Risk Factors Comparison 2025-03-03 to 2024-02-29 Form: 10-K

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In connection with any investment decision with respect to our securities, you should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10- K and in our other filings with the SEC. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common shares to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. SUMMARY An investment in our common shares is subject to a number of risks, including risks related to our product candidates, risks related to our business and risks related to our common shares. The following list of risk factors is not exhaustive. Please read the information in ~~the~~ **this** section captioned " **1A.** Risk Factors " for a more thorough description of these and other risks. Risks Related to Our Financial Position and Need for Additional Capital • We have a limited operating history, have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. • Deterioration in general economic conditions in the United States and globally, including the effect of prolonged periods of inflation on our suppliers, third- party service providers and potential partners, may have a negative impact on our business and results of operations. • An inability to raise capital when needed or on terms favorable to us could force us to curtail our planned operations and growth strategy. • Credit risk with respect to our investments or the financial institutions at which we deposit funds could adversely affect us. Risks Related to the Development of Our Product Candidates • We depend entirely on the success of a limited number of product candidates. • Clinical trials are very expensive, time consuming and difficult to design and implement, involve uncertain outcomes and may not be predictive of results of future trials. • Regulatory approval processes in the U. S. and foreign jurisdictions are lengthy, time consuming and unpredictable. • Our product candidates may fail to demonstrate safety and efficacy in clinical trials, or may cause serious adverse or unacceptable side effects. • We may become exposed to costly and damaging liability claims, which may not be covered by insurance. Risks Related to Commercialization of Our Product Candidates • We have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize any product candidate that may receive regulatory approval. • We operate in a highly competitive and rapidly changing industry. • Failure to obtain or maintain adequate coverage and reimbursement for our approved product candidates could limit our ability to market those products and decrease our ability to generate revenue. • Our product candidates, if approved, will be subject to ongoing regulatory oversight. • Our approved product candidates may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. Risks Related to Our Dependence on Third Parties • We rely on third parties to conduct our preclinical studies and clinical trials and to supply, manufacture and distribute clinical drug supplies for our product candidates, which may expose our business to risks. • We may not establish or maintain collaborations with third parties to develop or commercialize product candidates. Risks Related to Regulatory Compliance • Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. • Our business operations and relationships with investigators, health care professionals, consultants, third- party payors and customers are subject to federal and state healthcare and other laws. • We may not obtain or maintain orphan drug designation or exclusivity for our product candidates. • **Disruptions at the FDA and other government agencies could prevent new products from being developed or commercialized in a timely manner, or negatively impact the approval of an NDA, BLA or similar application.** Risks Related to Our Intellectual Property • We could lose market exclusivity earlier than expected. • If we were unable to obtain licenses from third parties on commercially reasonable terms or lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates. • Patent terms may not provide exclusivity for our product candidates for an adequate amount of time to realize sufficient commercial benefits. • Third parties may seek to invalidate our patents. • Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. Risks Related to Our Business Operations, Employee Matters and Managing Growth • Our future growth and ability to compete depend on, among other things, retaining key personnel and recruiting additional qualified personnel and on our ability to penetrate foreign markets. • Laws and regulations governing our international operations may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs. • We may encounter difficulties in managing our growth, which could disrupt our operations. • Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in improper activities. • Our business and operations may be materially adversely affected in the event of computer system failures or security breaches. Risks Related to Ownership of Our Common Shares • Substantially all of our total outstanding shares may be sold freely into the market. This could cause the market price of our common shares to drop significantly, even if our business is doing well. • Because we do not expect to pay dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain. • The trading price of our common shares **has been and** may **continue to** be volatile ~~and may fluctuate~~ . • If we are or become a passive foreign investment company, there could be adverse U. S. federal income tax consequences to U. S. holders. ~~Risks Related to Our Financial Position~~ **• We are a British Virgin Islands (" BVI") business company limited by shares,** and ~~Need~~ **the rights of shareholders are more limited under BVI law than under U. S. law. It may be difficult to enforce a U. S.** ~~for~~ **or** ~~Additional CapitalWe~~ **foreign**

judgment against us, our directors and our officers outside the United States. We have a limited operating history and have never generated any product revenues, which may make it difficult to evaluate the success of our business to date and to assess our future viability. We were incorporated on May 2, 2022 as a direct, wholly- owned subsidiary of the Former Parent. Our operations to date have been largely focused on organizing and staffing, raising capital and in- licensing the rights to, and advancing the development of, our product candidates, including conducting preclinical studies and clinical trials. We have not yet demonstrated an ability to obtain marketing approvals for any product candidates, manufacture products on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition. ~~Deterioration in general economic conditions in the United States and globally, including the effect of prolonged periods of inflation on our suppliers, third- party service providers and potential partners, may have a negative impact on our business and results of operations.~~ Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include, but are not limited to, **volatility in** ~~high levels of, and rising,~~ inflation ~~, high~~ and ~~rising~~ interest rates, ~~any~~ volatility in the capital markets, energy availability and costs, the negative impacts from pandemics and public health crises ~~(including any lingering or recurring adverse impacts from COVID- 19)~~, negative impacts resulting from the military conflict between Russia and ~~the~~ Ukraine **, geopolitical and trade tensions between the U. S. and China or other geopolitical events, potential protectionist trade policies adopted by the U. S. and other governments** , and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our business in the form of higher costs for labor and materials, higher investigator fees, possible reductions in pharmaceutical industry- wide spending on research and development and acquisitions and higher costs of capital. We have incurred significant operating losses since our inception as a business of the Former Parent and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability. Since our inception as a business of the Former Parent, we have incurred significant operating losses. Our net loss was $ **846. 4 million, $** 408. 2 million **, and** $ 570. 3 ~~million and $ 213. 8~~ million for the years ended December 31, **2024,** 2023 ~~,~~ **and** 2022 ~~and 2021~~ , respectively. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our product candidates has been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized product that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur have in the past and may in the future fluctuate significantly from quarter to quarter and year to year. Our expenses have increased, and we anticipate that our expenses will further increase substantially as we: • initiate, continue, or complete planned or ongoing clinical trials of our current product candidates, including related support activities; • continue to initiate and progress other supporting studies required for regulatory approval of our product candidates, including long- term safety studies, drug- drug interaction studies, preclinical toxicology and carcinogenicity studies; • make required milestone and royalty payments under the license agreements by which we acquired some of the rights to our product candidates; • initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue; • continue to build our portfolio of product candidates through the acquisition or in- license of additional product candidates or technologies; • continue to develop, maintain, expand and protect our intellectual property portfolio; • pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials; • ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval; • hire additional clinical, medical, commercial, and development personnel; and • incur additional legal, accounting and other expenses in operating as a public company. To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future product candidates for which we may obtain marketing approval, and satisfying any post- marketing requirements. We are only in the preliminary stages of most of these activities and, in some cases, have not yet commenced certain of these activities. We may never succeed in **commercializing** any **of** ~~or~~ **our product candidates** ~~all of these activities~~ and, even if we do, we may never generate sufficient revenue to achieve profitability. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our product candidates. If we are required by the FDA or other regulatory authorities such as the EMA to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future product candidates, our expenses could increase and profitability could be further delayed. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of the Company also could cause you to lose all or part of your investment. We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to curtail our planned operations and the pursuit of our growth strategy. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we

may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We **will require additional capital to complete our planned clinical development programs for our current product candidates to seek regulatory approval. Our expenses have increased and we** expect our expenses **to continue** to increase in connection with our ongoing activities, particularly as we continue to develop our product candidates. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. **If we receive regulatory approval for any of our product candidates, we may incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.** In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. Additionally, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution and, with respect to certain of our product candidates, the payment of milestone and royalty fees. ~~Furthermore, we expect to incur additional costs associated with operating as a public company.~~ As of December 31, ~~2023~~ **2024**, we had cash, cash equivalents and marketable securities of $ ~~381~~ **486**. ~~8~~ **0** million, excluding restricted cash of $ 3. ~~7~~ **4** million. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operating **and** ~~expenses,~~ financial commitments and other cash requirements for at least 12 months from the date of filing of this report. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including: • the scope, progress, results and costs of our ongoing and planned preclinical studies and clinical trials for our product candidates; • the timing and amount of milestone and royalty payments we are required to make under our license agreements; • the extent to which we in- license or acquire other product candidates and technologies; • the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; • our ability to establish strategic collaborations for the development or commercialization of some of our product candidates; and • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims brought by third parties against us. We will require additional capital to complete our planned clinical development programs for our current product candidates to seek regulatory approval. ~~If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.~~ Any additional capital- raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common shares to decline. As a result, we may not be able to access the capital markets as frequently as comparable companies. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired. Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams. Until such time as we can generate substantial product revenue, if ever, we expect to finance our operations through a combination of equity offerings, debt financings and license and development agreements in connection with any future collaborations. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity securities, including through our" at- the- market" equity program, or convertible debt securities. In such an event, our existing shareholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our common shares. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business. Further, if we raise additional capital through collaborations, strategic alliances, or marketing, distribution, licensing or funding arrangements with third parties, we may have to relinquish valuable rights to our intellectual property future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to ~~us. Credit risk with respect to our investments or the financial institutions at which we deposit funds could adversely affect~~ us. Financial instruments that expose us to concentrations of credit risk consist of cash, cash equivalents, and short- term debt securities. Market conditions and changing circumstances, many of which are beyond our control, could reduce the value of our investments or impair our ability to access our existing cash, cash equivalents or other investments. For example, rising interest rates could negatively impact the value of investments that are not held to maturity. We maintain cash deposits that are in excess of the Federal Deposit Insurance Corporation (“ FDIC ”) insurance limit in FDIC- insured financial institutions. If any financial institution with which we have a banking relationship were to be placed into receivership or become insolvent in the future, we may be unable to access, temporarily or over a longer- term, or we may lose, a portion of our funds on deposit with that institution. **Any** ~~For example, on March 10, 2023 and March 12, 2023, Silicon Valley Bank and Signature Bank, respectively, were placed into receivership with the FDIC, which resulted in~~

