

## Risk Factors Comparison 2024-02-27 to 2023-02-22 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with the other information in this Annual Report, including our consolidated financial statements and the related notes included in this Annual Report and in the section titled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations, ” before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Annual Report to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized elsewhere in this Annual Report and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also impair our business operations. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of a number of factors, including the risks described below. See the section titled “ Cautionary Note Regarding Forward- Looking Statements. ”

**Risks Related to the Merger** The conditions under the Merger Agreement to AbbVie’ s consummation of the Merger may not be satisfied at all or in the anticipated timeframe. On December 6, 2023, we entered into the Merger Agreement with AbbVie, Intermediate Holdco and Merger Sub, pursuant to which Merger Sub will be merged with and into Cerevel, with Cerevel surviving the merger as a wholly owned subsidiary of AbbVie. Consummation of the Merger is subject to approval by our stockholders; receipt of certain regulatory approvals; the expiration or termination of any applicable waiting period (and extensions thereof) under the Hart- Scott- Rodino Antitrust Improvements Act of 1976; obtaining all waivers and approvals under certain other specified antitrust laws, as applicable; the absence of any law or order by any governmental authority that would make illegal or otherwise prohibit, restrict or prevent the Merger; and other conditions specified in the Merger Agreement. As a result, there can be no assurance that the Merger will be consummated. These conditions are described in more detail in the Merger Agreement, which is filed as an exhibit to the Current Report on Form 8- K, filed with the SEC on December 7, 2023, and incorporated herein by reference. The Company intends to pursue all required approvals in accordance with the Merger Agreement. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given to the terms, conditions and timing of the approvals or that they will satisfy the terms of the Merger Agreement. Furthermore, we and our board of directors have been named as defendants in lawsuits brought by purported holders of our common stock challenging our board of directors’ actions in connection with the Merger and seeking, among other things, injunctive relief to enjoin the defendants from completing the Merger on the agreed- upon terms. See Note 17, Legal Proceedings, to our audited consolidated financial statements included elsewhere in this Annual Report for more information regarding such lawsuits. If a settlement or other resolution is not reached in the lawsuits and the plaintiffs secure injunctive relief prohibiting, delaying, or otherwise adversely affecting our ability to consummate the Merger, then such injunctive or other relief may prevent the Merger from becoming effective within the expected timeframe or at all. The announcement of, or a failure to consummate, the Merger could negatively impact our business, financial condition, results of operations or our stock price. Our announcement of having entered into the Merger Agreement could cause a material disruption to our business and there can be no assurance that the conditions to the consummation of the Merger will be satisfied. The Merger Agreement may also be terminated by us and / or AbbVie in certain specified circumstances, as described below. We are subject to several risks as a result of the announcement of the Merger Agreement, including, but not limited to, the following:

- if the Merger is not completed within the expected timeframe, or at all, the share price of our common stock will change to the extent that the current market price of our common stock reflects an assumption that the Merger will be consummated;
- certain costs related to the Merger, including the fees and / or expenses of our legal, accounting and financial advisors must be paid even if the Merger is not completed;
- pursuant to the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the Merger, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities;
- the attention of our management may be directed towards the consummation of the Merger and related matters, and their focus may be diverted from the day- to- day business operations of our company, including from other opportunities that might otherwise be beneficial to us;
- our inability to retain existing key employees or hire new capable employees, given the uncertainty regarding our future, in order to execute on our continuing business operations;
- a failure to complete the Merger within the proposed timeframe, or at all, may result in negative publicity and / or a negative impression of us in the investment community or business community generally;
- difficulties maintaining relationships with collaborators, vendors, and other business partners;
- third parties may determine to terminate and / or attempt to renegotiate their relationship with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise;
- upon termination of the Merger Agreement by us or AbbVie under specified circumstances, we would be required to pay a termination fee of

approximately \$ 283.1 million; and • we could be subject to litigation related to any failure to complete the Merger. In addition, our executive officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders generally. These interests include without limitation the following: • most members of the Board and each of our executive officers holds outstanding Cerevel equity awards; • each of our executive officers is party to an employment agreement and / or is a participant in a severance program that provides for severance payments and benefits upon a qualifying termination in connection with a change in control (referred to as a “ sales event ” therein), which includes the Merger; • each of our non- employee directors is subject to a compensation policy that provides upon the occurrence of a “ sale event ” (including the Merger), all equity retainer awards granted to non- employee directors will become fully vested and exercisable; • each of our executive officers is eligible to receive a prorated target bonus with respect to fiscal year 2024 if the Effective Time of the Merger occurs in 2024; and • certain of our executive officers’ compensatory payments were and / or will be subject to certain mitigation treatment in order to mitigate the potential impact of Sections 280G and 4999 of the United States Internal Revenue Code of 1986, as amended, or the Code, in connection with the Merger. The Merger Agreement contains provisions that could make it difficult for a third party to acquire us prior to the completion of the Merger. The Merger Agreement contains restrictions on our ability to obtain a third- party proposal for an acquisition of our company. These provisions include our agreement not to solicit or initiate any additional discussions with third parties regarding other proposals to acquire us, as well as restrictions on our ability to respond to such proposals, subject to fulfillment of certain fiduciary requirements of our board of directors. The Merger Agreement also contains certain termination rights, including, under certain circumstances, a requirement for us to pay to AbbVie a termination fee of approximately \$ 283.1 million. These provisions might discourage an otherwise- interested third- party from considering or proposing an acquisition of our company, even one that may be deemed of greater value to our stockholders than the Merger. Furthermore, even if a third- party elects to propose an acquisition, the concept of a termination fee may result in that third- party offering a lower value to our stockholders than such third- party might otherwise have offered. **Risks Related to**

**Our Business** The successful development of pharmaceutical products is highly uncertain. Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including: • clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint (s)) or have an unacceptable safety or tolerability profile; • failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow- up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application, or NDA, **or similar foreign applications**, preparation, discussions with the FDA **or foreign regulatory authorities**, an FDA **or foreign regulatory authority** request for additional preclinical or clinical data (such as long- term toxicology studies) or unexpected safety or manufacturing issues; • preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects; • post- marketing approval requirements; or • the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized. The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third- party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country- specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third- party payors could require us to conduct additional studies, including post- marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post- marketing information and reports and registration, and will need to continue to comply (or ensure that our third- party providers comply) with current Good Manufacturing Practices, or cGMPs, and **similar foreign requirements, and** Good Clinical Practices, or GCPs, for any clinical trials that we conduct post- approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post- approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post- approval could adversely affect our business, financial condition and results of operations. We are a clinical- stage biopharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future. We are a clinical- stage biopharmaceutical company with a limited operating history. We were formed in July 2018 and our operations to date have been limited to pre- commercial activities. Substantially all of our product candidates were initially developed by Pfizer, which we in- licensed pursuant to the Pfizer License Agreement, entered into shortly after our formation. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, manufacture any product 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 product commercialization. We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each

period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled \$ 432.8 million, \$ 351.5 million, and \$ 225.3 million and \$ 152.1 million for the years ended December 31, 2023, 2022, and 2021 and 2020, respectively. As of December 31, 2022-2023, we have had an accumulated deficit of \$ 967.8 million and had not yet generated revenues. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We anticipate that our expenses will increase substantially if, and as, we:

- advance our clinical-stage product candidates through clinical development, including as we advance these candidates into later-stage clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our the clinical operations development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities;
- advance our preclinical-stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Pfizer License Agreement and any future in-license or collaboration agreements; and
- make milestone, royalty, interest or other payments due under the Funding Agreements, our 2027 Notes and any future financing or other arrangements with third parties.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Additionally, our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates. We have never generated revenue from product sales and may never be profitable. Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, one or more product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us to achieve profitability. 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 may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to incur losses as we have since our inception, investors may not receive any return on their investment and may lose their entire investment. We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing approval for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates and will also be required to make certain milestone and royalty payments under the Pfizer License Agreement and the Funding Agreements. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop, and we may need substantial additional funding to complete the development and commercialization of our product candidates. Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments under the Pfizer License Agreement and the Funding Agreements;
- the royalty payments due under the Pfizer License Agreement and the Funding Agreements;
- the extent to which we in-license or acquire rights to other

products, product candidates or technologies; • our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all; • our receipt of additional funding from the Funding Investors under the Funding Agreements; • the settlement method used for the outstanding 2027 convertible senior notes, or the 2027 Notes; • our headcount growth and associated costs as we expand our research and development and market development and pre-commercial planning activities; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and • the costs of operating as a public company. We cannot be certain that additional funding will be available on acceptable terms, or at all. For instance, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our ~~common stock~~ **equity or debt securities** or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions ~~and or~~ market volatility resulting from global economic developments, political unrest, high inflation, **rising interest rates**, ~~the ongoing post-COVID-19 pandemic environment~~, **future public health epidemics** or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. **The Merger Agreement generally restricts our ability to pay any dividends on our common stock during the interim period between the execution of the Merger Agreement and the Effective Time (or the date on which the Merger Agreement is earlier terminated)**. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangement with collaborators on terms unfavorable to us or pursue **other merger or acquisition** strategies, all of which could adversely affect the holdings or the rights of our stockholders. We believe that our available financial resources will enable us to fund our operating expense and capital expenditure requirements through at least 12 months from the issuance date of our audited consolidated financial statements included elsewhere in this Annual Report. Our estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success. We currently have five clinical-stage product candidates as well as several other product candidates that are at various stages of preclinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our most advanced product candidates and indications and ensuring the development of additional potential product candidates and indications. Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for disorders of the brain and nervous system, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, royalty-based financing, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. In addition, royalty-based financing or debt financing, if available, may result in our relinquishing rights to valuable future revenue streams or fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing

