 million,~~ of current year funding is dependent upon and subject to U. S. congressional approval of a final appropriations bill. Future government shutdowns or slowdowns could also result in delays in the Company' s interactions with the SEC and other government agencies, which could impact the Company' s ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations. U. S. federal income tax reform or other changes in applicable tax law could adversely affect the Company' s business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U. S. Treasury Department and other governmental bodies. In recent years, many such changes have been made and may continue to occur in the future. For example, in March 2020, the CARES Act was signed into law, which included certain changes in tax law intended to stimulate the U. S. economy in response to the COVID- 19 coronavirus outbreak, including temporary beneficial changes to the treatment of **NOLs** ~~net operating losses~~ , interest deductibility limitations and payroll tax matters. Additionally, in December 2017, the TCJA was signed into law, which significantly reformed the Code. The TCJA included significant changes to corporate and individual

taxation, some of which could adversely impact an investment in the Company' s common stock. For example, under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year' s taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modified the TCJA with respect to the TCJA' s limitation on the deduction of NOLs and provided that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminated the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021 (but reinstated the limitation for taxable years beginning after December 31, 2020). As a result of such limitations, the Company may be required to pay federal income tax in some future year notwithstanding that it had a net loss for all years in the aggregate. More generally, recent and future changes in tax laws could have a material adverse effect on the Company' s business, cash flow, financial condition or results of operations. The Company faces risks associated with increased geopolitical uncertainty **, including as a result of evolving domestic and foreign tariff policies** . Ongoing and potential military actions across the globe, including the ongoing conflicts in Ukraine and the Middle East, as well as the sanctions, bans and other measures taken by governments, organizations and companies against the involved countries and certain citizens of those countries in response thereto, has increased the global political uncertainty and has strained the relations between a significant number of governments, including the U. S. The duration and outcome of these conflicts, any retaliatory actions or escalation, and the impact on regional or global economies is unknown but could have a material adverse effect on the Company' s business, financial condition and results of its operations **. In addition, the Trump administration has signaled intentions to substantially alter prior U. S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi- lateral trade agreements and treaties with foreign countries. In addition, the Trump administration has initiated, or is considering imposing, tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted, or are considering imposing, tariffs on certain U. S. goods. It remains unclear what the Trump administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, or increase the cost of materials purchased to manufacture our drug product and drug substance, and, thus, could adversely impact our business** . Unfavorable global economic conditions could adversely affect the Company' s business, financial condition or results of operations. The Company' s results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and, more recently, the COVID- 19 pandemic caused significant volatility and uncertainty in U. S. and international markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to the Company' s business, including weakened demand for its product candidates, if approved, or its ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain the Company' s suppliers, possibly resulting in supply disruption. Any of the foregoing could harm the Company' s business and it cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business. Epidemics, pandemics or other public health crises, including COVID- 19, could adversely affect the Company' s business. The Company' s operations could be significantly adversely affected by the effects of a widespread outbreak of epidemics, pandemics or other health crises, including COVID- 19. The Company cannot accurately predict the impact of epidemics and pandemics would have on our operations and the ability of third parties to meet their obligations under contracts or arrangements with the Company, including uncertainties relating to the ultimate geographic spread of epidemics and pandemics, the severity of the underlying diseases, the duration of outbreaks, and the length of travel and quarantine restrictions imposed by governments of affected countries. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could further affect the Company' s operations and ability to finance the Company' s operations. Political uncertainty may have an adverse impact on the Company' s operating performance and results of operations. General political uncertainty may have an adverse impact on the Company' s operating performance and results of operations. In particular, the ~~United States~~ **U. S.** continues to experience significant political events that cast uncertainty on global financial and economic markets ~~, especially in light of the upcoming presidential election~~ . It is presently unclear exactly what actions ~~a new~~ **our current** administration in the ~~United States would~~ **U. S. will** implement, and if implemented, how these actions may impact the pharmaceutical industry in the ~~United States~~ **U. S** . The Company holds its cash and cash equivalents that it uses to meet its working capital needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail. The Company holds its cash and cash equivalents that it uses to meet working capital needs in deposit accounts at certain third party financial institutions. The balances held in these accounts may exceed the FDIC, standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which the Company holds such funds fails or is subject to significant adverse conditions in the financial or credit markets, the Company could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact the Company' s short- term liquidity and ability to meet its obligations. For example, on March 10, 2023, Silicon Valley Bank, and on March 12, 2023, Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of Silicon Valley Bank and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the U. S. Department of the Treasury, the Federal Reserve and the FDIC. While the Company did not hold any of its funds in accounts with either of these institutions, if financial institutions in which the Company holds funds for working capital were to fail, the Company cannot provide any