~~all funds held at those banks being temporarily inaccessible by their customers. While we have no relationship with the financial institutions above, any~~ delay in our ability to access our cash, cash equivalents and investments, or the loss of some or all of such funds, could result in us not being able to pay our employees, vendors or others on a timely basis, or at all, and could hinder us from being able to enter into commercial arrangements that could be advantageous to us. Conversely, if any of our counterparties are impacted by any banking failures, that could impact their ability to transact with us. Any of the foregoing could adversely impact, possibly materially, our business and operations. ~~Risks Related to the Development of~~ Our ~~Product CandidatesOur~~ current business depends entirely on the success of a limited number of product candidates, which are in clinical development. If we do not obtain or are delayed in obtaining regulatory approval for and successfully commercialize one or more of our product candidates, our business, financial condition and results of operations could be materially impacted and we may never become profitable. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We do not have any products that have received regulatory approval, and therefore we have never generated any revenue from product sales, and we may never be able to develop product candidates that receive regulatory approval or are successfully commercialized after regulatory approval is received. Consequently, the revenue- generating potential of our business is unproven and uncertain. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of our product candidates; specifically, completion of our Phase 3 clinical trials of troriluzole in OCD, ~~execution~~ **completion** of clinical trials for BHV- 7000, including Phase 2 / 3 studies in epilepsy and ~~bipolar disorder and~~ a Phase 2 study in MDD, completion of a Phase 2 / 3 clinical trial of troriluzole in glioblastoma, execution of ~~clinical trials for BHV- 2000, including a Phase 3 clinical trial in SMA and~~ a Phase 2 clinical trial **for BHV- 2000** in metabolic disorders, ~~initiation~~ **completion** of ~~a~~ Phase **2 studies** ~~1 clinical trial~~ for BHV- ~~1300~~ - **2100** in **pain** ~~immune mediated diseases,~~ and **migraine,** initiation of a Phase 2 / 3 clinical trial for BHV- 8000 in Parkinson' s Disease **, completion of Phase 1 clinical trials for BHV- 1300, BHV- 1400, BHV- 1600, BHV- 1510, and initiation of Phase 1 clinical trials for BHV- 1310 and BHV- 1530** . As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of these product candidates. We cannot be certain that we will be able to submit a new drug application (" NDA "), biologics license application (" BLA ") or comparable applications in other jurisdictions for any of our product candidates within the timeframes we expect, or that any NDA, BLA or similar application we submit will be accepted by the FDA or comparable foreign regulators for filing in a timely manner or at all. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. The success of our product candidates will depend on various factors, including: • completing clinical trials that demonstrate our product candidates' efficacy and safety; • receiving marketing approvals from applicable regulatory authorities; • completing any post- marketing studies required by applicable regulatory authorities; • establishing commercial manufacturing capabilities; • launching commercial sales, marketing and distribution operations; • the prevalence and severity of adverse events experienced with our product candidates; • acceptance of our product candidates by patients, the medical community and third- party payors; • a continued acceptable safety profile following approval; • obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates; • competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and • qualifying for, maintaining, enforcing and defending our intellectual property rights and claims. Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. Our failure to achieve one or more of these factors in a timely manner or at all could materially harm our business, financial condition and results of operations. Clinical trials are very expensive, time- consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Clinical testing is expensive and can take many years to complete, and delay or failure can occur at any time during the clinical trial process. For example, in September 2021, we reported negative topline results from our Phase 3 clinical trial evaluating verdiperstat compared to placebo for the treatment of participants with MSA. In September 2022, we reported negative topline results from the Phase 2 / 3 HEALEY ALS Platform trial evaluating verdiperstat compared to placebo for the treatment of participants with ALS. At this time, we have no plans to continue development of verdiperstat in ALS, and we are evaluating whether or not to pursue any additional clinical trials evaluating verdiperstat in other disease indications. In addition, the results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for many of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later- stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected. Interim topline and preliminary data from our clinical trials that we 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. From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data

being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. We have limited experience in drug discovery and drug development. Because we in- licensed some of our investigational agents from other companies, including BHV- 2000 from BMS ~~and BHV- 5000~~ , we were not involved in and had no control over the preclinical and clinical development of these product candidates prior to entering into these in- license agreements. In addition, we are relying on the other companies from which we licensed our investigational agents to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable product candidate, and correctly collected and interpreted the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these product candidates. Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials **will** need to be redesigned, enroll an adequate number of patients on time or begin or be completed on schedule, if at all. The commencement and completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including: • the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials; • the delay or refusal of regulators (including the FDA) or ~~institutional review boards (“~~ IRBs ~~”)~~ to authorize us to commence a clinical trial; • regulators (including the FDA), IRBs, ethics committees of the institutions at which trials are being conducted or the data safety monitoring board for such trials requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements (including the FDA’ s current ~~Good Clinical Practice (“~~ GCP ~~”)~~ regulations) or our clinical protocols, safety concerns, adverse side effects, or lack of adequate funding to continue the clinical trial, among others; • changes in regulatory requirements, policies and guidelines; • delays or failure to reach agreement on acceptable terms with prospective clinical research organization (“ CROs ”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; delays in patient enrollment and variability in the number and types of patients available for clinical trials; • the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial; • having clinical sites deviate from the trial protocol or dropping out of a trial; • negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising; • safety or tolerability concerns (including due to reports from testing of similar therapies) that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others; • lower than anticipated retention rates of patients and volunteers in clinical trials; • our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial; • delays relating to adding new clinical trial sites; • difficulty in maintaining contact with patients after treatment, resulting in incomplete data; • delays in establishing the appropriate dosage levels; • the quality or stability of the product candidate falling below acceptable standards; • the inability to produce or obtain sufficient quantities of the product candidate to commence or complete clinical trials; and • exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, 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 regulatory approval of our product candidates. The regulatory approval processes of the FDA and comparable foreign regulatory agencies are lengthy, time-consuming and unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or abroad until we receive regulatory approval of an NDA or BLA from the FDA or approval from the EMA, NMPA or other applicable foreign regulatory agency. The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including those beyond our control, such as the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval is generally uncertain, may change during the course of a product candidate’ s clinical development and may vary among jurisdictions. Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we must demonstrate to the satisfaction of the FDA, EMA, NMPA or any comparable foreign regulatory agency ~~,~~ that such product candidates are safe and effective for their intended uses. The FDA, EMA, NMPA or any comparable foreign regulatory agency can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including: • the FDA, EMA, NMPA or the applicable foreign regulatory agency’ s disagreement with the number, design, conduct or implementation of our preclinical studies and clinical trials; • negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, EMA, NMPA or any comparable foreign regulatory agency for approval; • serious and unexpected drug- related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • our inability to demonstrate to the satisfaction of the FDA, EMA, NMPA or the applicable foreign regulatory agency that our product candidates are safe and effective for their proposed indications, or that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks; • the FDA’ s, EMA’ s,

NMPA' s or the applicable foreign regulatory agency' s disagreement with the interpretation of data from preclinical studies or clinical trials; • actions by the CROs that we retain to conduct our preclinical studies and clinical trials, which are outside of our control and that materially adversely impact our preclinical studies and clinical trials; • the FDA' s, EMA' s, NMPA' s or the applicable foreign regulatory agency' s disagreement regarding the formulation, labeling or the specifications of our product candidates; • the FDA' s, EMA' s, NMPA' s or the applicable foreign regulatory agency' s failure to approve the manufacturing processes or facilities of third- party manufacturers with which we contract; and • the potential for approval policies or regulations of the FDA, EMA, NMPA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. For example, with respect to our randomized, controlled clinical trial of troriluzole for the treatment of SCA, we undertook discussions with the FDA regarding the acceptability of the primary endpoint and necessary secondary endpoints, including our proposal to use a modified SARA scale. In our first Phase 2 / 3 clinical trial, the FDA stated that while certain items measured by the SARA scale appeared capable of reflecting a clinically meaningful benefit for patients depending on how the scoring of those items is defined, the use of the SARA scale was not appropriate as a primary endpoint in the trial. Based on our post- hoc analyses of data from the open- label extension phase of the trial, we proposed modifications to the SARA scale that we believe may address some of these shortcomings. Based on feedback received from the FDA, we incorporated trial design modifications that include utilization of a modified SARA scale. However, notwithstanding the feedback that we have received from the FDA, there remains substantial risk that the FDA or any foreign regulatory agency may nevertheless conclude that results obtained using the modified SARA scale would not be an adequate basis for approval. In addition, in our Phase 3 clinical trial (" Study BHV4157- 206") evaluating the efficacy and safety of troriluzole in adult patients with SCA, the primary endpoint, change from baseline to week 48 on the modified SARA scale, did not reach statistical significance in the overall SCA population as there was less than expected disease progression over the course of the study. Post- hoc analysis of efficacy measures by genotype suggests a treatment effect in patients with the SCA Type 3 (" SCA3") genotype. There is substantial risk that the FDA, EMA, NMPA or the applicable foreign regulatory agency may disagree with the interpretation of our data, and there can be no assurance that any such regulatory agency will find the data sufficient to support approval, or that we will not be required to conduct additional testing on the safety and efficacy of troriluzole. In May 2023, we presented further analysis of Study BHV4157- 206 by prespecified genotype strata that revealed consistent treatment effects of troriluzole in SCA3, which represented 41 % of study participants. These results were further supported by consistent results across the range of secondary and exploratory endpoints assessed in the SCA3 subgroup. In July 2023, the FDA informed us that it would not review the recently submitted NDA application for troriluzole given that the study' s primary endpoint was not met and thus, would not permit a substantive review. In **September 2024, we announced positive topline results from pivotal Study BHV4157- 206- RWE (NCT06529146) demonstrating the efficacy of troriluzole on the mean change from baseline in the f- SARA after 3 years of treatment. Study BHV4157- 206- RWE was designed, in discussion with the FDA, to assess the effectiveness of troriluzole in SCA after 3 years of treatment as measured by the change from baseline in the f- SARA. The study achieved the primary endpoint and showed statistically significant improvements on the f- SARA at years 1 and 2 and 3 and we submitted an NDA to the FDA in the fourth quarter of 2024 for all of SCA. In** October ~~,~~ 2023, the EMA informed us that our MAA for troriluzole (Dazluma) in the treatment of SCA has been validated and is now under review by EMA' s CHMP **. In the fourth quarter of 2024, we completed a clarification meeting with the CHMP Rapporteurs. The MAA documents were subsequently updated with a broader indication to include all SCA genotypes, in light of the new positive BHV4157- 206- RWE study data** . We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the EU and other key global markets, which requires compliance with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdiction. Failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Moreover, even if we were to obtain approval to market any product candidate we develop, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Our product candidates may fail to demonstrate safety and efficacy in clinical trials, or may cause serious adverse or unacceptable side effects that could prevent or delay regulatory approval and commercialization, limit the commercial profile of an approved label, increase our costs, necessitate the abandonment or limitation of the development of some of our product candidates or result in significant negative consequences following marketing approval, if any. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate efficacy or safety of the product candidate studied for the target indication. For example, in September 2021 we reported negative topline results from a Phase 3 clinical trial to evaluate the efficacy and safety of verdiperstat in participants with MSA. Results of the trial showed that verdiperstat did not statistically differentiate from placebo on the prespecified primary efficacy measure, nor on the key secondary efficacy measures. In September 2022, we reported negative topline results from the Phase 2 / 3 HEALEY ALS Platform trial evaluating verdiperstat compared to placebo for the treatment of participants with ALS. At this time, we do not have plans to pursue any additional clinical trials evaluating verdiperstat in ALS, but we are evaluating its potential in other disease indications. Moreover, undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay

or halt clinical trials and could result in a more restrictive label, the limitation of commercial potential or the delay or denial of regulatory approval by the FDA or a foreign regulatory agency. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we may need to abandon the development of certain product candidates or limit development to certain uses or sub- populations in which such side effects are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many compounds that initially showed promise in preclinical or early- stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound in the tested indication. Occurrence of serious treatment- related side effects could impede subject recruitment and clinical trial enrollment or the ability of enrolled patients to complete the trial, delay the clinical trial, and prevent receipt of regulatory approval from the FDA and other regulators. They could also adversely affect physician or patient acceptance of our product candidates or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised. Clinical trials of our product candidates by their nature are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. We have monitored the subjects in our studies for certain safety concerns and we have not seen evidence of significant safety concerns in our clinical trials. However, if one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects that had not previously been identified, a number of potentially significant negative consequences could result, including: • withdrawal or limitation by regulatory authorities of approvals of such product; • seizure of the product by regulatory authorities; • recall of the product; • restrictions on the marketing of the product or the manufacturing process for any component thereof; • requirement by regulatory authorities of additional warnings on the label, such as a " black box " warning or contraindication; • requirement that we implement a REMS or similar program or create a medication guide outlining the risks of such side effects for distribution to patients; • commitment to expensive additional safety studies prior to approval or post- marketing studies required by regulatory authorities of such product; • the product may become less competitive; • initiation of regulatory investigations and government enforcement actions; • initiation of legal action against us to hold us liable for harm caused to patients; and • harm to our reputation and resulting harm to physician or patient acceptance of our products. • Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations. We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. If we are unable to enroll a sufficient number of patients in our clinical trials, our timelines for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of our clinical trials altogether. We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors including: • the eligibility criteria for the trial in question; • the perceived risks and benefits of the product candidate in the trial; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off- label for these indications; • the size of the patient population required for analysis of the trial' s primary endpoints; • competition for patients for competitive product candidates undergoing clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • the design of the trial; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • the risk that patients enrolled in clinical trials will drop out of the trials before completion; • the ability to obtain and maintain patient consents; • the number of patients with the indication being studied; and • the proximity and availability of clinical trial sites for prospective patients. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. The current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. In addition, we have agreed to indemnify the licensors of the intellectual property related to our product candidates against certain intellectual property infringement claims. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates,

if approved. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects or identify patients who should not use our product candidates. Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all our liabilities. We **routinely review** ~~may need to increase~~ our insurance coverage ~~each time we commence a~~ **in consideration of our ongoing** clinical ~~trial~~ **trials** and **anticipated** ~~if we successfully commercialize~~ --- **commercial operations** ~~any product candidate~~. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. If serious adverse events or other undesirable side effects are identified during the use of our product candidates in trials, it may adversely affect our development of such product candidates. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt ~~nonclinical~~ **preclinical** studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If serious adverse events or other undesirable side effects or unexpected characteristics of our product candidates are observed in investigator- sponsored trials, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidate at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our product candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect. **We** ~~Risks Related to Commercialization of Our Product CandidatesWe~~ have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with suitable collaborators. We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party. Factors that may affect our ability to commercialize our product candidates on our own include: recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time- consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from such product candidates or be able to achieve or sustain profitability. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution of any approved product, our product revenue may be lower than if we directly marketed or sold such product. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third- party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. We operate in a highly competitive and rapidly changing industry. Failure to compete successfully could adversely affect our business, financial condition and results of operations. Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in- license, acquire, develop and obtain regulatory approval for new and innovative products on a cost- effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well- established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the EU and other jurisdictions. With respect to troriluzole, which we are currently developing for the treatment of ataxias and other neurologic disorders, with SCA as our initial indication, there are currently no approved drug treatments for SCA in the United States. We are also developing troriluzole for the potential treatment of OCD and other indications. If we continue to pursue these indications, we would face substantial competition from companies that develop or sell products that treat OCD. ~~With respect to BHV- 5000, which we are developing for the treatment of neuropsychiatric conditions the market size and competition will depend on each indication.~~ Many of the companies which we are competing with or which we may compete with in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry **have resulted in and** could **in the future** result in even more resources being concentrated among our competitors. Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in the biopharmaceutical industry. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidates that we may develop. Established biopharmaceutical companies may invest heavily to accelerate research and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome

price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, and in discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations. The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. 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 products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third- party payors will have an effect on our ability to successfully commercialize our product candidates, if approved, and attract additional collaboration partners to invest in the development of our product candidates. Assuming we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and adequate reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that becomes available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. Our competitors may offer their products and services on a less expensive basis to gain coverage and reimbursement from third- party payors. It is possible that a third- party payor may consider our product candidates as substitutable by less expensive therapies and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates, once approved. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such devices or therapies. Obtaining and maintaining reimbursement status is time- consuming and costly. No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that **further** changes in these rules and regulations are likely. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates **, if approved** . We expect to experience pricing pressures in connection with the sale of any of our **approved** product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations ~~,~~ and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for any products for which we may obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain coverage and adequate reimbursement approval for a product; • our ability to generate revenues and achieve or maintain profitability; and • the level of taxes that we are required to pay. Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promoting, sampling and record- keeping. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with ~~current good manufacturing practices (" cGMP ") regulations~~ and GCPs, for any clinical trials that we conduct post- approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. We may not be able to adapt to changes in existing requirements or the adoption of new requirements or policies. If there are changes in the application of legislation or regulatory policies, or if problems are

discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co- marketers fails to comply with regulatory requirements, the regulators could take various actions. These include: • issuing warning or untitled letters; • seeking an injunction or imposing civil or criminal penalties or monetary fines; • suspension or imposition of restrictions on operations, including product manufacturing; • seizure or detention of products, refusal to permit the import or export of products, or requesting that we initiate a product recall; • suspension or withdrawal of our marketing authorizations; • suspension of any ongoing clinical trials; • refusal to approve pending applications or supplements to applications submitted by us; • refusal to permit the import or export of products; or • requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant civil, criminal and administrative penalties. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expenses to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations. Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. Even if the FDA approves the marketing of any product candidates that we develop, physicians, patients, third- party payors or the medical community may not accept or use them. Efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may not be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. The degree of market acceptance of our product candidates that are approved for commercial sale will depend on a variety of factors, including: • the efficacy, cost, convenience and ease of administration, and other potential advantages compared to alternative treatments, including any similar generic treatments; • effectiveness of sales and marketing efforts; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement, and patients' willingness to pay out- of- pocket in the absence of third- party coverage or adequate reimbursement; • the prevalence and severity of any side effects; and • any restrictions on the use of our products, if approved, together with other medications. In addition, the potential market opportunity for our product candidates is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third- party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability. If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products sufficient periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected. Once an NDA is approved, the product covered thereby becomes a " reference listed drug " in the FDA' s publication, " Approved Drug Products with Therapeutic Equivalence Evaluations, " commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications (" ANDAs ") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. The FDA may not approve an ANDA for a generic product until any applicable period of non- patent exclusivity for the reference listed drug has expired. The ~~U. S. Federal Food, Drug, and Cosmetic Act (the " ~~FDCA ~~")~~ provides a period of five years of non- patent exclusivity for a new drug containing a new chemical element (" NCE "). Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug. While we believe that troriluzole, a prodrug of riluzole will be treated as an NCE under current FDA interpretations and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product. Competition that our products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates. **We** ~~Risks Related to Our Dependence on Third PartiesWe~~ rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed. We have historically conducted, and we intend to continue to conduct our clinical trials using our own clinical resources, while also leveraging expertise and assistance from medical institutions, clinical