financing could require a substantial amount of time and attention from our management team and may divert a disproportionate amount of our attention away from day- to- day activities, which may adversely affect our management team's ability to oversee the development of our product candidates. If we raise additional capital through collaborations, strategic alliances or marketing, distribution or licensing arrangements, or royalty- based financings with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain capital through arrangement with collaborators on terms unfavorable to us or pursue **other merger or acquisition** strategies, all of which could adversely affect the holdings or the rights of our stockholders. Covenants in our Funding Agreements place restrictions on our operating and financial flexibility and if we do not effectively manage our covenants, our financial condition and results of operations could be adversely affected. In April 2021, we entered into the Funding Agreements pursuant to which the Funding Investors committed to provide funding to support our development of tavapadon for the treatment of Parkinson's disease. The Funding Agreements impose various diligence, milestone payment, royalty payment and other obligations on us. Pursuant to the Funding Agreements, we are required to comply with various covenants relating to the conduct of our business and the development and commercialization of tavapadon, including obligations to use commercially reasonable efforts to develop and commercialize tavapadon in the United States and certain limits on our ability to incur indebtedness, create or incur liens or dispose of assets. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders. We are required to make payments to the Funding Investors upon the achievement of certain regulatory and sales milestones. In addition, if we suspend or terminate the development of tavapadon or fail to perform certain diligence obligations, under certain circumstances, we will pay the Funding Investors a combined amount equal to the total amount funded by the Funding Investors up to the date of termination, plus 12 % interest compounded annually. We may not have sufficient capital to make the required payments to the Funding Investors on a timely basis or at all. In conjunction with the Funding Agreements, we also entered into security agreements with the Funding Investors pursuant to which we granted the Funding Investors a security interest in the assets material to the development and commercialization of tavapadon in the United States to secure our obligations under the Funding Agreements. If we are unable to comply with such obligations, then the Funding Investors may be able to foreclose on the collateral that was pledged to the Funding Investors. Any of the foregoing events could significantly and adversely affect our financial condition and results of operations. Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed. To date, as an organization, we have not completed the development of any of our product candidates. Our future success and ability to generate revenue from our product candidates, which is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed. We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product- related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug **application**, or IND, **application** or comparable foreign applications or delays or failure in obtaining the necessary approvals **or allowances** from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates **observed** during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop- out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, ~~EMA~~ or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third- party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, ~~EMA~~ and comparable foreign regulatory authorities.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, ~~such as the EMA~~, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory

authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, jurisdictions outside of the United States, such as the European Union, or EU, or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to seek or obtain these approvals. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue. Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the EU, European Union or elsewhere; • the FDA, EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition, even if we were to obtain approval, 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. **In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi- center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three- year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as contract research organizations, or CROs, may impact our developments plans. It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through**

secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight- week consultation on reframing the UK legislation for clinical trials with specific aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The MHRA published its consultation outcome on March 21, 2023 in which it confirmed that it would update the existing legislation. The resulting legislative changes will ultimately determine the extent to which the UK regulations align with the CTR. Under the terms of the Protocol on Ireland / Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK not to closely align its regulations with the new approach has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and / or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be adversely impacted. The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates. ~~The general approach for~~ **In order to obtain** FDA approval of a new drug is ~~dispositive~~ **our product candidates, we must, among other things, demonstrate substantial evidence of the effectiveness of such product candidates. FDA has generally considered this demonstration to require** data gathered from two or more adequate and well- controlled clinical trials of the product candidate in the relevant patient population **, or in some cases, one adequate and well- controlled trial plus other confirmatory evidence**. Adequate and well- controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well- controlled or may request that we conduct additional clinical trials prior to **granting any** regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from **the FDA or other** regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our registration- directed Phase 3 program for tavapadon after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA or that the FDA will not require us to modify our trials or conduct additional testing, or that completing these trials will result in regulatory approval. ~~See the section entitled “Business — Our Lead Programs — Tavapadon — Our Solution — Tavapadon — Ongoing Clinical Trials — TEMPO- 1: Phase 3 Fixed- Dose Monotherapy (Early- Stage) Parkinson’ s Trial ” in this Annual Report for a~~ description of our discussions with the FDA regarding the proposed primary endpoint of our Phase 3 trials of tavapadon as ~~monotherapy in early- stage Parkinson’ s~~. Even if our Phase 3 clinical trials as monotherapy in early- stage Parkinson’ s achieve their primary endpoint, there can be no assurance that the FDA will find them sufficient to support approval if, for example, the FDA determines the contribution of the MDS- UPDRS Part II score to the primary endpoint results to be inadequate. Our Phase 2 early- stage Parkinson’ s trial of tavapadon did not use the MDS- UPDRS Part II score as a primary endpoint and was therefore not powered to show a statistically significant difference from placebo for this measure. In addition, based on our end- of- Phase 2 meeting with the FDA where we presented single- dose electrocardiogram, or ECG, multiple- dose ECG and a model- based analysis of Phase 1 data, we plan to collect time- matched **PK- pharmacokinetic** and ECG measures in a subset of patients as a sub- study in our ongoing Phase 3 fixed- dose monotherapy early- stage Parkinson’ s trial. However, there can be no assurance that we will not be required to conduct additional testing on the safety and tolerability of tavapadon, including with respect to arrhythmia. Additionally, we are developing CVL- 871 for the treatment of dementia- related apathy. There are no currently approved therapies for dementia- related apathy, and we may experience challenges in defining this indication. There are limited precedents for trial design, trial endpoints and regulatory pathway for this indication, which may make clinical development and regulatory approval of CVL- 871 more challenging. Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following: • the FDA, EMA or comparable foreign regulatory authorities may not file or accept our NDA or marketing application for substantive review; • the FDA, EMA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications; • the results of our clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that our product candidates’ clinical and other benefits outweigh their safety risks; • the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA, ~~EMA~~ or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Business interruptions resulting from the ~~ongoing~~ COVID- 19 pandemic or similar, **the post- COVID environment and other** public health crises could cause a disruption of the development of our product candidates and adversely impact our business. Public health crises such as pandemics or similar outbreaks could adversely impact our business. **For instance, We are closely monitoring the impact of the ongoing COVID- 19 pandemic on all aspects of our business and the post- COVID environment , including how it supply chain, labor market and other disruptions, has as well as volatility in the global financial markets, in each case, driven by the pandemic, have** impacted and may **further** continue to impact our **clinical trials**

operations and the operations of our ~~or preclinical studies~~ suppliers, vendors and business partners. For instance, ~~certain~~ the continued spread of COVID-19 has impacted and may further impact our clinical trials, ~~including~~ or preclinical studies. The onset of the COVID-19 pandemic caused brief pauses in patient screening and enrollment in our Phase 3 trials of tavapadon for the treatment of Parkinson's ~~s~~, ~~our Phase 2a trial~~ (which we subsequently resumed in the second half of 2020) ~~CVL- 871 for the treatment of dementia-related apathy and our Phase 1 trial of emraclidine in elderly healthy volunteers to support development in Alzheimer's disease psychosis, predominantly enroll elderly subjects~~, and we remain particularly vigilant about patient safety given the elderly nature of ~~this~~ ~~these~~ ~~population~~ ~~populations~~. While we have taken measures to revise clinical trial protocols to allow for remote visits, including home delivery of study medication, home health care visits to collect safety data and telemedicine visits to collect clinician-based trial assessments, such measures may not be sufficient to prevent missing data from impacting trial outcomes or delays in enrollment and trial completion caused by COVID- 19. The primary endpoint in our monotherapy early- stage Parkinson's trials is based, in part, on a physical assessment of motor symptoms performed by a clinician, which cannot be completed remotely, and, if a substantial number of subjects are unable ~~or unwilling~~ to complete in- person assessments, the completeness and interpretability of the data that we are able to collect from these trials or our other clinical trials would be impacted, which may create data integrity challenges, require changes to the statistical analysis plan, require the enrollment of additional subjects or otherwise negatively affect our ability to use such data to obtain regulatory approval. Similarly, if patients are reluctant to participate in our trials due to fears of COVID- 19 infection resulting from regular visits to a healthcare facility or unable to comply with clinical trial protocols due to quarantines or travel restrictions that impede patient movement or interrupt healthcare services, we may not be able to meet our current trial completion timelines. In addition, Paxlovid, a treatment for COVID- 19 ~~granted emergency use authorization / conditional approval~~ ~~approved~~ by health authorities in the U. S. and Europe, is contraindicated for concurrent use with some of our product candidates. As such, increased use of Paxlovid in the general population may cause delays in enrollment or increase the early termination rate in our clinical trials, which may impact our expected clinical trial timelines. In addition, COVID- 19, ~~the post- COVID environment or future public health crises~~ may impact our ability to retain principal investigators and site staff for our clinical trials ~~as~~. For instance, healthcare providers may have heightened exposure to COVID- 19 or may be impacted due to prioritization of hospital resources toward the pandemic and restrictions on travel. Our clinical trial sites may be located in geographies that are disproportionately affected by the COVID- 19 pandemic or actions taken by governmental and health authorities to address the pandemic. Furthermore, as a result of supply chain, labor market and other disruptions driven by the pandemic ~~and the post- COVID environment~~, COVID- 19 has impacted and may further negatively affect our operations or the operations of our vendors, suppliers and business partners, including the third- party contract research organizations, or CROs, clinical sites and other vendors that we rely upon to carry out our clinical trials or the operations of our third- party manufacturers and other suppliers, which could result in delays or disruptions in the supply of our product candidates. The negative impact COVID- 19 or the post- COVID environment has on patient enrollment, site staffing or treatment or the timing and execution of our clinical trials has caused and could cause further delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business and financial results. COVID- 19 ~~has~~ ~~and the post- COVID environment have~~ also caused volatility in the global financial markets, including ~~growing~~ inflationary headwinds, which may negatively affect our ability to raise additional capital on attractive terms or at all. The extent to which COVID- 19 ~~and the post- COVID environment~~ impacts ~~impacts~~ ~~impact~~ our business, results of operations and financial condition will depend on future developments, which, despite progress in vaccination efforts, are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning the severity of COVID-19, such as new variants or subvariants, which may impact rates of infection and vaccination efforts and the extent and effectiveness of actions to contain COVID- 19 or treat its impact, including vaccination campaigns, COVID- 19 treatments and lockdown measures, among others. In addition, recurrences or additional waves of COVID- 19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage were to experience prolonged business shutdowns or other disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates. We have in- licensed the rights to substantially all of our current product candidates from Pfizer, for which they undertook prior research and development. We had no involvement with or control over the preclinical and clinical development of any of our product candidates prior to obtaining our in- license. In addition, we had no involvement in the development of third- party agents designed to be used in combination with our product candidates, such as L- dopa, which we intend to study in combination with tavapadon in our Phase 3 adjunctive late- stage Parkinson's trial. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or in- license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected. If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates. The results observed from preclinical studies or early- stage clinical trials of our product candidates may not necessarily be predictive of the results of later- stage clinical trials that we conduct. Similarly, positive