assurances that such governmental agencies would take action to protect its uninsured deposits in a similar manner. The Company may also, from time to time, maintain investment accounts with other financial institutions in which it holds its investments and, if access to the funds the Company uses for working capital is impaired, the Company may not be able to sell investments or transfer funds from its investment accounts to new accounts on a timely basis sufficient, or without incurring a loss or penalty as a result of such sale, to meet its working capital needs. Certain stockholders could attempt to influence changes within the Company which could adversely affect the Company' s operations, financial condition and the value of its common stock. One or more of the Company' s stockholders may from time to time seek to acquire a significant or controlling stake in the Company, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes to the Company' s Board or corporate governance policies. Campaigns by stockholders to effect changes at publicly traded companies are sometimes led by investors seeking to increase short- term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time- consuming, could disrupt the Company' s operations and divert the attention of the Company Board and senior management, and could adversely affect the Company' s operations, financial condition, and the value of its common stock ~~. The Company may not be able to enter into a transaction with a suitable acquiror or licensee for its product candidate TSC or any transaction entered into may not be on terms that are favorable to the Company. As previously announced, in connection with Diffusion' s strategic review process during 2022- 23, Diffusion made the decision to voluntarily pause the development program for TSC, Diffusion' s lead drug candidate prior to the Merger. Currently, the Company does not intend to pursue the development of TSC and believes the primary path available to derive value from its TSC- related assets would be to find a suitable acquiror or licensee. Although the Company' s management has contacted numerous parties to assess their potential interest in such a transaction, to date, the Company has been unable to identify an interested counterparty. Furthermore, even if the Company is able to identify such a counterparty, supporting diligence activities conducted by potential acquirors or licensees and negotiating the financial and other terms of an agreement or license are typically long and complex processes, and the results of such processes cannot be predicted. There can be no assurance that the Company will enter into any transaction as a result of these effort or that any transaction involving the Company' s TSC- related assets will be entered into or, if entered into, will be on terms that are favorable to the Company. Furthermore, the Company cannot predict the impact that such a transaction or, alternatively, a failure to monetize the TSC assets in any material way, might have on its stock price~~ . Artificial intelligence presents risks and challenges that can impact the Company' s business including by posing security risks to confidential information, proprietary information, and personal data. Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to the Company' s business operations. The Company may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. The Company' s vendors may incorporate generative artificial intelligence tools into their offerings, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit the Company' s or its vendors' ability to maintain an adequate level of service and experience. **Additionally, artificial intelligence algorithms may be flawed, datasets may be insufficient or biased, and ineffective artificial intelligence development or deployment could lead to other compliance violations.** If the Company, its vendors, or its third- party partners experience an actual or perceived violation of applicable privacy or data protection **, intellectual property, or other** laws or regulations, or a cybersecurity incident due to the use of generative artificial intelligence, the Company could be subject to regulatory fines, investigations, enforcement actions, penalties and other liabilities, claims for damages from affected individuals, and the Company may lose valuable intellectual property and confidential information and its reputation and the public perception of the effectiveness of its privacy or cybersecurity measures could be harmed. **Several jurisdictions around the globe, including Europe and the U. S., have already proposed or enacted laws governing artificial intelligence, and the Company may need to commit significant resources to maintain business practices that comply with the evolving regulatory landscape. The Company' s competitors or other third parties may incorporate artificial intelligence into their products more quickly and successfully than the Company, which could impair the Company' s ability to compete effectively and adversely affect the Company' s results of operations.** Any of these outcomes could damage the Company' s reputation, result in the loss of valuable property and information, and adversely impact its business. **For example, the Company' s approach to the treatment of DLB focuses in large part on neflamapimod' s ability to inhibit the intra- cellular enzyme p38α. Through the use of artificial intelligence and large language models, competitors could seek to identify alternative p38α inhibiting compounds and repurpose those assets to compete with neflamapimod in the future.** ITEM 1B. UNRESOLVED STAFF COMMENTS