investigators, contract laboratories and other third parties, such as contract research organizations as appropriate. We are reliant upon such third parties to assist us in conducting GCP- compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third- parties, we will have only limited control over their actual performance of these activities. We and our CROs and other vendors are required to comply with cGMP, GCP and ~~good laboratory practices (“~~ GLP ~~”)~~, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EU and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP- compliant preclinical studies and GCP- compliant clinical trials and have limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or any comparable foreign regulatory agency may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory agency, such regulatory agency will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process. While we will have agreements governing their activities, we are not, and will not be , able to control whether or not our CROs devote sufficient time and resources to our future preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. If our CROs do not successfully carry out their contractual duties or obligations, or 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 our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition. We rely completely on third- party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole- source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. We do not currently have, nor do we plan to acquire, the internal infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the active pharmaceutical ingredients (“ APIs ”) and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates. In addition, our results of operations and cash flows could be adversely impacted by any inability to obtain favorable terms from our suppliers, including any acceleration of payment terms to our suppliers and / or the imposition of more restrictive credit terms and other contractual requirements. While we have auditing rights with all our current manufacturing counterparties, we do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day- to- day compliance with cGMPs for production of both APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If our contract suppliers or manufacturers fail to achieve and maintain compliance with applicable laws and regulatory requirements, our business could be adversely affected in a number of ways, and cause, among other things: • an inability to initiate or continue clinical trials of our product candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates; • subjecting third- party manufacturing facilities or our own facilities to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our product candidates; • suspension of manufacturing of our product candidates; • revocation of obtained approvals; and • inability to meet commercial demands for our product candidates in the event of approval. Further, if the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws and regulatory requirements, or

for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all. We may rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. We may also have sole- source suppliers for one or more of our other product candidates. Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier or manufacturer fails to supply or manufacture, as applicable, product on a timely basis or in the requested amount, fails to meet regulatory requirements or our specifications, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source, or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement suppliers, manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases, we may be required to get regulatory approval to use alternative suppliers and manufacturers, and this process of approval could delay production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects. In addition, these contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier' s or manufacturer' s facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved. We expect to continue to depend on third- party contract suppliers and manufacturers for the foreseeable future, but supply and manufacturing arrangements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers may attempt to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third- party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our product candidates may be delayed or interrupted. In addition, third- party suppliers and manufacturers may have the ability to increase the price payable by us for the supply of the APIs and other substances and materials used in our product candidates, in some cases without our consent. Additionally, any damages to or destruction of our third- party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to have our product candidates manufactured on a timely basis. Furthermore, if a contract manufacturer or supplier becomes financially distressed or insolvent, or discontinues our relationship beyond the term of any existing agreement for any other reason, this could result in substantial management time and expense to identify, qualify and transfer processes to alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply. In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging. We, or third- party manufacturers on whom we rely, may be unable to successfully scale- up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any. As we prepare for later- stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third- party suppliers or manufacturers. In order to conduct larger or late- stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale- up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third- party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. We may in the future enter into collaborations with third parties to develop and commercialize our product candidates. If these collaborations are not successful, or if we are not able to establish or maintain these collaborations, our business could be harmed. Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund

expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. Collaboration arrangements are complex and time- consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, and the terms of any collaborations or other arrangements that we may establish may not be favorable to us. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing or alternative products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, including for example, that the collaborators may not: adequately perform their obligations under the collaboration agreement ; devote sufficient resources to the collaboration to ensure success ; or agree with us on the strategy or tactical aspects of the collaboration. If any such potential future collaborations do not result in the successful development and commercialization of product candidates, or if one of our future collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our potential future collaborators. **We** ~~Risks Related to Regulatory ComplianceWe~~ are required to comply with a wide variety of laws and regulations, and are subject to regulation by various federal, state and foreign agencies, and our failure to comply with existing and future regulatory requirements could adversely affect our results of operations and financial condition. Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. Our operations are subject to a broad array of regulatory requirements globally. We are subject to federal, state, local, international and transnational laws and regulations, including the operating, quality and security standards of the FDA, the U. S. Department of Health and Human Services (" HHS "), and other regulatory authorities such as the EMA, and in the future, any changes to such laws and regulations could adversely affect us. In particular, changes in the FDA' s regulation of drug discovery and development or manufacturing processes could adversely affect our results of operations and financial condition. We may be required to register for permits and / or licenses with the FDA, HHS, or other regulatory authorities such as the EMA, and there can be no assurance that we will be able to maintain or renew existing permits, licenses or other regulatory approvals or obtain, without significant delay, future permits, licenses or other approvals needed for the operation of our business. Any noncompliance by us with applicable laws and regulations or the failure to maintain, renew or obtain necessary permits and licenses could have an adverse effect on our results of operations and financial condition. In the United States, the EU, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, the" ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. **In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011 (known as Medicare sequestration) and subsequent extensions, which began in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken.** Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS is developing new payment and delivery models, such as bundled payment models. HHS moved 30 % of Medicare payments to alternative payment models tied to the quality or value of services in 2016. Additionally, HHS ~~had~~ **has** set a ~~goal of moving 50 % of Medicare payments into these alternative payment models by the end of 2018, but in 2019, it discontinued this performance goal and replaced it with a new~~ developmental goal to increase the percentage of Medicare health care dollars tied to APMs incorporating downside risk, with a target of ~~40~~ **55** % for fiscal year ~~2021~~ **2024 and 60 % for fiscal year 2025** . We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Further, there have

been several recent U. S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. ~~For example~~ **The IRA** , **enacted** in ~~September 2018~~ **August 2022** , ~~CMS announced it will allow~~ **among other things directs HHS to negotiate the price of certain single- source drugs and biologics covered under** Medicare **and imposes rebates under Medicare** ~~Advantage Plans the option to use step therapy for~~ Part B ~~drugs beginning January 1, 2019, and in May 2019, CMS finalized a new rule that would require direct- to- consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. However, this rule was struck down by a federal court before it went into effect. Although some of these and other proposals will require authorization through additional legislation to become effective, members of Congress and the Biden Administration have stated that they will continue to seek new legislative and administrative measures to control drug costs. In response to an~~ **and** ~~Executive Order from President Biden, the Secretary of HHS issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. In late 2021, Democrats included drug pricing reform provisions reflecting elements of the plan in a broader spending package — such as capping~~ Medicare Part D ~~patients~~ **to penalize price increases that outpace inflation. These provisions have started to take effect progressively starting in fiscal year 2023, although the Medicare drug price negation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue and update guidance as these programs are implemented. In January 2025, President Trump revoked several Biden- era executive orders which included efforts to lower the cost of prescription drugs for people on Medicare and Medicaid, increasing protections for Medicaid enrollees and enhancing the Affordable Care Act. Notably, Biden ' s Executive Order 14087** ~~out- of- pocket costs~~ , ~~establishing penalties for drug prices~~ **which ordered the testing of three new Medicare and Medicaid pricing negotiation models, was revoked. It is currently unclear how the IRA will be implemented, but it could have a significant impact on companies in the pharmaceutical industry** that **are within its scope. The Company does not currently have any** ~~increase faster than inflation in Medicare, and authorizing the federal government to negotiate prices on certain select, high- cost~~ drugs ~~under Medicare Parts B and D~~ **that are impacted by the IRA** . At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. **Further** ~~On May 30~~ , ~~2018,~~ the ~~Trickett Wendler, Frank Mongiello, Jordan McLinn,~~ **Supreme Court struck down the Chevron doctrine in June 2024 in Loper Bright Enterprises v. Raimondo** and ~~Matthew Bellina Right to Try Act~~ **Relentless Inc. v. Department** of **Commerce** ~~2017 was signed into law~~ . The ~~law, among~~ **Chevron doctrine gave deference to regulatory agencies in litigation against the FDA and** other **agencies** ~~things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase 1 clinical trial~~ . ~~Under certain circumstances~~ **As a result** , **more companies may bring lawsuits against the** ~~eligible patients can seek treatment without enrolling in clinical trials and without obtaining~~ FDA ~~approval under~~ **to challenge longstanding decisions and policies of** the FDA ~~expanded access program~~ **, which could undermine the FDA' s authority, lead to uncertainties in the industry and disrupt the FDA' s normal operations, which could delay the FDA' s review of our applications** . In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize any of our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information

privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third- party payors, subject to various U. S. federal and state healthcare laws and regulations, including, without limitation, the U. S. federal Anti- Kickback Statute, the U. S. federal civil and criminal false claims laws and Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities proposed sales and marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U. S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The U. S. laws that may affect our ability to operate include: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the U. S. federal Health Insurance Portability and Accountability Act of 1996 (“ HIPAA ”) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“ HITECH ”) enacted as part of the American Recovery and Reinvestment Act of 2009, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, on covered entities subject to HIPAA (i. e., health plans, healthcare clearinghouses and certain healthcare providers), as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information, to safeguard the privacy, security and transmission of individually identifiable health information from any unauthorized use or disclosure; • the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • the U. S. federal Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’ s Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; • analogous state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; • state laws that require pharmaceutical companies to comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; • state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; • state and local laws that require the registration of pharmaceutical sales representatives; and • state laws governing the privacy and security of personal information, including personal health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Ensuring that our internal operations and current and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in