results from such preclinical studies or early- stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, while darigabat demonstrated anti- epileptic activity similar to lorazepam, a commonly prescribed benzodiazepine, or BZD, in a Phase 2 photoepilepsy trial, only seven patients were treated with darigabat in that trial and we may not be able to replicate the observed results from that trial in our ongoing Phase 2 proof- of- concept trial in focal epilepsy. Similarly, while darigabat demonstrated anxiolytic effects in a model of carbon dioxide inhalation that is associated with symptoms of anxiety / panic in healthy participants, we may not be able to replicate these results in patients with panic disorder. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. For instance, although they both activate muscarinic receptors, in later- stage trials, emraclidine may not be able to replicate the anti- psychotic benefit observed in prior clinical trials of xanomeline. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials. For instance, in our Phase 3 clinical trials for tavapadon in Parkinson' s, we are using a slower titration method than was used in prior clinical trials. While we believe that the slower titration method may mitigate certain gastrointestinal and other adverse events, we cannot provide any assurances that it will provide the desired effects and it may result in unanticipated issues. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. For instance, prior clinical trials conducted by Pfizer with certain of our product candidates before we in- licensed them were terminated before conclusion of the trials. These trials included a Phase 2 trial of tavapadon in late- stage Parkinson' s, a concurrent Phase 2 clinical trial of tavapadon in early- stage Parkinson' s and two Phase 2 trials of darigabat. These clinical trials did not meet their primary endpoints and, even though we believe the data generated from these trials support our rationale for further clinical development of these product candidates, our belief is partially based on post- hoc analyses of such data. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards, or IRBs, or other reviewing bodies **such as ethics committees** may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective 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;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third- party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re- examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third- party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate **efficacy and safety results** adequate ~~efficacy and safety~~ to **obtain** ~~result in~~ regulatory approval to market our product candidates for the indications that we are pursuing. If later- stage clinical trials do not produce favorable results, our

ability to obtain regulatory approval for our product candidates will be adversely impacted. Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. Delays in our development of tavapadon in the United States could also prevent us from, or delay us in, receiving ~~additional~~ **the remaining payments** ~~payment~~ under the Funding Agreements, as well as put us in potential breach of our development and commercialization obligations under the Funding Agreements. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes 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 **or publicly disclose** interim, topline or preliminary data from our clinical trials. **These publications or disclosures are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.** 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. **Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business.** If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed. For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development

objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed. We may be subject to additional risks because we intend to evaluate our product candidates in combination with other compounds. We intend to evaluate our product candidates in combination with other compounds. The use of our product candidates in combination with other compounds may subject us to risks that we would not face if our product candidates were being administered as a monotherapy. For instance, in our Phase 3 adjunctive late-stage Parkinson's trial, we are evaluating tavapadon in combination with L- dopa for the treatment of late- stage Parkinson's, and L- dopa's safety issues may be improperly attributed to tavapadon or the administration of tavapadon with L- dopa may result in safety issues that such other therapies or tavapadon would not have when used alone. **The outcome and cost of developing Developing combination therapies using a product candidate to be used with other compounds is difficult also exposes us to predict and dependent on a number of factors additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop. If the FDA or similar foreign regulatory authorities revoke the approval of any proposed combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market such product candidates for combination therapy regimens. Additionally, if the third- party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities outside our control. If we experience efficacy or for safety issues in our clinical trials in or for commercialization, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which our product candidates are being administered with other compounds, we may not receive regulatory approval for our product candidates, which could would have an adverse effect on prevent us from ever generating revenue or our achieving profitability business, financial condition, results of operations and prospects**

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Patient enrollment is affected by many factors, including:

- the effects of the ongoing COVID- 19 pandemic **and the post- COVID environment** on our ability to recruit and retain patients ;
- including as a result of potential heightened exposure to COVID- 19, prioritization of hospital resources toward the pandemic and unwillingness by patients to enroll or comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services;
- the patient eligibility criteria defined in the protocol;
- the size **and nature** of the patient population required for analysis of the trial's primary endpoints;
- the **severity of the disease or condition under investigation;**
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any **new** drugs that may be approved for the indications that we are investigating ;
- **patient referral practices of physicians;**
- **the ability to monitor patients adequately during and after treatment** ;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

For instance, enrollment in our Phase 3 TEMPO program of tavapadon in Parkinson's has been impacted due to residual post-COVID landscape challenges and other factors. **Following a detailed review of all environmental factors, data are expected from TEMPO- 3 in mid- year 2024 and TEMPO- 1 and TEMPO- 2 in the second half of 2024.** Furthermore, we are currently evaluating darigabat in a Phase 2 proof- of- concept trial in focal epilepsy, known as REALIZE. The recent approval and increased uptake of certain partial- onset seizure treatments, which are contraindicated in the REALIZE trial, as well as patients not meeting the necessary seizure frequency requirements and post- COVID landscape challenges at the clinical trial sites, have impacted our expected timeline for this trial. **Slower** As a result, we anticipate a delay in the REALIZE readout beyond 2023. **Following a detailed review of all environmental factors, we plan to provide updated timing on the REALIZE readout by mid- year than- expected enrollment in the U. S. and delays in the startup of certain ex- U. S. clinical sites have impacted and may further impact the expected timeline for data for both Phase 2 EMPOWER trials of emraclidine in schizophrenia.**

Because certain of the prior clinical trials of our product candidates were terminated prior to the conclusion of the trial, we may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for such product candidates if we are unable to sufficiently demonstrate the potential of such product candidates to them. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might

have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials. Finally, business disruptions, including those relating to natural disasters **(including as a result of climate change)**, geopolitical incidents or macroeconomic conditions, may disrupt our clinical trials. For instance, **certain** our Phase 3 TEMPO program of **our ongoing clinical trials tavapadon in Parkinson's includes** **include select** less than 10% of our clinical sites located in Ukraine, **and, as a result of the war in Ukraine, we are not enrolling any new patients at those clinical sites at this time**. The ongoing **conflict war in Ukraine** has impacted and may further impact our ability to collect and interpret data from patients who were enrolled at those clinical sites, **and further disruptions at those clinical sites may result in delays to our clinical trials**. We will continue to closely monitor the rapidly evolving geopolitical situation in Ukraine and its impact on our clinical trial operations and timelines. **We may from time to time implement mitigation measures to improve patient enrollment, but such mitigation measures may not sufficiently improve enrollment in a timely enough fashion (for instance, it could take longer than we expect to add new clinical sites, especially in new countries, and we may not be able to sufficiently increase enrollment at existing clinical sites), may have a negative impact on the quality of our data or may result in increased costs**. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of the company to decline and limit our ability to obtain additional financing if needed. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA **or comparable foreign regulatory authorities** notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained. Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of tavapadon, a dose-dependent increase in the frequency of nausea and headache was observed, with nausea, vomiting, dyskinesia, fall, fatigue, sleep disorder and tremors being the most common adverse events leading to discontinuation of tavapadon. In clinical trials of emraclidine, some moderate treatment-emergent increases in heart rate and blood pressure were observed following single doses of emraclidine (> 10 mg), which may be due to emraclidine's activity on the M4 receptor subtype and its subsequent reduction of striatal dopamine levels. These observed cardiovascular changes were asymptomatic and transient in nature, generally peaking within one to four hours following an oral dose before being generally resolved within 24 hours without intervention. In our Phase 1b trial of emraclidine, modest asymptomatic elevations in blood pressure and heart rate were observed with emraclidine compared to placebo, which decreased over time. Placebo-adjusted heart rate changes two hours post-dose at week six were 4.4 and 5.3 beats per minute for the emraclidine 30 mg once-daily and 20 mg twice-daily groups, respectively. The average blood pressure changes at week six for both emraclidine cohorts showed no clinically meaningful differences versus placebo. We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly. Moreover, clinical trials of our product

candidates are conducted in carefully defined sets 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. **Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product. Other potentially significant negative consequences associated with adverse events include: • we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace; • regulatory authorities may withdraw or modify their approvals of a product; • we may be required to conduct post- marketing studies; • we may be required to change the way a product is administered; • we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; • a product may become less competitive, and • our reputation may suffer. Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.**

We have concentrated our research and development efforts on the treatment of disorders of the brain and nervous system, a field that faces certain challenges in drug development. We have focused our research and development efforts on addressing disorders of the brain and nervous system. Efforts by pharmaceutical companies in this field have faced certain challenges in drug development. In particular, many neuroscience diseases such as panic disorder, schizophrenia or dementia- related apathy rely on subjective patient- reported outcomes as key endpoints. This makes them more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. There can be no guarantee that we will successfully overcome these challenges with our product candidates or that we will not encounter other challenges in the development of our product candidates. Even if any of our product candidates receives regulatory 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, in which case we may not generate significant revenues or become profitable. We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. Many of the indications for our product candidates have well- established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and / or cost- effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance. Efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. For example, even if tavapadon ultimately receives regulatory approval, we may have difficulty in convincing the medical community that tavapadon' s selective dopamine D1 / D5 receptor partial agonism has the potential to deliver promising therapeutic benefits above and beyond nonselective dopamine agonists. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and safety of the product; • the potential advantages of the product compared to competitive therapies; • the prevalence and severity of any side effects; • whether the product is designated under physician treatment guidelines as a first-, second- or third- line therapy; • our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices; • the product' s convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try, and of physicians to prescribe, the product; • limitations or warnings, including distribution or use restrictions contained in the product' s approved labeling; • the strength of sales, marketing and distribution support; • changes in the standard of care for the targeted indications for the product; and • availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third- party payors. Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects. If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. Although the development and commercialization of our current product candidates are our initial focus, as part of our longer- term growth strategy, we plan to develop other product candidates. In addition to the product candidates in our clinical- stage pipeline, we have in- licensed additional assets that are in earlier stages of development. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates, and also may choose to in- license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time- consuming