other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. We have obtained orphan drug designation in the United States for troriluzole in SCA and for taldefgrobep alfa in SMA and in the EU for taldefgrobep alfa in SMA. We may seek orphan drug designation for other product candidates in the future. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication during that time period. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even when we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a later drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non- compliance. We are subject to rules and regulations by various governing bodies, including, for example, the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded, and to new and evolving regulatory measures under applicable law, including the laws of the BVI. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue- generating activities to compliance activities. Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed. **Disruptions at the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and the approval of an NDA, BLA or similar application. The ability of the FDA to review and approve new products can be affected by a variety of factors, including the ability to hire and retain key personnel, including senior leadership, government budget and funding levels and related government shutdowns, the ability to 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 and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs in the future, it could significantly impact the ability of the FDA to timely review and process our submissions. In addition, FDA- regulated industries, such as ours, face substantial uncertainty in regard to the regulatory environment we will face as we proceed with research and development efforts under the new presidential Administration in the U. S. For example, recent personnel reduction measures have significantly impacted and could continue to impact the FDA' s ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the new Administration has proposed action to freeze or reduce the budget of the NIH as relates to its funding for medical research, which could in turn decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. State governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations,**

policies or guidance, there could be a material adverse effect on us and our business. Changes to legislation or regulations in the British Virgin Islands could lead to increased costs for us to comply with additional regulatory and reporting requirements. As the global regulatory and tax environment evolves, we may be subject to new or different statutory and regulatory requirements. For example, on January 1, 2019, the Economic Substance (Companies and Limited Partnerships) Act, 2018 of the British Virgin Islands (the " Economic Substance Act ") came into force and was amended on October 1, 2019 and June 29, 2021 and remains subject to further amendments, additional regulations and guidance on interpretation from the regulator. We strive to conduct our business in a manner that is in compliance with the Economic Substance Act. However, the imposition of additional requirements due to further amendments, additional regulations or new guidance on interpretation of these laws may create additional costs that may be borne by us or otherwise affect our management and operation ~~. Risks Related to Our Intellectual PropertyWe could lose market exclusivity earlier than expected~~ . We own or license patents in the U. S. and foreign countries that protect our products, their methods of use and manufacture, as well as other innovations relating to the advancement of our science to help bring new therapies to patients. We also develop brand names and trademarks for our products to differentiate them in the marketplace. We consider the overall protection of our patents, trademarks, licenses and other intellectual property rights to be of material value and act to protect these rights from infringement. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know- how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know- how, continuing technological innovation and in- licensing opportunities to develop, strengthen and maintain the proprietary position of our products and development programs. In the biopharmaceutical industry, a substantial portion of an innovative product' s commercial value is usually realized during the period in which the product has market exclusivity. A product' s market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovative drug is entitled. Patents are a key determinant of market exclusivity for most pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient (s), various uses of a drug product, discovery tools, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country. Market exclusivity can also be influenced by regulatory data protection (" RDP "). Many developed countries provide certain non- patent incentives for the development of medicines. For example, in the U. S., the EU, the United Kingdom, Japan, and certain other countries, RDP intellectual property rights are offered to: (i) provide a time period of data protection during which a generic company is not allowed to rely on the innovator' s data in seeking approval; (ii) restore patent term lost during drug development and approval; and (iii) provide incentives for research on medicines for rare diseases, or orphan drugs, and on medicines useful in treating pediatric patients. These incentives can extend the market exclusivity period on a product beyond the patent term. Product Exclusivity – United ~~StatesIn~~ -- **States In** the United States, biopharmaceutical products are protected by patents with varying terms depending on the type of patent and the filing date. A significant portion of a product' s patent life, however, is lost during the time it takes an innovative company to develop and obtain regulatory approval of a new drug. As compensation, at least in part, for the lost patent term due to regulatory review periods, the innovator may, depending on a number of factors, apply to the government to restore lost patent term by extending the expiration date of one patent up to a maximum term of five years, provided that the extension cannot cause the patent to be in effect for more than 14 years from the date of drug approval. A company seeking to market an innovative pharmaceutical in the U. S. must submit a complete set of safety and efficacy data to the FDA. If the innovative pharmaceutical is a chemical product, the company files an NDA. If the medicine is a biological product, a BLA is filed. The type of application filed affects RDP exclusivity rights. Small Molecule ~~ProductsA~~ - **Products A** competitor seeking to launch a generic substitute of small molecule drug in the U. S. must file an ANDA with the FDA. In the ANDA, the generic manufacturer needs to demonstrate only " bioequivalence " between the generic substitute and the approved NDA drug. The ANDA relies upon the safety and efficacy data previously filed by the innovator in its NDA. An innovator company is required to list certain of its patents covering the medicine with the FDA in what is commonly known as the FDA' s Orange Book. The FDA cannot approve an ANDA until after the innovator' s listed patents expire unless there is a successful patent challenge. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA and allege that one or more of the patents listed in the Orange Book under an innovator' s NDA is either invalid or not infringed (a Paragraph IV certification). The innovator then must decide whether to file a patent infringement suit against the generic manufacturer. From time to time, ANDAs, including Paragraph IV certifications, are filed with respect to certain of our products. In addition to patent protection, certain innovative pharmaceutical products can receive periods of regulatory exclusivity. An NDA that is designated as an orphan drug can receive seven years of exclusivity for the orphan indication. During this time period, neither NDAs nor ANDAs for the same drug product can be approved for the same orphan use. A company may also earn six months of additional exclusivity for a drug where specific clinical studies are conducted at the written request of the FDA to study the use of the medicine to treat pediatric patients, and submission to the FDA is made prior to the loss of basic exclusivity. Medicines approved under an NDA can also receive several types of RDP. An innovative chemical pharmaceutical product is entitled to five years of RDP in the U. S., during which the FDA cannot approve generic substitutes. If an innovator' s patent is challenged, as described above, a generic manufacturer may file its ANDA after the fourth year of the five- year RDP period. A pharmaceutical drug product that contains an active ingredient that has been previously approved in an NDA, but is approved in a new formulation, but not for the drug itself, or for a new

indication on the basis of new clinical studies, may receive three years of RDP for that formulation or indication. Biologic ~~productsThe ---~~ **products The ACA** ~~U. S. healthcare legislation enacted in 2010~~ created an approval pathway for biosimilar versions of innovative biological products that did not previously exist. Prior to that time, innovative biologics had essentially unlimited regulatory exclusivity. Under the new regulatory mechanism, the FDA can approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full Biologics License Application (" BLA"). After an innovator has marketed its product for four years, any manufacturer may file an application for approval of a " biosimilar " version of the innovator product. However, although an application for approval of a biosimilar version may be filed four years after approval of the innovator product, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. The law also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA. In the U. S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. Second, statutory and regulatory provisions in the U. S. limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent (s) or the current forms of regulatory exclusivity. Foreign ~~RegulationIn --~~ **Regulation In** order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Although many of the issues discussed above with respect to the United States apply similarly in the context of the EU and other geographies, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. European ~~UnionA --~~ **Union A** typical route used by innovator companies to obtain marketing authorization of pharmaceutical products in the EU is through the " centralized procedure. " A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a MAA with the EMA. After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a " mutual recognition procedure, " in which an application is made to a single member state, and if the member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states. After obtaining marketing authorization approval, a company must obtain pricing and reimbursement for the pharmaceutical product, which is typically subject to member state law. In certain EU countries, this process can take place simultaneously while the product is marketed but in other EU countries, this process must be completed before the company can market the new product. The pricing and reimbursement procedure can take months and sometimes years to complete. Throughout the EU, all products for which marketing authorizations have been filed ~~after October / November 2005~~ are subject to an " 8 2 1 " regime. Eight years after the innovator has received its first community authorization for a medicinal product, a generic company may file a MAA for that product with the health authorities. If the MAA is approved, the generic company may not commercialize the product until after either 10 or 11 years have elapsed from the initial marketing authorization granted to the innovator. The possible extension to 11 years is available if the innovator, during the first eight years of the marketing authorization, obtains an additional indication that is of significant clinical benefit in comparison with existing treatments. For products that were filed prior to October / November 2005, there is a 10- year period of data protection under the centralized procedures and a period of either six or 10 years under the mutual recognition procedure (depending on the member state). In contrast to the U. S., patents in the EU are not listed with regulatory authorities. Generic versions of pharmaceutical products can be approved after data protection expires, regardless of whether the innovator holds patents covering its drug. Thus, it is possible that an innovator may be seeking to enforce its patents against a generic competitor that is already marketing its product. Also, the European patent system has an opposition procedure in which generic manufacturers may challenge the validity of patents covering innovator products within nine months of grant. In general, EU law treats chemically- synthesized drugs and biologically- derived drugs the same with respect to intellectual property and data protection. In addition to the relevant legislation and annexes related to biologic medicinal products, the EMA has issued guidelines that outline the additional information to be provided for biosimilar products, also known as generic biologics, in order to review an application for marketing approval. ~~JapanIn~~ **In** Japan, medicines of new chemical entities are generally afforded eight years of data exclusivity for approved indications and dosage. Patents on pharmaceutical products are enforceable. Generic copies can receive regulatory approval after data exclusivity and patent expirations. As in the U. S., patents in Japan may be extended to compensate for the patent term lost during the regulatory review process. In general, Japanese law treats chemically- synthesized and biologically- derived drugs the same with respect to intellectual property and market exclusivity. Rest of the ~~WorldIn --~~ **World In** countries outside of the U. S., the EU and Japan, there is a wide variety of legal systems with respect to intellectual property and market exclusivity of pharmaceuticals. Most other developed countries utilize systems similar to either the U. S. or the EU. Among developing countries, some have adopted patent laws and / or regulatory exclusivity laws, while others have not. Some developing countries have formally adopted laws in order to comply with World Trade Organization (" WTO ") commitments, but have not taken steps to implement these laws in a meaningful way.