development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. In addition, we intend to devote substantial capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: • the research methodology used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates obsolete; • product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights; • a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. In the future, we may also seek to in- license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in- licensing of third- party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in- licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all. In addition, future acquisitions may entail numerous operational and financial risks, including: • exposure to unknown liabilities; • disruption of our business and diversion of management' s time and attention to develop acquired products or technologies; • incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; • higher than expected acquisition and integration costs; • difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel; • increased amortization expenses; • impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and • inability to motivate key employees of any acquired businesses. If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired. The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our products may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected. Our pipeline includes product candidates for a variety of neuroscience diseases. There is no precise method of establishing the actual number of patients with any of these disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of Parkinson' s, epilepsy and schizophrenia, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our products, if approved, may be indicated for or used by only a subset. Moreover, certain of our product candidates are being developed for indications that are novel, such as dementia- related apathy. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. ~~For instance, due to slower than expected enrollment, we now expect data from our CVL- 871 Phase 2a trial in dementia- related apathy in the second half of 2024.~~ If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits. Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected. The clinical and commercial landscapes for the treatment of neuroscience diseases are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of

drug candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We believe that a significant number of product candidates are currently under development for the same indications we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled “ Business — Competition ” in this Annual Report for examples of the competition that our product candidates face. In most cases, we do not currently plan to run head- to- head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head- to- head clinical trial data. Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors’ products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive. If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of any product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third- party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates. We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties’ internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates. Factors that may inhibit our efforts to commercialize our product candidates on our own include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates. 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. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates,

if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for any of our future approved products; • injury to our reputation; • withdrawal of clinical trial participants; • termination of clinical trial sites or entire trial programs; • significant litigation costs; • substantial monetary awards to, or costly settlements with, patients or other claimants; • product recalls or a change in the indications for which they may be used; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies. Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. Insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects. ~~Cyberattacks~~ ~~Cyber-attacks~~ or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third- party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations. We, along with our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants, utilize information technology, or IT, systems and networks to process, transmit and store electronic information, **including confidential information such as proprietary business information and personal information of our employees and contractors**, in connection with our business activities. As use of digital technologies has increased, **our IT systems and those of our third- party service providers, strategic partners and other contractors or consultants are increasingly vulnerable to attack, damage and interruption from** cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e. g., ransomware), viruses, **malicious code**, spamming, phishing attacks ~~or and~~ ~~other means~~ **social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation- state- supported actors, natural disasters, terrorism, war, telecommunication and electrical failures or other threats.** ~~Deliberate~~ ~~Deliberate~~ attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', CROs', third- party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. We may not be successful in preventing ~~cyber-attacks~~ ~~or identifying cyberattacks and~~ **may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate** ~~or successfully mitigating~~ ~~mitigate~~ **their effects due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence**. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other ~~cyberattacks~~ ~~cyber-attacks~~. Similarly, our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants may not be successful in protecting our clinical and other data that is stored on their systems. Any ~~cyberattack~~ ~~cyber-attack~~, data breach or destruction or loss of data could result in a violation of applicable U. S. and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and / or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of ~~cyberattacks~~ ~~cyber-attacks~~ or other data security breaches and may incur significant additional expense to implement further data protection measures. Our ability to use our net operating losses and research and development tax credits to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ ~~2023~~, we had U. S. federal net operating loss carryforwards totaling \$ ~~448-533~~ ~~.7-2~~ million, all of which have an indefinite carryforward period. As of December 31, ~~2022~~ ~~2023~~, we had state net operating loss carryforwards totaling \$ ~~438-549~~ ~~.3-0~~ million, with \$ ~~433-542~~ ~~.4-2~~ million expiring at various dates between 2031 and ~~2042~~ ~~2043~~ and the remaining \$ ~~4-6~~ ~~.9-8~~ million having an indefinite carryforward period. As of December 31, ~~2022~~ ~~2023~~, we also had U. S. federal and state research and development tax credit



carryforwards of \$ 21-33. 3 million and \$ 3-4. 2-9 million, respectively, which begin to expire in 2039 for federal purposes and 2034 for state purposes. The net operating losses which are limited in life and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the ~~U. S. Internal Revenue Code, as amended, or the Code,~~ a corporation that undergoes an “ ownership change ” is subject to limitations on its ability to utilize its pre- change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5 % of a corporation’ s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in the future, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. If we determine that an ownership change has occurred and our ability to use our historical NOLs or credits is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. Section 382 and 383 of the Code would apply to all net operating loss and tax credit carryforwards, whether the carryforward period is indefinite or not. Furthermore, our ability to utilize our historical NOLs or credits is conditioned upon us attaining profitability and generating U. S. federal and state taxable income. We are a clinical- stage biopharmaceutical company with a limited operating history. We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U. S. federal or state taxable income necessary to utilize our historical NOLs or credits that may be subject to limitation by Sections 382 and 383 of the Code. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing we conduct in connection with Section 404 of the Sarbanes- Oxley Act **of 2022, as amended, or the Sarbanes- Oxley Act**, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. If we identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports or applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We also could become subject to investigations by the ~~NASDAQ~~ **Nasdaq** Stock Market, or Nasdaq, the SEC or other regulatory authorities. Additionally, pursuant to Section 404 of the Sarbanes- Oxley Act, we are now required to furnish a report by our management on our internal control over financial reporting and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Our compliance with such requirement necessitates that we incur substantial accounting expense and expend significant management efforts. We will continue to dedicate significant internal and external resources to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective, or such conclusion may not be reached within the prescribed timeframe. The price of our common stock could decline substantially due to a loss of confidence in the reliability of our financial statements.

**Risks Related to Managing our Business and Operations** We depend heavily on our executive officers, third- party consultants and others and our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of their services or our inability to hire and retain such personnel would materially harm our business. Our success depends, and will likely continue to depend, upon our ability to hire, and our ability to retain the services of our executive officers and other key employees within our organization. Our executive officers and other key employees may terminate their employment with us at any time. The loss of their services might impede the achievement of our operational and strategic objectives. Our ability to compete in the biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. In particular, we will need to retain and, in some cases, hire, qualified personnel with expertise in clinical development and operations, preclinical research and development, manufacturing, quality management, medical and regulatory affairs, finance and accounting and other areas in connection with the continued development of our product candidates. We currently rely, and for the foreseeable future will continue to rely, on third- party consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development objectives and activities as well as the development of our commercialization strategies. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully and the culture fit to be a leader in our organization. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key

personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. **Further, inflationary pressure may increase our costs, including employee compensation costs or result in employee attrition to the extent our compensation does not keep up with inflation, particularly if our competitors' compensation does. The Merger may make it more difficult to attract and retain qualified employees due to the uncertainty about whether or when the transaction will close and the impact of the Merger on our employees.** There can be no assurance that the services of third-party consultants and advisors will continue to be available to us on a timely basis when needed, that we will be able to manage our existing consultants and advisors or that we can find qualified replacements on economically reasonable terms, or at all. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified consultants and advisors, our ability to develop and commercialize our product candidates will be limited. We may not be able to hire and / or retain a sufficient number of employees or employees with the required expertise to develop our product candidates or operate our business successfully. As of December 31, ~~2022~~ **2023**, we had ~~298~~ **334** full-time employees. Our focus on the development of multiple initial product candidates requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and / or retain adequate staffing levels to develop our product candidates or run our operations and / or to accomplish all of the objectives that we otherwise would seek to accomplish. If we are not able to effectively expand our organization by hiring new qualified employees, our clinical trials may be delayed or terminated, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals. Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk that our employees, independent contractors, consultants, collaborators and CROs may engage in fraudulent conduct or other illegal activity. 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 comply with these laws or regulations. Misconduct by those parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities that violates: • study and trial protocols or the FDA regulations or similar regulations of comparable non- U. S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; • manufacturing standards; • federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non- U. S. regulatory authorities; and • laws that require the reporting of financial information or data accurately. 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. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards 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 and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations. We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations. To manage these growth activities, 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. Our management may need to devote a significant amount of their attention to managing these growth activities. Due to our limited financial resources, **our limited operating history** 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 or any necessary relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or any necessary relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates. Risks Related to Our Organizational Structure Bain Investor and Pfizer have