Enforcement of WTO actions is a long process between governments, and there is no assurance of the outcome. We are dependent on licensed intellectual property in our business. If we are unable to obtain licenses from third parties on commercially reasonable terms or lose our rights to such licensed intellectual property, or if our rights are determined to be narrower than we understand them to be, we may not be able to continue developing or commercializing our product candidates. We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business, including, for example, an agreement with ALS Biopharma and Fox Chase Chemical Diversity Center, Inc., pursuant to which we were assigned intellectual property rights relating to troriluzole, a license agreement with Yale University, pursuant to which we were granted certain patent rights to develop and commercialize riluzole- based products, another license agreement with Yale University pursuant to which we acquired exclusive, worldwide rights to Yale' s intellectual property directed to its MoDE platform, a license agreement with Highlightll, pursuant to which we were granted exclusive rights to develop and commercialize Highlightll' s brain penetrant dual TYK2 / JAK1 inhibitor program, a license agreement with Bristol- Myers Squibb, pursuant to which we were granted exclusive rights to develop and commercialize taldefgrobep alfa ~~,~~ ~~license agreements with AstraZeneca, pursuant to which we were granted exclusive licenses relating to BHV- 5500 and verdiperstat, a license agreement with AstraZeneca, pursuant to which we were granted an exclusive license to BHV- 2200~~ , and a license agreement with KU Leuven, pursuant to which we were granted an exclusive license to develop and commercialize the TRPM3 antagonist platform. We may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and / or commercial diligence obligations, payment of milestones and / or royalties and other obligations, such as non- compete periods for certain collaboration targets and rights of first negotiation for development of certain programs. Typically, in our licenses, we have control over the filing, prosecution, maintenance and enforcement of the licensed intellectual property. However, in some cases, we do not control prosecution of the licensed intellectual property, or do not have the first right to enforce such intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop, manufacture or commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer of or granting of rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information. If our licensors fail to comply with their obligations under these agreements, such as, for example, by failing to maintain or enforce patents licensed to us, exclusivity relating to the products covered by the license may be diminished or lost. Our rights under license agreements could be determined to be narrower than we understand them to be. Also, if it is found that our licensors were not the original inventors of the licensed intellectual property, or were not the first to file patent applications, then we may lose rights to the licensed intellectual property. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues. Disputes between us and our licensors have arisen and may arise in the future. For example, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues, including our right to sublicense patents and other rights to third parties; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; • our right to transfer or assign the license; and • the effects of termination. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop, manufacture or commercialize the affected product candidates. It may be necessary or desirable for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would seek to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or payment of royalties and / or other forms of compensation. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. Patent terms may not provide exclusivity for our product candidates for an adequate amount of time for us to realize commercial benefits. Patents have a limited lifespan. In the United States and most of the world, the statutory expiration of a patent is generally 20 years from the first filing date. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive products, including generic products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates may not provide us with exclusivity for an adequate amount of time for us to realize commercial benefits. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the EU. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process, subject to a statutory maximum of fourteen (14) years from the regulatory approval and an additional six months of pediatric exclusivity if available. Similar regulations regarding

patent term extensions, or supplementary protection certificates, are available in some countries such as the EU, United Kingdom, Japan and Korea. However, we may not receive a patent term restoration, a supplementary protection certificate or extension if we fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain a patent term restoration, a supplementary protection certificate or extension, or the term is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. ~~Third parties may seek to invalidate our patents.~~ Once granted, patents may remain open to invalidity challenges including opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation actions in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims which are the subject of the challenge, or may lose the allowed or granted claims altogether. Generic manufacturers seeking to launch a generic substitute of small molecule drug in the U. S. typically engage in patent challenges. We expect that as early as four (4) years after the approval of our products, one or more generic manufactures may allege that one or more of the patents listed in the Orange Book under our NDA is either invalid or not infringed (a Paragraph IV certification). We then must decide whether to file a patent infringement suit against such generic manufacturer (s). Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could ~~. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business~~. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe 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 our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our technology, such as our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. If, in the context of seeking approval for one of our product candidates subject to approval via Section 505 (b) (2), we were required to file a Paragraph IV certification against any patents of a third party, we would additionally be at risk of an automatic stay if litigation is initiated, thereby potentially delaying our approval or market entry. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In addition to claims of infringement made by third parties against us, we have in the past and may again in the future file claims of infringement and / or trade secret misappropriation against third parties who infringe, or misappropriate, our patents and / or trade secrets or those of our licensors. This can occur as a counter claim in an infringement suit against us or as a direct claim against the third party. Our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable or claims challenging the scope of the intellectual property rights we own or control. The outcome following legal assertions of invalidity and unenforceability is unpredictable. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions or other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished and the market price of our common stock could decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business. We are subject to other risks relating to our intellectual property. In addition to the risk factors described above, we consider the items below to be relevant for consideration in the assessment of the Company' s intellectual property position. • Changes in intellectual property laws or regulations in the U. S. or other countries could negatively affect our business. Similarly, changes in the interpretation of such laws or regulations could have an impact on our business. For example, U. S. Supreme Court has ruled on several patent cases in recent years, such as Impression Products, Inc. v. Lexmark International, Inc., Association for Molecular Pathology v. Myriad Genetics, Inc., Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, decisions by courts may lead to legislation impacting our ability to obtain or enforce our intellectual property. • Our ability to enforce our intellectual property outside of the U. S. is dependent on the laws of jurisdiction in which the alleged infringement occurred, the ability to engage in discovery to obtain evidence and the availability of meaningful recoveries, e. g., damages and injunctions. The laws of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual

property, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. As a result, our business may be harmed by limitations on our ability to protect our technology through the enforcement of our intellectual property in certain countries outside the U. S. • The U. S. government may seek to exercise its rights under the Bayh- Dole Act of 1980 in programs that have received government funding. This exercise of rights could require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party the U. S. Government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). • We rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, third party collaborators, contract manufacturers, consultants, advisors and other third parties. An unauthorized disclosure or use of our trade secrets can have an adverse impact on our business. • Other innovator companies may independently develop alternative technologies to our technologies without infringing our intellectual property rights, such as, for example, by developing compounds that function according to the same mechanism of action as our compounds, but are chemically distinct from ours and are not covered by the claims of the patents that we own or control. • Litigation involving intellectual property can be generally time consuming and expensive. Litigation or other legal proceedings relating to intellectual property claims is unpredictable and generally expensive and time- consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our valuation. ~~Risks Related to~~ Our ~~Business Operations, Employee Matters and Managing GrowthOur~~ future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel. We are highly dependent on the management, development, clinical, financial and business development experience of our senior management. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or employees. The competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly- skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could harm our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States and the EU. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including: • economic weakness, including inflation, or political instability in particular economies and markets; • the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • tariffs and trade barriers; • other trade protection measures, import or export licensing requirements or other restrictive actions by U. S. or foreign governments; • longer accounts receivable collection times; • longer lead times for shipping; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • workforce uncertainty in countries where labor unrest is common; • language barriers for technical training; • reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics; • foreign currency exchange rate fluctuations and currency controls; • differing foreign reimbursement landscapes; • uncertain and potentially inadequate reimbursement of our products; and • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. ~~Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.~~ Despite the implementation of security measures, our internal computer systems, and those of our CROs, CMOs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although we have not experienced a material security breach or disruption to date, we may experience a material security breach or disruption in the future in the event such security breach or disruption results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including individually identifiable health information or the personal data of employees or former employees, access to our clinical data or disruption of the manufacturing process. We are also vulnerable to cybersecurity incidents through cyberattacks by hackers, user error, phishing scams or other malfeasance, as well as cybersecurity incidents involving our employees, business partners, collaborators or other third parties. This type of breach of our cybersecurity may compromise our

confidential information or our financial information and adversely affect our business, reputation, financial condition, results of operations or result in legal proceedings. Additionally, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including date concerning health, is subject to the EU General Data Protection Regulation, or GDPR ~~, which became effective on May 25, 2018~~. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing data concerning health and other sensitive data, obtaining consent of the individuals to whom the personal data relates to process their personal data, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4 % of annual global turnover, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Various U. S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non- compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. Moreover, these new laws and regulations could diverge and conflict with each other in certain respects. As new privacy- related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non- compliance and reporting obligations in the case of data breaches, have increased and may further increase. ~~Laws and regulations governing our international operations may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.~~ As we expand our operations outside of the United States, we will be required to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are subject to U. S. laws governing international business activities, including U. S. economic sanctions, export controls and anti- corruption laws, including the ~~Foreign Corrupt Practices Act (the "~~ FCPA ~~")~~, compliance with which is expensive and difficult, particularly in countries in which corruption is a recognized problem. As a result, these laws may preclude us from developing, manufacturing or selling certain product candidates outside of the United States, which could limit our growth potential and increase our development costs. If our employees or agents violate our policies or we fail to maintain adequate record keeping and internal accounting practices to accurately record our transactions, we may be subject to regulatory sanctions. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Violations of U. S. economic sanctions, export controls and anti- corruption laws, or allegations of such acts, could damage our reputation and subject us to civil or criminal investigations in the United States and in other jurisdictions and related shareholder lawsuits, could lead to substantial civil and criminal, monetary and nonmonetary penalties and could cause us to incur significant legal and investigatory fees which could adversely affect our business, consolidated financial condition and results of operations. We **have expanded and** expect to **further** expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As our clinical development progresses, we **have experienced and** expect **to continue** to experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical operations, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our ~~anticipated future~~ growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such ~~anticipated~~ growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect

and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. We may be subject to securities litigation, which is expensive and could divert management attention. Our share price **has been and** may **continue to** be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. ~~Securities litigation against us~~ **Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome** could result in **payments of** substantial ~~costs~~ **damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Defending against litigation is costly** and **time- consuming, and could** divert our management' s attention ~~from~~ **and resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or** other ~~business concerns~~ **interim proceedings or developments** , which **could have a negative effect on the market price of our common shares. Any of the foregoing** could seriously harm our business ~~. Risks Related to Ownership of Our Common SharesAn active trading market for our common shares may not be sustained, or be liquid enough for investors to resell our common shares quickly or at the market price. Our common shares began trading on the NYSE on October 4, 2022. Although trading in our common shares has developed, we cannot assure you that an active trading market will be sustained or that any trading market will continue to be liquid. If an active market for our common shares is not sustained, it may be difficult for our shareholders to sell shares without depressing the market price for the shares or to sell their shares at all. An inactive market may also impair our ability to raise capital to continue to fund operations by selling our common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration~~ . The trading price of our common shares has in the past been and could in the future be volatile and fluctuate due to factors beyond our control, and purchasers of our common shares could incur substantial losses. Our share price has in the past been and could in the future be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our shareholders and investors may not be able to sell their common shares at or above the price paid for the shares. The market price for our common shares may be influenced by many factors, including: • positive or negative results, including preliminary or topline results, of preclinical studies and clinical trials reported by us, strategic partners or competitors; • any progress or delay in the commencement, enrollment and the ultimate completion of clinical trials; • technological innovations or commercial product introductions by us or competitors; • failure to successfully develop and commercialize any of our product candidates; • developments, announcements or changes in government regulations relating to drug products, including related to drug pricing, reimbursement and healthcare coverage; • delays in in-licensing or acquiring additional complementary product candidates; • developments concerning proprietary rights, including patents and litigation matters; • public concern relating to the commercial value or safety of any of our product candidates; • financing or other corporate transactions, or inability to obtain additional funding; • announcements relating to our arrangements with strategic partners; • failure to meet or exceed expectations of the investment community; • actual or anticipated variations in our operating results; • changes in financial estimates by us or by any securities analysts who might cover our shares; • announcements by therapeutic drug product providers related to pricing of therapeutics; • announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors; • publication of research reports or comments by securities or industry analysts; • failure to attract or retain ~~of~~ key personnel; • sales of our common shares, including sales by our directors and officers or specific shareholders; • general market or regulatory conditions in the pharmaceutical industry or in the economy as a whole; • other events and factors, many of which are beyond our control; and • other factors described in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K. These and other market and industry factors **have caused and** may **in the future** cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common shares. ~~Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Defending against litigation is costly and time- consuming, and could divert our management' s attention and resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common shares.~~ If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common shares and our trading volume could decline. The trading market for our common shares ~~will depend~~ **depends** in part on the research and reports that securities or industry analysts publish about us or our business. Equity research analysts may elect not to initiate, and our current equity research analysts may not elect to continue to provide research coverage of our common shares, and such lack of research coverage may adversely affect the market price of our common shares. **We** ~~Even if we~~ do ~~have equity research analyst coverage, we will~~ not have any

control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause our share price or trading volume to decline. Anti- takeover provisions in our amended memorandum and articles of association (" Amended Memorandum and Articles of Association ") could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management and limit the market price of our common shares. Provisions in our Amended Memorandum and Articles of Association may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board. Among other things, these provisions: • establish a classified Board such that not all members of the Board are elected at one time; • allow the authorized number of our directors to be changed only by resolution of our Board; • limit the manner in which shareholders can remove directors from the Board; • establish advance notice requirements for shareholder proposals that can be acted on at shareholder meetings and nominations to our Board; • require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent; • limit the ability of members to requisition and convene general meetings of members; and • authorize our Board to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our members without shareholder approval, which could be used to institute a shareholder rights plan, or so- called " poison pill, " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board. Any provision of our Amended Memorandum and Articles of Association or BVI law that has the effect of delaying or deterring a change of control could limit the opportunity for our shareholders to receive a premium for their common shares, and could also affect the price that some investors are willing to pay for our common shares. ~~Substantially all of our total outstanding shares may be sold freely into the market. This could cause the market price of our common shares to drop significantly, even if our business is doing well.~~ Sales of substantially all of our common shares in the public market, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. Substantially all of our common shares are freely tradable, without restrictions or further registration under the Securities Act, subject to certain restrictions applicable to shares held by our affiliates as defined in Rule 144 under the Securities Act ~~. Because we do not expect to pay dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain~~ . We have never declared or paid any dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The decision to pay future dividends to shareholders will be at the discretion of our Board after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares. ~~Effective December 31, 2023, we are a large accelerated filer and no longer qualify as a smaller reporting company or emerging growth company, which will increase our costs and demands on management. Based on the Company' s public float as of June 30, 2023, we became a " large accelerated filer " and lost " emerging growth company " status on December 31, 2023. Additionally, due to the Company' s public float as of June 30, 2023, we no longer qualify as a " smaller reporting company. " However, we are not required to reflect the change in our " smaller reporting company " status, or comply with the associated increased disclosure obligations, until our quarterly report for the three- month period ended March 31, 2024. Due to this upcoming transition, we are devoting significant time and efforts to implement and comply with the additional standards, rules and regulations that will apply to us upon becoming a large accelerated filer and losing our smaller reporting company and emerging growth company status, diverting such time from the day- to- day conduct of our business operations. Compliance with the additional requirements of being a large accelerated filer have increased our legal, accounting and financial compliance costs as of year- end, and these costs will continue to increase. These requirements include, but are not limited to: • compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting; • compliance with any requirement that is adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • full disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and • compliance with the requirements of holding a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Due to the complexity and logistical difficulty of implementing the standards, rules and regulations that apply to a large accelerated filer, there is an increased risk that we may be found to be in non- compliance with such standards, rules and regulations or to have significant deficiencies or material weaknesses in our internal controls over financial reporting. Any failure to maintain effective disclosure controls and internal control over financial reporting could materially and adversely affect our business, results of operations, and financial condition and could cause a decline in the trading price of our common shares.~~ We are a BVI business company limited by shares and ~~,~~ the holders of our common shares may have fewer protections as a shareholder of our company, because judicial precedent regarding the rights of shareholders is more limited under BVI law than that under U. S. law. Our corporate affairs are governed by our Amended Memorandum and Articles of Association as amended and restated from time to time, the BVI Business Companies Act (As Revised) (the " BVI Act ") and the common law

of the BVI. The rights of shareholders to take legal action against our directors, actions by minority shareholders and the fiduciary responsibilities of our directors under BVI law are to a large extent governed by the common law of the BVI. The common law of the BVI is derived in part from comparatively limited judicial precedent in the BVI as well as from English common law, which has persuasive, but not binding, authority on a court in the BVI. The rights of our shareholders and the fiduciary responsibilities of our directors under BVI law therefore are not as clearly established as they would be under statutes or judicial precedents in some jurisdictions in the United States. In particular, the BVI has a less exhaustive body of securities laws as compared to the United States, and some states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the BVI. There is no statutory recognition in the BVI of judgments obtained in the U. S., although the courts of the BVI will in certain circumstances recognize and enforce a non- penal judgment of a foreign court of competent jurisdiction without retrial on the merits. As a result of all of the above, holders of our common shares may have more difficulty in protecting their interests through actions against our management, directors or controlling shareholders than they would as shareholders of a U. S. company. They may have greater difficulty securing legal advice about the law of the BVI than they would U. S. and state law, and the relatively less developed nature of the BVI' s securities law may leave investors with less certainty about the validity and strength of any claims they believe they may have against us. In addition, other differences between BVI and U. S. law, as well as the terms of our Amended Memorandum and Articles of Association, may result in shareholders having different potential influence than they would under various U. S. state laws with respect to matters such as officer and director actions, mergers and acquisitions, dispositions of assets, takeover efforts, and other corporate decision making. Shareholders in BVI business companies may not be able to initiate shareholder derivative actions, thereby depriving a shareholder of the ability to protect its interests. While statutory provisions do exist in BVI law for derivative actions to be brought in certain circumstances, shareholders in BVI business companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect to any such action, may result in the rights of shareholders of a BVI business company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. The BVI courts are also unlikely to: (i) recognize or enforce against us judgments of courts in the United States based on certain civil liability provisions of U. S. securities law; or (ii) to impose liabilities against us, in original actions brought in the BVI, based on certain civil liability provisions of U. S. securities laws that are penal in nature or that relate to taxes or similar fiscal or revenue obligations or would be viewed as contrary to BVI public policy or the proceedings pursuant to which judgment was obtained were contrary to natural justice. There is no statutory recognition in the BVI of judgments obtained in the United States. However, the courts of the BVI will in certain circumstances recognize such a foreign judgment and treat it as a cause of action in itself which may be sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that: • the U. S. court issuing the judgment had jurisdiction in the matter and the company either submitted to such jurisdiction or was resident or carrying on business within such jurisdiction and was duly served with process; • the judgment is final and for a liquidated sum; • the judgment given by the U. S. court was not in respect of penalties, taxes, fines or similar fiscal or revenue obligations of the company; • in obtaining judgment there was no fraud on the part of the person in whose favor judgment was given or on the part of the court; • recognition or enforcement of the judgment in the British Virgin Islands would not be contrary to public policy; and • the proceedings pursuant to which judgment was obtained were not contrary to natural justice. The British Virgin Islands courts are unlikely: • to recognize or enforce against the Company, judgments of courts of the U. S. predicated upon the civil liability provisions of the securities law of the U. S.; and • to impose liabilities against the Company, predicated upon the certain civil liability provisions of the securities laws of the U. S. so far as the liabilities imposed by those provisions are penal in nature. The laws of the BVI relating to the protection of minority shareholders differ from those under U. S. law and, in some circumstances, may offer less protection. The BVI Act includes the following statutory remedies which minority shareholders in the company can rely upon: • If the company or a director of the company engages in or proposes to engage in conduct, that contravenes the BVI Act or our Amended Memorandum and Articles of Association, a shareholder may apply to the BVI court for an order directing the company or its director (s) to comply with or restraining the company or a director from engaging in conduct that contravenes the BVI Act or our Amended Memorandum and Articles of Association. • Under the BVI Act, minority shareholders have a statutory right to bring a derivative action in the name of and on behalf of the company in circumstances where the company has a cause of action against its directors. This remedy is available at the discretion of the BVI court which will take a number of factors into account before granting or refusing a leave to proceed to the relevant shareholder, including whether such action is in the interests of the company, the cost of such action and whether there are alternative remedies that the shareholder concerned may rely upon. • A shareholder of the company may bring an action against the company for breach of duty owed to him or her as a shareholder. This would typically be relevant in a situation where a shareholder is aggrieved by the company for breach of an entitlement or right under the company' s memorandum and articles of association. • A shareholder of the company who considers that the affairs of the company have been, are being or likely to be, conducted in a manner that is, or any act or acts of the company have been, or are, likely to be oppressive, unfairly discriminatory, or unfairly prejudicial to him in that capacity, may apply to the BVI court for an order to remedy the situation. Again, this is a discretionary remedy and the BVI court will only award it if they are satisfied that it is just and equitable to do so. • A shareholder may, in certain circumstances, apply for liquidators to be appointed over the affairs of a company under the BVI' s Insolvency Act 2003 (as amended) (the " BVI Insolvency Act "). Shareholders can also by resolution appoint a liquidator of a BVI business company under the BVI Act if the company is solvent or under the BVI Insolvency Act if the company is insolvent. In addition to the statutory rights outlined above, there are common law rights for the protection of shareholders that may be invoked, largely dependent on English common law. Under the general rule pursuant to English common law known as the rule in Foss v. Harbottle, a court will generally refuse to interfere with the management of a company at the insistence of a