significant influence over us, and may have interests different from yours. As of December 31, 2022-2023, Bain Investor and Pfizer own, collectively, approximately 56-51.2-3% of the outstanding shares of our common stock. Furthermore, so long as they own certain specified amounts of our equity securities, Bain Investor and Pfizer have certain rights to nominate our directors. As long as such entities each own or control a significant percentage of outstanding voting power, they will have the ability to strongly influence all corporate actions requiring stockholder approval, including the election and removal of directors and the size of our board of directors, any amendment of our certificate of incorporation or bylaws, or the approval of **the Merger or any other** merger or other significant corporate transaction, including a sale of substantially all of our assets. Some or all of these entities may have interests different than yours. For example, because these entities acquired their shares at prices substantially below the price at which other stockholders may have purchased shares or have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders. As a “ controlled company ” within the meaning of Nasdaq listing standards, we qualify for exemptions from certain corporate governance requirements. We have the opportunity to elect any of the exemptions afforded a controlled company. Because Bain Investor and Pfizer, together, control more than a majority of the total voting power of our common stock, we are a “ controlled company ” within the meaning of Nasdaq listing standards. Under Nasdaq rules, a company of which more than 50 % of the voting power is held by another person or group of persons acting together is a “ controlled company ” and may elect not to comply with the following Nasdaq rules regarding corporate governance: • the requirement that a majority of our board of directors consist of independent directors; • the requirement to have a nominating / corporate governance committee composed entirely of independent directors and a written charter addressing the committee ’ s purpose and responsibilities; • the requirement to have a compensation committee composed entirely of independent directors and a written charter addressing the committee ’ s purpose and responsibilities; and • the requirement of an annual performance evaluation of the nominating / corporate governance and compensation committees. Currently, 10 of our 11-12 directors are independent directors, and we have an independent nominating and corporate governance committee and an independent compensation committee. However, for as long as the “ controlled company ” exemption is available, our board of directors in the future may not consist of a majority of independent directors and may not have an independent nominating and corporate governance committee or compensation committee. As a result, in the future, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq rules regarding corporate governance. Our Amended and Restated Registration and Shareholder Rights Agreement provides that the doctrine of corporate opportunity does not apply with respect to certain of our stockholders, directors, non- voting observers or certain of their affiliates who are not our or our subsidiaries’ full- time employees. The doctrine of corporate opportunity generally provides that a corporate fiduciary may not develop an opportunity using corporate resources or information obtained in their corporate capacity for their personal advantage, acquire an interest adverse to that of the corporation or acquire property that is reasonably incident to the present or prospective business of the corporation or in which the corporation has a present or expectancy interest, unless that opportunity is first presented to the corporation and the corporation chooses not to pursue that opportunity. The doctrine of corporate opportunity is intended to preclude officers, directors or other fiduciaries from personally benefiting from opportunities that belong to the corporation. Pursuant to the Amended and Restated Registration and Shareholder Rights Agreement, dated October 27, 2020 and as amended, by and between us and the other parties thereto, to the fullest extent permitted by law, the doctrine of corporate opportunity and any analogous doctrine does not apply to (1) Bain Investor, Pfizer, ARYA Sciences Holdings II and Perceptive Life Sciences Master Fund Ltd, (2) any member of our board of directors, non- voting observer or any officer who is not our or our subsidiaries’ full- time employee or (3) any affiliate, partner, advisory board member, director, officer, manager, member or shareholder of Bain Investor, Pfizer, ARYA Sciences Holdings II or Perceptive Life Sciences Master Fund Ltd who is not our or our subsidiaries’ full- time employee (any such person listed in (1), (2) or (3) being referred to herein as an External Party). Therefore, we have renounced any interest or expectancy in, or being offered an opportunity to participate in, business opportunities that are from time to time presented to any External Party. As a result, the External Parties are not prohibited from operating or investing in competing businesses. We therefore may find ourselves in competition with the External Parties, and we may not have knowledge of, or be able to pursue, transactions that could potentially be beneficial to us. Accordingly, we may lose a corporate opportunity or suffer competitive harm, which could negatively impact our business or prospects. Our certificate of incorporation and amended and restated bylaws, and Delaware law, contain certain provisions, including anti- takeover provisions, that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable. Our certificate of incorporation and amended and restated bylaws, or our bylaws, and the General Corporation Law of the state of Delaware, or the DGCL, contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors or depress the trading price of shares of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our board of directors or taking other corporate actions, including effecting changes in our management. Among other things, our certificate of incorporation and bylaws include provisions: • permitting our board of directors to issue shares of preferred stock, including “ blank check ” preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; • that create a classified board of directors whose members serve staggered terms, with one class being elected each year by our stockholders; • regarding the limitation of the liability of, and the indemnification of, our directors and officers; • prohibiting stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of stockholders after such date and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors; • requiring that a special meeting of stockholders may be called only by a majority of our board of directors, which could delay the ability of stockholders to force consideration of a proposal or to take

action, including the removal of directors; • controlling the procedures for the conduct and scheduling of our board of directors and stockholder meetings; • permitting our board of directors to amend our bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and • regarding advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our board of directors. These provisions, alone or together, could delay or prevent hostile takeovers and changes in our control or changes in our board of directors or management. In addition, our certificate of incorporation includes a provision substantially similar to Section 203 of the DGCL, which may prohibit certain stockholders holding 15 % or more of our outstanding capital stock from engaging in certain business combinations with us for a specified period of time. Our bylaws designate specific courts as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a preferred judicial forum for disputes with us or our directors, officers, stockholders, employees or agents. If, however, our forum provisions are found to be unenforceable, we and our stockholders may incur additional costs associated with resolving such matters. Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (5) any action asserting a claim against us governed by the internal affairs doctrine; provided, however, that the foregoing provisions will not apply to any claims arising under the Exchange Act or the Securities Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these forum provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. These choice of forum provisions in our bylaws may impose additional litigation costs on stockholders in pursuing such claims and may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If our forum provisions are found to be unenforceable, we and our stockholders may incur additional costs associated with resolving such matters. The Court of Chancery of the State of Delaware and the U. S. District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

**Risks Related to Our Dependence on Third Parties** We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed. We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB **or ethics committee** approval, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and are enrolling patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA **and certain foreign regulatory authorities** ~~requires~~ **require** us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA **and comparable foreign regulatory authorities** ~~enforces~~ **enforce** these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. **Similar requirements may exist in foreign jurisdictions.** We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA **or comparable foreign regulatory authorities** may require us to perform additional clinical trials before approving our product candidates, which

would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA **or comparable foreign regulatory authorities** will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. For instance, we have terminated the participation of one investigator involved with our clinical trials due to issues observed during a site monitoring visit, and we notified the FDA accordingly. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post- COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. Accordingly, enrollment in some of our clinical trials has been slower than expected as a result of these changes in the post- COVID clinical trial landscape. These contractors 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 impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed. We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. Any of the third- party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. Although we believe we have diversified our risk by engaging a number of CROs and other third- party organizations and there are a number of other CROs we could engage to continue these activities, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects. In particular, we plan to rely on a hybrid functional service provider, or FSP, approach, where, rather than relying on a small number of third- party services providers for a full suite of services, we plan to use a wider number of third- party service providers on an à la carte basis grouped by specific function. We may not be able to realize the cost savings typically associated with the hybrid FSP approach, or this approach may require us to incur increased startup or integration costs. Our hybrid FSP approach may also require us to manage and monitor an increased number of service providers and contractual relationships. Finally, this approach may require us to handle certain functions, such as collecting, transmitting and storing patient data in compliance with applicable data privacy laws, internally rather than outsourcing them to third parties. Handling these functions internally may require us to spend more time and capital hiring and training employees, and any failure to do so successfully may negatively impact our operations. Under the Funding Agreements, the Funding Investors have the right to suspend payments to us or take other actions that may be adverse to our interests in certain circumstances. Under the Funding Agreements, while the Funding Investors agreed to provide up to an additional ~~approximately \$ 31.3 million and \$ 25.0 million~~ **in April 2024 on the second and third anniversaries of the effective date of the Funding Agreements, respectively**, such ~~payments~~ **payment are is** subject to certain customary funding conditions, and, if those funding conditions are not satisfied or waived, we will not receive such ~~payments~~ **payment**. The Funding Investors may also suspend their obligation to make payments to us following the occurrence of enumerated events such as an uncured material breach, a material adverse effect (which includes certain adverse developments related to the development and regulatory approval of tavapadon) or a bankruptcy event. The Funding Investors' obligation to make development payments will resume upon their notice to us that the condition allowing them to suspend payments has been resolved or cured to their reasonable satisfaction. The Funding Investors may terminate their obligation to make any further development payments if such condition is not resolved or cured within 12 months. If the Funding Investors' payment obligations terminate in these circumstances, we will remain obligated to make the milestone and royalty payments contemplated in the Funding Agreements to the Funding Investors in the event we nonetheless receive FDA approval for tavapadon and commercialize tavapadon in the United States. Our ability to receive payments under the Funding Agreements also depends on the ability of the Funding Investors to meet their funding commitments. If we do not receive additional payments under the Funding Agreements, our business, results of operations, cash flows and financial condition could be adversely affected. We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or

pharmaceutical companies for the commercialization of such product candidates. We face significant competition in seeking appropriate collaborators. 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 potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations. We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us. Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients, or APIs, or drug products when needed or at an acceptable cost. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties. We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. For instance, there are a limited number of suppliers who have spray-dried dispersion capabilities required to manufacture darigabat, and we can provide no assurance that we will be able to find an alternative manufacturer **on at an acceptable price terms**. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We

may be unable to conclude agreements for commercial supply with third- party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive. Many of the third- party manufacturers we rely on have only recently begun working with us and have limited or no experience manufacturing our API and final drug products. If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials. Even if we are able to establish and maintain arrangements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the failure of the third- party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance; • manufacturing delays if our third- party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us; • limitations on supply availability resulting from capacity and scheduling constraints of third parties; • the possible breach of manufacturing agreements by third parties because of factors beyond our control; • the possible termination or non- renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and • the possible misappropriation of our proprietary information, including our trade secrets and know- how. If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. Additionally, if any third- party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third- party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third- party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third- party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third- party manufacturer or require us to obtain a license from such third- party manufacturer in order to have another third party manufacture our product candidates. If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third- party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third- party manufacturers on satisfactory terms, which could delay our commercialization. Some of our manufacturers are located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U. S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA **or comparable foreign regulatory authorities in connection with any NDA or other application we may submit**. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs **and similar foreign requirements**. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and / or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain

compliance with the applicable cGMP requirements. Any failure to comply with cGMP **and similar foreign** requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved. The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs **and similar foreign requirements**. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP **or similar foreign** requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained. If any third- party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third- party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third- party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations. We may need to maintain licenses for APIs from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates. Should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to these APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs. Risks Related to Government Regulation Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, ~~the EMA~~ **or** comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and **similar foreign requirements and** GCP requirements for any clinical trials that we conduct post- approval. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP **and similar foreign** regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP **and similar foreign requirements** and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or 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. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient- reported outcome



measures. The FDA may also require a ~~risk evaluation and mitigation strategies, or~~ REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, 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. In addition, if the FDA, ~~EMA~~ or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA **or comparable foreign regulatory authorities** to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals; • product seizure or detention or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. Additionally, ~~under FDORA~~, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA **and certain foreign regulatory authorities** strictly ~~regulate~~ **regulate** marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, ~~EMA~~ and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. While we may in the future seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations. The FDA and comparable foreign regulatory authorities offer certain designations for product candidates ~~that~~. **These programs** are designed to encourage the research and development of product candidates that are intended to address **serious** conditions ~~with significant unmet medical need~~. These designations may confer benefits such as additional interaction with regulatory authorities, ~~a potentially accelerated regulatory pathway and~~ **priority eligibility for expedited review procedures**. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits. For example, we may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a ~~therapy~~ **drug or biologic** that is intended, alone or in combination with one or more other ~~therapies~~ **drugs or biologics**, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. ~~As a condition of approval under the accelerated approval pathway, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. For therapies~~ **product candidates** that have been designated as ~~breakthrough~~ **Breakthrough Therapies**, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. ~~Therapies designated as~~ **Product candidates receiving breakthrough Breakthrough Therapy Designation** therapies by the FDA are also ~~eligible for accelerated approval~~ **receive the same benefits associated with Fast Track Designation, described below**. Designation as a ~~breakthrough~~ **Breakthrough therapy-Therapy** is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a ~~breakthrough~~ **Breakthrough therapy-Therapy**, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification. ~~The~~ **Furthermore, the** FDA has granted Fast Track Designation for emraclidine for the treatment of hallucinations and delusions