minority of its shareholders who express dissatisfaction with the conduct of the company' s affairs by the majority or the Board. However, every shareholder is entitled to have the affairs of the company conducted properly according to law and the constituent documents of the company. As such, if those who control the company have persistently disregarded the requirements of company law or the provisions of the company' s Amended Memorandum and Articles of Association, then the courts will grant relief. Generally, the areas in which the courts will intervene are the following: (1) an act complained of which is outside the scope of the authorized business or is illegal or not capable of ratification by the majority; (2) acts that constitute fraud on the minority where the wrongdoers control the company; (3) acts that infringe on the personal rights of the shareholders, such as the right to vote; and (4) where the company has not complied with provisions requiring approval of the shareholders, which are more limited than the rights afforded minority shareholders under the laws of many states in the United States. Having regard to the above, the protection available to minority shareholders under BVI law may be more limited than under the laws of some jurisdictions in the United States. It may be difficult to enforce a U. S. or foreign judgment against us, our directors and our officers outside the United States, or to assert U. S. securities laws claims outside of the United States. As a BVI business company, it may be difficult for a shareholder to effect service of process within the United States upon us, our directors and officers, or to enforce against us, or them, judgments obtained in U. S. courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state therein. Additionally, it may be difficult to assert U. S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U. S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U. S. law, is applicable to the claim. Further, if U. S. law is found to be applicable, the content of applicable U. S. law must be proved as a fact, which can be a time- consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. Accordingly, it may be difficult or impossible for you to bring an action against us in the BVI if you believe your rights under the U. S. securities laws have been infringed. In addition, there is uncertainty as to whether the courts of the BVI would recognize or enforce judgments of U. S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the U. S. or any state and it is uncertain whether such British Virgin Islands courts would hear original actions brought in the British Virgin Islands against us or such persons predicated upon the securities laws of the U. S. or any state. Changes in tax law, determinations by tax authorities or changes in our effective tax rates may adversely affect our business and financial results. Under current law, we expect to be treated as a non- U. S. corporation for U. S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) our ability to use net operating loss carryforwards to offset future taxable income and any adjustments to the amount of the net operating loss carryforwards we can utilize; and (5) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles. We may also become subject to income, withholding or other taxes in jurisdictions by reason of our activities and operations, and it is possible that taxing authorities in such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. ~~Since 2017~~ **In particular** , **the Organization for Economic Co- operation and Development and** the G20 ~~/ OECD~~ Inclusive Framework **on Base Erosion and Profit Shifting (the " Inclusive Framework ")** has ~~been working~~ **put forth two proposals — Pillar One and Pillar Two — that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework' s global corporate minimum tax rate of 15 %, and various countries (both within and outside the European Union) have enacted new law implementing Pillar Two or have draft legislation proposed for adoption. The OECD continues to release additional guidance** on ~~addressing~~ the ~~tax challenges arising from the digitalization of the economy and has proposed a~~ two- pillar ~~tax approach~~ **framework,** with **widespread implementation anticipated in 2024** ~~pillar one referring to the re- allocation of taxing rights, addressing issues such as where tax should be paid and on what basis (i. e., where sustained and significant business is conducted, regardless of a physical presence), and pillar two ensuring a minimum tax to be paid by multinational enterprises~~ . We are ~~unable~~ **continuing** to ~~predict when and how~~ **evaluate the potential impact on future periods of** the Inclusive Framework **, pending legislative adoption by individual** ~~agreement will be enacted into law in the~~ countries ~~in ,~~ which ~~we operate, and it is possible that the implementation of the Inclusive Framework agreement, including the global minimum corporate tax rate,~~ could have ~~a material effect~~ **an adverse impact** on our ~~liability for corporate taxes and our consolidated~~ effective tax rate ~~when we fall into the scope of the rules. If we are or become a passive foreign investment company~~ , ~~there could be adverse U. S. federal~~ income tax **expense and cash flows** ~~consequences to U. S. holders~~ . If we are or become a passive foreign investment company (" PFIC ") for any taxable year during which a U. S. holder holds our shares, the U. S. holder would be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. Under the Code, we would be a PFIC for any taxable year in which (1) 75 % or more of our gross income consisted of passive income or (2) 50 % or more of the average quarterly value of our assets consisted of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes, but is not limited to, dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations and subject to certain exceptions, a non- U. S. corporation that directly or indirectly owns at least 25 % by value of the shares of another corporation is treated as if it held its proportionate

share of the assets and received directly its proportionate share of the income of such other corporation. Although we believe our common shares should not currently be stock of a PFIC for U. S. federal income tax purposes and do not expect to become a PFIC in the foreseeable future, we cannot provide any assurances regarding our PFIC status for any current or future taxable years. The determination of whether we are a PFIC is a fact- intensive determination made on an annual basis applying principles and methodologies which in some circumstances are unclear and subject to varying interpretation. In particular, the determination of whether we are a PFIC and the characterization of our assets as active or passive may depend in part on (i) our current and intended future business plans which are subject to change, and (ii) the application of certain " look- through " rules. For our current and future taxable years, the total value of our assets for PFIC testing purposes may fluctuate considerably from time to time, and is dependent on our application (which inherently involves an element of judgment) of the relevant valuation assumptions and methodologies. Under the income test, our status as a PFIC depends on the composition of our income which, in our current and future taxable years, we may not be able to fully control, for example, with respect to income attributed to us from entities owned 25 % or more by us. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering. Therefore, we cannot provide any assurance regarding our PFIC status for any past, current or future taxable years. In certain circumstances, a U. S. holder of shares in a PFIC may alleviate some of the adverse tax consequences described above by making a " qualified electing fund " (" QEF ") election to include in income its pro rata share of the corporation' s income on a current basis. However, a U. S. holder may make a QEF election with respect to our common shares only if we agree to furnish such U. S. holder annually with a PFIC annual information statement as specified in the applicable U. S. Treasury Regulations. We currently do not intend to prepare or provide the information that would enable U. S. holders to make a QEF election if we are treated as a PFIC for any taxable year, and U. S. holders of our common shares should assume that a QEF election will not be available. U. S. holders should consult their own tax advisors with respect to the operation of the PFIC rules and related reporting requirements in light of their particular circumstances, including the advisability of making any election that may be available. Mail addressed to us may not reach us in a timely manner. Mail addressed to the Company and received at its registered office will be forwarded unopened to the forwarding address supplied by Company to be dealt with. None of the Company, its directors, officers, advisors or service providers (including the organization which provides registered office services in the BVI) will bear any responsibility for any delay howsoever caused in mail reaching the forwarding address. Such risk will be borne solely by the Company' s shareholders. Our Amended Memorandum and Articles of Association provide that unless we consent in writing to the selection of an alternative forum, the courts of the British Virgin Islands shall, with certain limited exceptions, be the sole and exclusive forum for certain disputes between us and our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our Amended Memorandum and Articles of Association provide that unless we consent in writing to the selection of an alternative forum, the courts of the British Virgin Islands shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company' s members, (iii) any action asserting a claim arising pursuant to any provision of British Virgin Islands law or the Amended Memorandum and Articles of Association, or (iv) any action asserting a claim against the Company governed by the internal affairs doctrine, and that each shareholder consents to the exclusive jurisdiction of the courts of the British Virgin Islands over all such claims or disputes. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over actions brought under the Securities Act or the rules and regulations promulgated thereunder. Furthermore, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the forum selection provision in our Amended Memorandum and Articles of Association will not apply to actions or suits brought to enforce any liability or duty created by the Securities Act, Exchange Act or any claim for which the federal district courts of the United States of America are, as a matter of the laws of the United States of America, the sole and exclusive forum for determination of such a claim. This choice of forum provision may increase a shareholder' s cost, impose additional litigation costs and limit the shareholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees, although our shareholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder and may therefore bring certain claims in another appropriate forum. Any person or entity purchasing or otherwise acquiring any of our shares or other securities, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions. It is possible that a court could find such a choice of forum provision to be inapplicable or unenforceable, and if a court were to find this provision in our Amended Memorandum and Articles of Association to be inapplicable or unenforceable in an ~~82~~ **action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could have an adverse effect on our business, results of operations and financial condition.**