associated with Alzheimer's disease psychosis and CVL- 871 for the treatment of dementia- related apathy, and we may seek Fast Track Designation for some of our other product candidates. If a ~~therapy~~ **drug or biologic** is intended for the treatment of a serious or life- threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may ~~apply~~ **be eligible** for Fast Track Designation. **Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.** The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. The receipt of Fast Track Designation for emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis and for CVL- 871 for the treatment of dementia- related apathy, and any future receipt of Fast Track Designation for other product candidates, does not guarantee a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Some of our programs may be partially supported by government grant awards, which may not be available to us in the future or subject us to federal regulations such as "march- in" rights, certain reporting requirements and a preference for U. S. industry. We have received ~~a notice~~ **notices** of award for cooperative grant funding from the National Institute on Drug Abuse, or NIDA, to support the development of CVL- 354 in opioid use disorder. To fund a portion of our future research and development programs, we may apply for additional grant funding from NIDA or other governmental agencies. However, funding by these governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Therefore, we cannot assure you that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates. Moreover, any intellectual property rights generated through the use of U. S. government funding are subject to the Bayh- Dole Act of 1980, or Bayh- Dole Act. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if the government determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations, which we refer to as march- in rights. The U. S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. As a result of any funding from NIDA, or if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh- Dole Act. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects. Our relationships with healthcare providers and physicians and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. ~~It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations.~~ Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third- party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. ~~As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal~~ **Federal** and state healthcare laws and regulations that may affect our ability to operate include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or

rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil fines and criminal penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties; • the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “ cause ” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “ whistleblower ” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the 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 further amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose certain requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them - ~~the~~ that involve the use, creation, maintenance, receipt or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there are additional federal, state and non-U. S. laws which govern the privacy and security of health and other personal information in certain circumstances to which we may be subject and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; • the U. S. federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which ~~require~~ **requires** applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U. S. Centers for Medicare & Medicaid Services, or CMS, within the U. S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians, **certain non- physician practitioners including** nurse practitioners, certified nurse anesthetists, **anesthesiologist assistants**, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals and to disclose ownership and investment interests held by physicians and their immediate family members; • federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs; **and** • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers ; ~~and~~ • many state laws that govern the privacy of personal information in specified circumstances. For example, in California, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the sale of personal information, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the CCPA, other personal information collection practices may be subject to the CCPA and possible changes to the CCPA may broaden its ~~scope~~ **scope**. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to

make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. ~~Privacy and data protection laws from outside of the United States, including, for example, the European Union General Data Protection Regulation and the UK Data Protection Act 2018, or, collectively, the GDPR, also govern the privacy and security of personal information, including health information in some circumstances, and many of these laws differ from each other in significant ways, thus complicating compliance efforts. In addition, in the United States, there are a number of states that have enacted laws that govern the privacy and security of personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.~~ The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare ~~and privacy~~ laws, as well as responding to possible investigations by government authorities, can be time and resource- consuming and can divert a company's attention from the business. Ensuring that our internal operations 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 administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, defending against any such actions can be costly and 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, our ability to operate our business and our results of operations could be adversely affected. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably. The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third- party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor's determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. **In Private health insurers and the other United States, third- party payors in the principal decisions about U. S. often follow the coverage and reimbursement policies of government payors, including the for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare or Medicaid programs and private payors tend to follow CMS to a substantial degree.** Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in

healthcare legislation and regulatory initiatives. Moreover, increasing efforts by governmental and other 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. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. **For We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional information related** downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to **marketing** generate revenue, attain profitability, or commercialize our products. Legislative and **reimbursement** regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be. In addition, in some **certain** foreign countries, the proposed pricing **please read “ — EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our** a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products **in** for which their **the EU** national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member **member** State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States **states** and generally prices tend to be significantly lower. ” Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost- containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For instance, in August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that allow the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, create **an a \$ 2, 000** out- of- pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. In particular, the IRA allows CMS to begin negotiating prices for certain high- cost Medicare- covered small molecule drugs after they have spent seven years on the market. **On August 29, 2023, CMS announced the list of the first ten drugs that will be subject to price negotiations.** Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. All of our disclosed product candidates are small molecule drugs and certain of them are being developed in indications that may rely heavily on Medicare reimbursement, such as Parkinson’ s disease and Alzheimer’ s disease psychosis. Accordingly, these new price- negotiation provisions may have a negative impact on our future revenue and profits. **The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’ s Medicare drug price negotiation program**. The effect of IRA on our business and the healthcare industry in general is not yet fully known. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for our products by third- party payors, coverage policies and third- party payor reimbursement rates may change at any time. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical

products. Congress has indicated that it will continue to seek new legislative measures to control drug costs. **These-- The laws continuing efforts of the government, insurance companies, managed care organizations and future state other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:** • the demand for any of our product candidates, if approved; • the ability to set a price that we believe is fair for any of our product candidates, if approved; • our ability to generate revenues and federal achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. We expect that healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or which may result in additional reductions in Medicare and other healthcare reforms funding and otherwise affect the prices we may obtain prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any of, may be. On December 13, 2021, Regulation No 2021 / 2282 on Health Technology Assessment, ~~our~~ or HTA, amending Directive 2011 / 24 / EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned product- products candidates. This Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal, and provides the basis for cooperation at the EU level which we may obtain regulatory approval or for joint clinical assessments in the these frequency areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact which any such product candidate is prescribed or for used patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. Off- label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits. If our product candidates are approved by the FDA or comparable foreign regulatory authorities, we may only promote or market our product candidates in a manner consistent with their FDA- approved labeling (or the label approved by foreign regulatory authorities). We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as “ off- label uses. ” We cannot, however, prevent a physician from using our product candidates off- label, when in the physician’ s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our product candidates for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off- label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Inadequate funding for the FDA or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency FDA and comparable foreign regulatory authorities, have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA or, other government agencies and comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies and comparable foreign regulatory authorities, which would 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 employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA and comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Separately Since March 2020, in when foreign and domestic inspections were largely placed on hold, the FDA has been working to resume pre- pandemic levels of inspection activities, including for routine surveillance, bioresearch monitoring and pre- approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances a complete response to letter or defer action on the application until an inspection can be completed. During the ongoing COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA postponed most 2- s inability to complete required inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. Even though the FDA has since resumed standard inspection operations, and

any resurgence of the virus may lead to other inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities, it could significantly impact the EU drug marketing and reimbursement regulations may materially affect our ability of the FDA to market and receive coverage for or our products in the other EU Member States regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures. Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to reward improper performance generally is typically governed by the national anti-bribery laws of EU Member member States states and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001 / 83 / EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the European Union. Payments made to physicians in certain EU Member member States states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member member States states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member member States states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in some foreign countries, including some countries in the European Union, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, some EU Member member States states have the option to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member member States states and parallel distribution, or arbitrage between low-priced and high-priced EU Member member States states, can further reduce prices. An EU Member member State state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected. We are subject to evolving global data protection laws and regulations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations. The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In the U. S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and

regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (CCPA) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Other states, such as California, Virginia, Colorado, Utah and Connecticut have recently enacted similar consumer privacy laws that grant rights to data subjects and place privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the CCPA, such state privacy laws some observers note that the CCPA and similar legislation proposed at the state and federal level could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, we may seek to conduct clinical trials in the United Kingdom or the European Economic Area, or the EEA, and may become subject to additional European data privacy laws, regulations and guidelines. We will be subject to the data protection laws of the European Union and United Kingdom in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. For example, the European Union General Data Protection Regulation (EU GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA or in the context of our activities within the EEA. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the EU GDPR, and subject to additional compliance obligations and to local law derogations. Since the beginning of 2021, after the end of the transition period following the withdrawal of the United Kingdom from the European Union, or Brexit, we may also be subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR) which imposes separate but similar obligations to those under the EU GDPR and comparable penalties, including fines of up to £ 17.5 million or 4 % of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. The subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the European Union and United Kingdom, which may lead to additional compliance costs and could increase our overall risk. The EU and UK GDPR (collectively, the GDPR), which deals with the processing of personal data and on the free movement of such data, imposes a broad range of strict requirements, including requirements relating to having lawful bases for processing personal data and transferring such information outside the EEA / UK, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease / change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and / or civil claims (including class actions). The GDPR imposes strict rules on the transfer of personal data out of the EEA / UK to countries not regarded by European Commission and the United Kingdom government as providing adequate protection, or the third countries, including the United States. These and the efficacy and longevity of current transfers transfer are prohibited unless mechanisms between the European Economic Area, or the EEA, an and appropriate safeguard specified by data protection the United States remains uncertain. Case laws law from is implemented, such as the Court of Justice of the European Union (CJEU) states that reliance on the Standard Contractual Clauses clauses or the SCCs, a standard form of contract approved by the European Commission, or a derogation applies. The UK has as published its own an adequate personal data transfer mechanism, the International Data alone may not necessarily be sufficient in all circumstances and that Transfer Agreement must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed and an International Data Transfer Addendum, Executive Order on 'Enhancing Safeguards or for the IDTA, United States Intelligence Activities' which enables introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU- US Data Privacy Framework (DPF), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a EU GDPR transfer mechanism to U. S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. On October 12, 2023, the UK and Extension to the DPF came into effect (has as implemented approved by the UK Government), as a similar UK GDPR



**data Transfer transfer Equivalence Test mechanism to U. S. entities self-certified under the UK Extension to the DPF.** We expect will be required to carry out Equivalence Tests and transition to the new form of SCCs and IDTA in relation to our existing **legal complexity and uncertainty regarding international** agreements with service providers outside the EEA / UK who we utilize for the processing of EEA / UK personal data **transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged** and any international transfers to the United States and to other parties outside jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to **make certain operational changes and we will have to implement revised standard contractual clauses and the other relevant documentation for existing** EEA / UK who we transfer EEA / UK personal data to. The international transfer **transfers within** obligations under the EU and UK data protection regimes will require **required time frames** effort and cost and may result in us needing to make strategic considerations around where EEA / UK personal data is located and which service providers we can utilize for the processing of EEA / UK personal data, particularly as the enforcement around GDPR international transfer compliance obligations is currently unclear. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime. This may lead to additional compliance costs and could increase our overall risk. We cannot assure you that our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our reputation and materially harm our business. As **we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. As** a result of our business combination with a special purpose acquisition company, regulatory obligations may impact us differently than other publicly traded companies. On October 27, 2020, Cerevel Therapeutics, Inc. completed a business combination with ARYA, a special purpose acquisition company, or SPAC, pursuant to which we became a publicly traded company. As a result of this transaction, regulatory obligations have, and may continue, to impact us differently than other publicly traded companies. For instance, the SEC and other regulatory agencies may issue additional guidance or apply further regulatory scrutiny to companies like us that have completed a business combination with a SPAC. Managing this regulatory environment, which has and may continue to evolve, could divert management's attention from the operation of our business, negatively impact our ability to raise additional capital when needed or have an adverse effect on the price of our common stock. Additional laws and regulations governing international operations could negatively impact or restrict our operations. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U. S. Foreign Corrupt Practices Act, or FCPA, prohibits any U. S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. 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. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non- U. S. activities to increase in time. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Risks Related to Our Intellectual Property We depend and expect in the future to continue to depend on in- licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose **our license licensed** rights, which would substantially harm our

business. We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We are and may in the future become a party to license agreements pursuant to which we in-license key intellectual property for our product candidates and their use. Soon after we began our operations in July 2018, we entered into the Pfizer License Agreement pursuant to which we in-licensed substantially all of our current product candidates and the patents and patent applications related to them. The Pfizer License Agreement excludes the field of treatment of prevention, diagnosis, control and maintenance of inflammatory bowel diseases and disorders in humans by compounds or products exerting a therapeutic effect on Leucine- Rich Repeat Kinase 2, or the LRRK2 field, which is retained by Pfizer. The Pfizer License Agreement imposes various diligence, milestone payments, royalty, insurance and other obligations on us. For example, under the terms of the Pfizer License Agreement, we are obligated to use commercially reasonable efforts to develop and seek regulatory approval for each of the product candidates licensed to us in certain designated countries. If we fail to comply with any of these obligations, Pfizer may have the right to terminate the Pfizer License Agreement, in which event we would not be able to develop or market our product candidates covered by such licensed intellectual property. Upon Pfizer's termination of the Pfizer License Agreement for our material breach or either party's termination for bankruptcy, insolvency or other similar proceeding or force majeure, we would grant Pfizer an exclusive, sublicensable, royalty-free, worldwide, perpetual license under certain intellectual property we develop during the term of the Pfizer License Agreement. Any termination of our existing or future licenses could result in the loss of significant rights and would cause material adverse harm to our ability to commercialize our product candidates. See the section entitled "Business — Pfizer License Agreement" in this Annual Report for additional information. Additionally, Pfizer has an exclusive right of first negotiation in the event that we seek to enter into **any certain significant transaction-transactions** with a third party with respect to a product either globally or in certain designated countries. Significant transactions include exclusive licenses, assignments, sales, exclusive co-promotion arrangements, and other transfers of all commercial rights to a product globally or in the designated countries, as well as exclusive distribution agreements globally or in certain designated countries. This right of first negotiation may limit or delay our ability to enter into arrangements with other companies related to our product candidates and could discourage, delay or prevent a merger, acquisition or change of control of our company. Disputes may also 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;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of in-licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- 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.

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 and commercialize the affected product candidates. The Pfizer License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payments, royalty, insurance and other obligations, and our failure to comply could give the applicable licensor a right to terminate the license, thereby impairing or preventing us from developing and marketing the product candidates covered by the applicable agreement. Although we have the right to control the maintenance, prosecution and enforcement of rights in-licensed under the Pfizer License Agreement, we are required to conduct our activities in compliance with the terms of the Pfizer License Agreement, which imposes on us certain obligations and grants Pfizer certain rights with respect to these activities. Additionally, we may have limited control over the maintenance, prosecution or enforcement of other rights that we in-license, and we may also have limited control over activities previously or separately conducted by our licensors. For example, we cannot be certain that activities conducted by Pfizer or any other present or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may also have limited control over other intellectual property that is not licensed to us but that may be related to our in-licensed intellectual property. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves. We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer. Our success depends in part on our ability to protect our intellectual property, and patent terms may be inadequate to protect our competitive position. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection for our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is affected by the extent to which we have rights under valid and enforceable patents that cover these activities. If our patents expire, or we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the statutory expiration of a patent is generally 20 years from its earliest U. S. non-provisional filing date. While various extensions such as patent term adjustments and / or extensions, may be available, the life of a patent, and the protection it affords, is limited. Our current composition of matter patents, and patents that may issue from our pending patent applications, covering new chemical entities, pharmaceutical

compositions comprising those entities, and their use in methods of treating various diseases and / or disorders, which we licensed from Pfizer, in connection with the formation of our company, are expected to expire between 2033 and 2039, not including any patent term extensions or adjustments. Our earliest patents may expire before, or soon after, our product candidates achieve marketing approval in the United States or foreign jurisdictions. Once the patents protecting any of our product candidates expire, we may be open to competition from competitive products, including generics. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The expiration of the patents covering our lead product candidates, and our inability to secure additional patent protection, could also have a material adverse effect on our business, results of operations, financial condition and prospects. The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. The strength of patents in the biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license now or in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, the patents covering our product candidates may not adequately protect our product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, **manufacture or commercialize**, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, and most patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or any pending applications, or that we or, if applicable, a licensor were the first to invent the technology or file patent applications directed to it. Our competitors also may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patents or any patent applications, which could require us to obtain rights to issued patents covering such technologies. Furthermore, for U. S. applications in which at least one claim is entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U. S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of the application. For U. S. applications in which all claims are entitled to a priority date after March 16, 2013, third parties can provoke derivations proceedings to determine if we or our licensor, as the case may be, derived the invention from them. If we or one of our licensors is a party to such proceedings involving a U. S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. We may be required to disclaim part or all of the term of certain patents or certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would not be held by a court to be invalid or unenforceable or that even if our patents are valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will independently develop products which have the same effect as our products and which do not infringe our patents or other intellectual property rights or will design around the claims of patents that cover our products. The degree of future protection for our patent applications and patents is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or to design around those claims; • the APIs in our current product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to their formulation or method of use; • we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regard to any in-licensed patents and patent applications funded by U. S. government grants, leading to the loss of patent rights or their exclusivity; • we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; • the laws of foreign countries may not protect our or our licensors', as the case may be, patent rights to the same extent as the laws of the United States; • the claims of our owned or

in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates; • our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; • the inventors of owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable because such omissions or inclusions are held to be done with deceptive intent; • we may engage in scientific collaborations with one or more third parties, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; or • we may not develop additional proprietary technologies for which we can obtain patent protection. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to patent protection, we rely heavily upon know- how and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived or completed by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may, for example, not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, the subject of our trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. In addition, courts outside the United States are sometimes less willing to protect trade secrets than U. S. courts. Thus, we may not be able to meaningfully protect our trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Third- party claims of intellectual property infringement may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of products or their methods of use or manufacture. There may also be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court or jury to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, or uses or formulations thereof, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and any patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: • infringement and other intellectual property claims, which, regardless of merit, may be expensive and time- consuming to litigate and may divert our technical and management personnel' s attention from our core business; • substantial damages for infringement, which we may have to pay if a court or jury decides that the product candidate or technology at issue infringes on or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; • a court

prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do; • if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our products; and • redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In any third- party litigation, there could also 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 the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U. S. C. § 271. If and when any of our product candidates are approved by the FDA, third parties may then seek to enforce their U. S. patents by filing a patent infringement lawsuit against us. While we may believe that any claims of such patents that could otherwise materially adversely affect commercialization of our product candidates, if approved, and of which we are now aware, are not valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is “ clear and convincing, ” a heightened standard of proof. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Third parties may assert that our employees, consultants, collaborators or partners have wrongfully used or disclosed confidential information or misappropriated trade secrets. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. This risk is similarly applicable with respect to claims by third parties against any current or future licensors. We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license now or in the future. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we in- license or that we may own or in- license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self- executing, for example, as part of employment or consulting agreements, or may be breached. Our licensors may face similar obstacles. We or our licensors could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership, including in derivation proceedings in the USPTO. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition. We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. For example, we may develop products containing our compounds and pre- existing pharmaceutical compounds. Our product candidates may also require specific formulations to work effectively and efficiently and rights to these formulations may be held by others. We may be unable to acquire or in- license any compositions, formulations, methods of use, processes or other third- party intellectual property rights from third parties that may be necessary or important to our business operations. We may also fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop or in- license such alternatives or replacement technology, which may not be feasible. 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. Additionally, we may from time to time collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution’ s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are

acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. In many cases, these institutions also have obligations to the U. S. government or other funding sources. These obligations may restrict the scope of any license that we may be able to negotiate. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per eligible drug may be extended and only those claims covering the approved drug, an approved method for using it or a method for manufacturing it may be extended. Patent term extensions tied to marketing approval in foreign jurisdictions may also be available for our patents. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter such infringement or unauthorized use, we may be required to file infringement claims in various jurisdictions, which can be expensive and time- consuming. If legal proceedings are initiated against a third party to enforce a patent covering one of our product candidates, the third- party defendant could counterclaim that the patent is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware, or not appreciative of its potential relevance, during prosecution. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. In addition, a court may refuse to stop the other party from using the technology at issue on the grounds that the public interest favors the third party' s continued use of our technology on a royalty basis. An adverse result in any litigation or defense proceedings could also put any related patent applications at risk of not issuing or being unable to be the basis of future litigation. Defense of these claims of invalidity, regardless of their merit, as well as assertion of our infringement claims, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Third parties may also choose to challenge the patentability of claims in our U. S. patents by requesting that the USPTO review the patent claims in an ex- parte re- examination, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. Third parties may also choose to challenge our patents in patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices. The costs of these opposition or nullity proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices, then our patents may be cancelled or narrowed in scope. 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 such litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent applications and patents. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result, if not cured, in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and

failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Changes in patent law in the United States and in ex- U. S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing and proposing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents, particularly those directed to pharmaceutical and biopharmaceutical products and uses could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how these decisions or any future decisions by the U. S. Congress, the federal courts or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents. Under the Leahy- Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a “ first- to- invent ” to a “ first- to- file ” system. Under a “ first- to- file ” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post- grant review system. The effects of these changes are now being felt in the prosecution of pending patent applications and the enforcement of issued patents. The effect of these changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, now and in the future, all of which could have a material adverse effect on our business and financial condition. **On June 1, 2023, the European Unitary Patent system and the European Unified Patent Court, or UPC, were successfully launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system started and granted thereafter, are subject to the jurisdiction of the UPC, unless affirmatively opted out. This was a significant change in European patent practice, and deciding whether to opt- in or opt- out of the Unitary Patent practice entails strategic and cost considerations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’ s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt- in or opt- out of Unitary Patent status will require coordinating with co- applicants, if any, adding complexity to any such decision.** We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world is expensive. While many of our licensed patents, including the patents covering our lead product candidates, have been issued in major markets and other countries, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States where we have issued patents, or from selling or importing products made using our inventions in other jurisdictions. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do not have patent protection or where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biopharmaceutical products, which could make it difficult for us or our licensors to stop the infringement of our owned or licensed patents or marketing of competing products by third parties in violation of our proprietary rights generally. The initiation of proceedings for infringement against third parties or by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could also result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and any related patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits that we initiate or are initiated against us and the damages or other remedies awarded in lawsuits that we initiate, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and

trade names, we may not be able to compete effectively and our business may be adversely affected. Risks Related to Our Common Stock and Convertible Senior Notes The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, • our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, ~~including as a result of COVID-19~~; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; • our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive; • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; • the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to develop additional product candidates; • the level of demand for our product candidates should they receive approval, which may vary significantly; • the changing and volatile U. S. and global economic environments, **including the impact of inflation and rising interest rates, and domestic or international political instability**; and • future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation. The stock market in general, and Nasdaq and biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Historically, securities class action litigation has often been brought against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which could harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs. Conversion of the 2027 Notes will dilute the ownership interest of our existing stockholders or may otherwise depress the price of our common stock. The conversion of some or all of the 2027 Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the 2027 Notes may encourage sales of our common stock by investors who view the 2027 Notes as a more attractive means of equity participation in us and / or short selling of our common stock pursuant to hedging or arbitrage activity that we expect many investors in the 2027 Notes to employ. In addition, anticipated conversion of the 2027 Notes into shares of our common stock could depress the price of our common stock. Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders. We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees and directors under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it. We have never declared or paid any cash dividends on our capital stock and have no current plans to pay cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant. **The Merger Agreement generally restricts our ability to pay any dividends on our common stock during the interim period between the execution of the Merger Agreement and the Effective Time (or the date on which the Merger Agreement is earlier terminated).** As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the 2027 Notes. As of December 31, ~~2022~~ **2023**, we had \$ ~~496-569~~ **6** million of liabilities, including \$ ~~57-112~~ **3-2** million of secured financing liabilities pursuant to the Funding Agreements and \$ ~~335-337~~ **5-4** million aggregate carrying value of indebtedness pursuant to the 2027 Notes. We may also incur additional indebtedness (including financial liabilities) to meet future financing needs. We are not restricted under the terms of the Indenture from incurring additional debt, securing then- existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the Indenture that could have the effect of diminishing our ability to make payments on our indebtedness, including the 2027 Notes, when due. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial



condition by, among other things: • increasing our vulnerability to adverse economic and industry conditions; • limiting our ability to obtain additional financing on acceptable terms or at all; • requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes; • limiting our flexibility to plan for, or react to, changes in our business; • diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2027 Notes; and • placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the 2027 Notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under any then- existing indebtedness. If we fail to comply with these covenants or to make payments under any then- existing indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and any then- existing other indebtedness becoming immediately payable in full. We may be unable to raise the funds necessary to repurchase the 2027 Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and any other then- existing indebtedness may limit our ability to repurchase the 2027 Notes or pay cash upon their conversion. Noteholders may, subject to a limited exception, require us to repurchase their 2027 Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the 2027 Notes to be repurchased, plus accrued and unpaid interest, if any to, but excluding, the fundamental change repurchase date. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the 2027 Notes or pay any cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing any other indebtedness may restrict our ability to repurchase the 2027 Notes or pay any cash amounts due upon conversion. Our failure to repurchase the 2027 Notes or pay any cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing any other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under any other indebtedness and the 2027 Notes. For additional information on the 2027 Notes, please read Note 9, 2027 Convertible Senior Notes, to our audited consolidated financial statements included elsewhere in this Annual Report. Provisions in the Indenture could delay or prevent an otherwise beneficial takeover of us. Certain provisions in the 2027 Notes and the Indenture could make a third- party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make- whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the 2027 Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable. The accounting method for convertible debt securities that may be settled in cash, such as the 2027 Notes, could have a material effect on our reported financial results. The accounting method for reflecting the 2027 Notes on our consolidated balance sheets, accruing interest expense for the 2027 Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition. In August 2020, the Financial Accounting Standards Board published an Accounting Standards Update, which we refer to as ASU 2020- 06, which simplified certain of the accounting standards that apply to convertible notes. ASU 2020- 06 eliminated the cash conversion and beneficial conversion feature models that require separate accounting for embedded conversion features as a component of equity. Instead, the entity would account for the convertible debt or convertible preferred stock securities as a single unit of account, unless the conversion features require bifurcation and recognition as derivatives. Additionally, the guidance requires entities to use the if- converted method for all convertible instruments in the diluted earnings per share calculation and to include the effect of potential share settlement for instruments that may be settled in cash or shares. ASU 2020- 06 became effective for us beginning on January 1, 2022. In accordance with ASU 2020- 06, the 2027 Notes are reflected as a liability on our consolidated balance sheets, with the initial carrying amount equal to the principal amount of the 2027 Notes, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the 2027 Notes. As a result of this amortization, the interest expense that we expect to recognize for the 2027 Notes for accounting purposes will be greater than the cash interest payments we will pay on the 2027 Notes, which will result in lower reported net income or higher reported net loss, as the case may be. In addition, the shares of common stock underlying the 2027 Notes are reflected in our diluted earnings per share using the “ if converted ” method, in accordance with ASU 2020- 06. Under that method, diluted earnings per share would generally be calculated assuming that all the 2027 Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti- dilutive. The application of the if- converted method may reduce our reported diluted earnings per share to the extent we are profitable in the future, and accounting standards may change in the future in a manner that may adversely affect our diluted earnings per share. Furthermore, in certain circumstances, including if any of the conditions to the convertibility of the 2027 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2027 Notes as a current, rather than a long- term, liability. This reclassification could be required even if no noteholders convert their 2027 Notes and could materially reduce our reported working capital. Future offerings of debt or equity securities by us may adversely affect the market price of our common stock. In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium- term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the

capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and / or cash from operations. Issuing additional shares of our common stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

**General Risk Factors** **Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, including those affecting the financial services industry, could adversely affect our business operations and our financial condition and results of operations. Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, the post- COVID environment or other factors, could materially and adversely affect our business operations. For instance, actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each swept into receivership, and uncertainty remains over liquidity concerns in the broader financial services industry. We may maintain cash balances at third- party financial institutions in excess of the FDIC standard insurance limit. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board announced a program to provide up to \$ 25. 0 billion of loans to financial institutions secured by certain of such government securities held by financial institutions, widespread demands for customer withdrawals or other liquidity needs of financial institutions may exceed the capacity of such program, and there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of such banks or financial institutions, or that they would do so in a timely fashion. These events could result in a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations, including, but not limited to, the following:**

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- potential or actual breach of statutory, regulatory or contractual obligations, including obligations that require us to maintain letters of credit or other credit support arrangements; or
- termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements.

**In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our partners, vendors or suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a vendor or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any partner, vendor or supplier, or the failure of any partner to make payments when due, or any breach or default by a partner, vendor or supplier, or the loss of any significant supplier relationships, could cause us to suffer material losses and may have a material adverse impact on our business.**

Changes in tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock. Securities research analysts may establish and publish their own periodic projections

for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline. There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including: • a limited availability of market quotations for our securities; • reduced liquidity for our securities; • a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; • a limited amount of news and analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. The price of our common stock may be volatile. The price of our common stock may fluctuate due to a variety of factors, including: • **our failure to complete, delays in completing, or other developments related to the pending Merger**; • changes in the industries in which we and our customers operate; • variations in our operating performance and the performance of our competitors in general; • material and adverse impact of the ~~ongoing~~ COVID-19 pandemic **and post-COVID environment** on the markets and the broader global economy; • actual or anticipated fluctuations in our quarterly or annual operating results; • publication of research reports by securities analysts about us, our competitors or our industry; • the public's reaction to our press releases, other public announcements and filings with the SEC; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • additions and departures of key personnel; • changes in laws and regulations affecting our business; • commencement of, or involvement in, litigation involving us; • changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; • the volume of shares of our common stock available for public sale; and • general economic and political conditions such as recessions, **rising** interest rates, **inflation**, fuel prices, foreign currency fluctuations, international tariffs, **boycotts, curtailment of trade and other business restrictions**, social, political and economic risks, **natural disasters** and acts of war or terrorism, **such as the conflicts involving Ukraine and Russia, or Israel and its surrounding regions**. These market and industry factors may materially reduce the market price of shares of our common stock regardless of our operating performance. ~~111~~ **73**