Risk Factors Comparison 2025-03-21 to 2024-03-29 Form: 10-K

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Our recurring operating losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern, if we are unable to obtain additional financings. Management has concluded that substantial doubt exists about the Company' s ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report on Form 10- K. As of December 31, ~~2023~~ **2024**, we had cash and cash equivalents of $ **10. 6 million** ~~5, 754, 720~~ and current liabilities of $ **3. 9 million** ~~4, 279, 110~~. We believe that we have sufficient resources available to support our development activities and business operations and satisfy our obligations into the ~~second~~ **fourth** quarter of ~~2024~~ **2025**. We do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10- K to support our operations for at least the 12 months following the date that the financial statements are issued. We will require substantial additional financing to fund our ongoing clinical trials and future operations, and to continue to execute our corporate strategy. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to explore various dilutive and non- dilutive opportunities, including equity and debt financings, strategic partnerships, business development and other transactions. The future success of the Company is dependent upon our ability to obtain additional funding. There can be no assurance, however, that we will be successful in obtaining sufficient amounts of funding, on terms acceptable to us, or at all. Failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued. The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, ~~2023~~ **2024** contains an explanatory paragraph relating to our ability to continue as a going concern. The auditor' s opinion on our audited financial statements for the year ended December 31, ~~2023~~ **2024** includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern for the next twelve months from the date of the financial statements included in this Annual Report on Form 10- K. While we believe that we will be able to raise the capital we need to continue our operations, there are no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our development efforts. Accordingly, our business, prospects, financial condition, and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical stage biopharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of $ **24. 6 million and $** 56 **. 2 million** ~~, 204, 313 and $ 25, 328, 567~~ for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. ~~As of~~ **In addition, the Company' s operating loss was $ 26. 7 million and $ 45. 0 million for the years ended** December 31, **2024 and** 2023 **, respectively. As of December 31, 2024**, we had an accumulated deficit of $ **134. 8 million** ~~110, 259, 087~~. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including our preclinical and clinical work, and to intellectual property. We expect to incur significant additional operating losses for the next several years, at least, as we advance ~~Buntanetap~~ **buntanetap** and any other product candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other product candidates, if approved. The costs of advancing product candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our product candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we: ● continue to progress our development in AD and PD with additional **pivotal Phase 3** studies, or conduct clinical trials for any other product candidates; ● scale- up cGMP drug supply manufacturing and complete necessary work to support an NDA for ~~Buntanetap~~ **buntanetap** in AD or in PD; **29** ● are required by the FDA to complete additional toxicological / pharmacological studies to support an NDA for ~~Buntanetap~~ **buntanetap** in AD or in PD; ● establish a sales, marketing and distribution infrastructure to commercialize our drug, if approved, and for any other product candidates for which we may obtain marketing approval; ● maintain, expand and protect our intellectual property portfolio; ● hire additional clinical, scientific and commercial personnel; ● add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts, as well as to support our requirements as a public reporting company; and ● acquire or in- license or invent other product candidates or technologies. Furthermore, our ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under " — Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval " and " — Risks Related to Commercialization. " This will require us

to be successful in a range of challenging activities, including completing clinical trials of ~~Buntanetap~~ **buntanetap** and any other product candidates, acquiring additional product candidates, obtaining regulatory approval for ~~Buntanetap~~ **buntanetap** and any other product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our company will be materially and adversely affected. Furthermore, this could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will require substantial additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of ~~Buntanetap~~ **buntanetap**. The development of biopharmaceutical product candidates is capital- intensive. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of ~~35Buntanetap~~ **buntanetap**. If we obtain receive regulatory approval for ~~Buntanetap~~ **buntanetap** or any other product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. We will require additional capital for the further development and potential commercialization of ~~Buntanetap~~ **buntanetap** and may also need to raise additional funds sooner to pursue a more accelerated development of ~~Buntanetap~~ **buntanetap**. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of ~~Buntanetap~~ **buntanetap** or any other product candidates. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Based on our current operating plan, we believe that our current cash and cash equivalents ~~and funding from existing grants~~ will enable us to fund our operating expenses and capital expenditure requirements ~~until~~ **into** the ~~second~~ **fourth** quarter of ~~2024~~ **2025**. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our current cash and cash equivalents will not be sufficient to complete development of ~~Buntanetap~~ **buntanetap** or any other product candidates, and we will require substantial capital in order to advance ~~Buntanetap~~ **buntanetap** or any other product candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by ~~potential~~ **30potential** worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, inflation, progression of geopolitical events (including in the relation to the conflict between Russia and Ukraine **and the conflict between Hamas and Israel**), diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop ~~Buntanetap~~ **buntanetap** or any other product candidates. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: ● the initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for ~~Buntanetap~~ **buntanetap** or any other future product candidates; ● the clinical development plans we establish for ~~Buntanetap~~ **buntanetap** and any other future product candidates, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities; ● the number and characteristics of product candidates that we discover or in- license and develop; ● the outcome, timing and cost of regulatory meetings and reviews by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect; ● the requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for ~~Buntanetap~~ **buntanetap** and any future product candidates and our anticipated timing for seeking approval in such jurisdictions ; ● the costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property and proprietary rights; ● the effects of competing technological and market developments; ● the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, CMC **,** quality and commercial personnel ; ~~36~~ ● the costs and timing of the implementation of commercial- scale manufacturing activities, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages; ● the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; ● our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products ; ● the

terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements ; and ● the costs associated with any products or technologies that we may in- license or acquire; Conducting clinical trials and preclinical studies and potentially identifying future product candidates is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to ~~obtain~~ **31obtain** regulatory approval and commercialize ~~Buntanetap~~ **buntanetap** or any future product candidates. If approved, ~~Buntanetap~~ **buntanetap** and any future product candidates may not achieve ~~commercial~~ **commerciab** success. Our commercial revenue, if any, will initially be derived from sales of ~~Buntanetap~~ **buntanetap** , which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised. Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, ~~as~~ **that** we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. 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 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 that 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 capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us and / or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we would be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose. We have limited operating history and no history of commercializing pharmaceutical products. We were established and began operations in 2008. Our operations to date have been primarily focused on conducting preclinical and clinical studies. We have not yet demonstrated the ability to successfully complete a large- scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. ~~37As~~ **As** we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, reliance should not be placed upon the results of any particular quarterly or annual period as indications of future operating performance. Our ability to use our tax net operating losses is uncertain. We have incurred significant net operating losses since our inception. As of December 31, ~~2023~~ **2024** , we had U. S. federal net operating loss carryforwards of approximately $ ~~38~~ **54** . 1 million. Our ability to utilize these net operating losses to offset future tax liabilities depends on the successful development of our product candidates and future financial performance. Additionally, our net operating losses may be subject to Section 382 of the Internal Revenue Code of 1986, as amended (“ Section 382 ”). Generally, if an ownership change occurs within three years of the closing date of an entity’ s most recent change in control transaction, any existing net operating losses and certain built- in losses would be subject to an additional limitation, pursuant to Section 382. Change in control as defined by Section 382 occurs when there is an ownership change among stockholders owning directly or indirectly 5 % or more of our common stock, as well as an aggregate ownership change with respect to such stockholders of ~~more~~ **32more** than 50 % of our common stock. We have not yet conducted a comprehensive study to assess whether a change of ownership as defined by Section 382 has occurred since our inception. If it is determined that we are unable to use our net operating losses to reduce future tax liabilities, our financial condition, results of operations, and cash flows may be adversely affected. Inflation could adversely affect our business and results of operations. While inflation in the United States has been relatively low in recent years, during ~~2022 and~~ 2023 **and 2024** , the economy in the United States encountered a material level of inflation. The **residual** ~~impact~~ **impacts** of COVID- 19, geopolitical developments such as the Russia- Ukraine **and Israel- Hamas** conflict and global supply chain disruptions continue to increase uncertainty in the outlook of near- term and long- term economic activity, including whether inflation will continue and how long, and at what rate. Increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and

uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, **Isreal and Hamas,** terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, or on less favorable terms than we would otherwise choose. In addition, if one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our clinical development goals on schedule and on budget. ~~38Risks~~ -- **Risks** Related to Development, Clinical Testing, Manufacturing and Regulatory ApprovalWe are heavily dependent on the success of ~~Buntanetap~~ **buntanetap** , our most advanced product candidate, which is still under clinical development, and if this drug does not receive regulatory approval or is not successfully commercialized, our business will be materially harmed. We do not have any products that have gained regulatory approval. Currently, our lead clinical stage product candidate is ~~Buntanetap~~ **buntanetap** . As a result, our business is entirely dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize ~~Buntanetap~~ **buntanetap** in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. We cannot commercialize ~~Buntanetap~~ **buntanetap** in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize ~~Buntanetap~~ **buntanetap** outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of ~~Buntanetap~~ **buntanetap** for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well- controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that ~~Buntanetap~~ **buntanetap** is safe and effective for use for that target indication and that the manufacturing ~~facilities~~ **33facilities** , processes and controls are adequate. If the FDA is not satisfied with the quantity and nature of the data we collect, we may be forced to undertake additional preclinical studies or clinical trials to obtain regulatory approval, which will lead to delays in our clinical development plans and cause us to incur additional costs, both of which may have a material adverse effect on our business. Even if ~~Buntanetap~~ **buntanetap** were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval for ~~Buntanetap~~ **buntanetap** in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other product candidate that we may in- license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for ~~Buntanetap~~ **buntanetap** , we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third- party and government payors. If we are unable to successfully commercialize ~~Buntanetap~~ **buntanetap** , we may not be able to earn sufficient revenue to continue our business. If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired. Research programs to identify product candidates 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: ● competitors may develop alternatives that render any product candidates we develop obsolete ; ● any product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights ; ● a product candidate may 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 physicians, patients, the medical community or third- party payors. We have limited financial and personnel resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause it to fail to capitalize on viable commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product. If we are unsuccessful in identifying and developing additional product ~~39candidates~~ -- **candidates** or are unable to do so, our business, results of operations, cash flows, financial condition and / or prospects may be materially and adversely affected. Business disruptions could harm our ability to complete or could materially delay our clinical trials, as well as cause disruptions to the FDA and other governmental authorities. Our operations and the operations of our suppliers, contract research organizations (" CROs "), hospitals, clinical trial sites, regulators, consultants and other third parties with whom we conduct business could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme

weather conditions, fires, and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third- party manufacturers or suppliers to produce ~~Buntanetap~~ **buntanetap** and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our product candidate. Our ability to obtain clinical or, if approved, commercial, supplies of ~~Buntanetap~~ **buntanetap** or any future product candidates could be disrupted if the operations of these suppliers were affected by a man- made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of ~~the~~ **34the** foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Clinical trials are expensive, time- consuming and difficult to design and implement, and involve an uncertain outcome. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, ~~Buntanetap~~ **buntanetap** and our other product candidates may not have favorable results in later preclinical and clinical studies or receive regulatory approval. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development. Furthermore, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to: ● the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; ● obtaining regulatory approval to commence a trial; ● reaching an 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; ● obtaining Institutional Review Board (“ IRB ”) approval at each site, or Independent Ethics Committee (“ IEC ”) approval at sites outside the United States; ● recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers; ● patients failing to complete a trial or return for post-treatment follow- up; ● imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols; ● clinical sites deviating from trial protocol or dropping out of a trial; ● addressing patient safety concerns that arise during the course of a trial; ● adding a sufficient number of clinical trial sites; ~~or~~40 **or** ● manufacturing sufficient quantities of product candidate for use in clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board (“ DSMB ”) ~~,~~for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in “ — Risks Related to Our Dependence on Third Parties. ” ~~The~~ **35The** 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 ~~Buntanetap~~ **buntanetap** or any other product candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the 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. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for ~~Buntanetap~~ **buntanetap** or any other product candidate. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. Approval from the FDA and comparable foreign authorities may be delayed or denied for a variety of reasons, including: ● 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; ● serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing the active ingredient in our product candidates; ● negative or ambiguous results from our clinical trials or results that 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 preclinical studies or clinical trials; ● the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; ● the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and / or the specifications of our product candidates; ● the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with 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. ~~41Prior~~ -- **Prior** to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical

studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. For diseases like AD and PD, the FDA has stated that one single Phase 3 trial is adequate for approval if it demonstrates robust and unquestionable efficacy. However, the circumstances under which a single adequate and controlled study can be used as the sole basis of demonstrating efficacy of a drug are exceptional. The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including: ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; **36** ● the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug; ● the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; ● the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market ~~Buntanetap~~ **buntanetap** or another product candidate, which would significantly harm our business, results of operations and **future commercial** prospects. In addition, the FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency 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. We have concentrated our research and development efforts on the treatment of AD and PD, diseases that have seen limited success in drug development. Further, ~~Buntanetap~~ **buntanetap** is based on a new approach to treating AD and PD, which makes it difficult to predict the time and cost of development and subsequent obtaining of regulatory approval. Efforts by biopharmaceutical and pharmaceutical companies in treating AD and PD have seen limited success in drug development, and there are ~~no~~ **few** FDA- approved disease modifying therapeutic options available for patients with AD and PD. As a result, the design and conduct of clinical trials of ~~Buntanetap~~ **buntanetap** or any future product candidate may take longer, be more costly or be less effective as a result of the novelty of development in these diseases. We cannot be certain that our approach will lead to the development of approvable or marketable products. In some cases, we may use endpoints or methodologies that regulatory authorities may not consider to be clinically meaningful and that we may not continue to use in clinical trials or that we may determine after the initiation of the trial to no longer be an appropriate endpoint or methodology. Any such regulatory authority may require evaluation of additional or different clinical endpoints in our clinical trials or ultimately determine that these clinical endpoints do not support marketing approval. In addition, if we are required to use additional or different clinical endpoints by regulatory authorities, ~~Buntanetap~~ **buntanetap** may not achieve or meet such clinical endpoints in our clinical trials. Even if a regulatory authority finds our clinical trial success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidate. Further, even if we do achieve the prespecified criteria, our trials may produce results that are unpredictable or inconsistent with the results of other efficacy endpoints in the trial. Regulatory authorities also could give overriding weight to other efficacy endpoints over a primary endpoint even if we achieve statistically significant results on that primary endpoint if we do not do so on our secondary efficacy endpoints. Regulatory authorities also weigh the benefits of a product against its risks and may view the efficacy results in the context of safety as not being supportive of approval. The ~~only~~ **majority of** drugs approved by the FDA to treat AD and PD to date address **only** the diseases' symptoms. ~~No~~ **Only a small number of** new treatments have been approved for AD since 2003. From 2004 to ~~2023~~ **2025**, phase 2 and 3 clinical trials for unique compounds with various mechanisms of ~~42action --~~ **action** intended to combat AD had a development success rate of just ~~2~~ **8** %. AD drug candidates have the highest failure rate of nearly 100 %, compared to 50 % to 80 % for all other drug candidates. As a result, the FDA has a limited set of products to rely on in evaluating ~~Buntanetap~~ **buntanetap**. This could result in a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of ~~Buntanetap~~ **buntanetap** for the treatment of AD and PD. We cannot be sure that ~~Buntanetap~~ **buntanetap**, or any other product candidate we develop, will ultimately prove to be safe and effective, scalable or profitable. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe novel treatments. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates progress through clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, ~~the~~ **37the** manufacturing process being used to produce clinical material for our planned clinical trials is different than that used in prior trials of ~~Buntanetap~~ **buntanetap**. There can be no assurance that such changes will achieve these intended objectives. These changes and any future changes we may make to ~~Buntanetap~~ **buntanetap** or any future product candidates may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential marketing approval and jeopardize our ability to commercialize ~~Buntanetap~~ **buntanetap** or any future product candidates, if approved, and generate revenue. We may develop ~~Buntanetap~~ **buntanetap** and future product candidates for use in combination with other therapies, which could expose us to additional regulatory risks. We may develop ~~Buntanetap~~ **buntanetap** and future product candidates for use in combination with one or more other approved therapies for AD or PD. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with

other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved AD or PD therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved AD and PD therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including: ● the patient eligibility and exclusion criteria **as** defined in the protocol; ● the size of the patient population required for analysis of the trial' s primary endpoints; ● the nature and design of the trial protocol; ● the existing body of safety and efficacy data with respect to the product candidate; ~~43~~ ● the proximity of patients to clinical sites; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● 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 we are investigating; ● competing clinical trials being conducted by other companies or institutions; ● our ability to obtain and maintain patient consents; ~~and~~ **and38** ● the risk that patients enrolled in clinical trials will drop out of the trials before completion. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and recruiting patients may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow- up periods. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved or authorized therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a specified number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials. The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, results of early clinical trials may differ from results of later clinical trials due to changes in patient population size. The clinical trials that we have completed to date included a limited patient population, and we may observe differences in the safety and efficacy of ~~Buntanetap~~ **buntanetap** and our other product candidates as the patient population increases in size. Accordingly, the data that we have observed to date may not be reflective of ongoing and future clinical trial data. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for ~~Buntanetap~~ **buntanetap** are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval. Further, others, including regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects. ~~44Interim~~ -- **Interim** " top- line " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are further subject to audit and verification procedures that could result in material changes in the final data. Furthermore, undue reliance on interim analyses may be detrimental to our long- term clinical development plans, which could harm our business, operating results, prospects or financial condition. From time to time, we may publish interim " top- line " or preliminary data from our clinical studies, which is 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. 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 evaluate all data fully and carefully. Preliminary or " top- line " 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 ~~business~~ **39business** prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. Moreover, 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 drug, product candidate or our business. If the interim " topline " or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, ~~Buntanetap~~ **buntanetap** and any future product candidates ~~may be harmed, which could harm our business, operating results, prospects or financial condition. Furthermore, our Phase 3 PD Study and Phase 2 / 3 AD Study each included interim analyses. Our Phase 3 PD Study incorporated an interim analysis at two months, the results of which were disclosed on March 31, 2023. Based on the results of the interim analysis, we proceeded with the Phase 3 PD Study as planned in accordance with the previously established protocol. We disclosed the results of the interim analysis for our Phase 2 / 3 AD Study on October 23, 2023, and as for the PD study based on the outcome of the interim analysis we proceeded with the study as planned. The Phase 2 / 3 AD study was completed on February 13, 2024. We plan to consult with the FDA following completion of the full analyses of the two studies, to obtain feedback on our planned AD and PD studies, including conducting disease- modifying studies and open label extensions. Accordingly, if the interim data upon which we have relied on is shown to be materially different from the final, complete study results, the basis upon which we set forth our development plans may be called into question and our ability to obtain approval for, and commercialize, Buntanetap~~ may be harmed, which could harm our business, operating results, prospects or financial condition. Our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. As is the case with biopharmaceuticals generally, it is likely that there may be adverse side effects associated with ~~Buntanetap~~ **buntanetap** or any future product candidates' use. Serious adverse events or undesirable side effects caused by ~~Buntanetap~~ **buntanetap** or any other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Patients treated with ~~Buntanetap~~ **buntanetap** to date, at high doses have experienced adverse events that include nausea, vomiting and dizziness. If unacceptable side effects arise in the development of our product candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel ~~45using~~ **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 patient injury or death. Any of these occurrences may harm our business, financial condition and **future commercial** prospects significantly. Moreover, if ~~Buntanetap~~ **buntanetap** or any future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many product candidates that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the product candidates. It is possible that as we test ~~Buntanetap~~ **buntanetap** or any future product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw approvals of such product; **40** ● regulatory authorities may require additional warnings on the label, such as a " black box " warning or contraindication; ● additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; ● we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients; ● we could be sued and held liable for harm caused to patients; ● the product may become less competitive; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if

approved, and could significantly harm our business, results of operations and **future commercial** prospects. The market opportunities for ~~Buntanetap~~ **buntanetap** or any other product candidates, if approved, may be smaller than we anticipate, which could adversely affect our business, financial condition and results of operations. We expect to initially seek approval for ~~Buntanetap~~ **buntanetap** for AD and PD in the U. S. The precise incidence and prevalence for the conditions we aim to address with ~~Buntanetap~~ **buntanetap** or any future product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on a number of internal and third- party estimates. These estimates have been derived from a variety of sources, including relevant scientific literature, patient foundations and market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these indications. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. The total addressable market across all of the potential indications for ~~Buntanetap~~ **buntanetap** and any future ~~46product~~ -- **product** candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such product candidate which receives marketing approval for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of such product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition and results of operations. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications. We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates. Further, even if marketing approval is obtained, we have no experience as a company in commercializing products. We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA- required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. ~~Any~~ **41Any** delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business. Furthermore, we have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If ~~Buntanetap~~ **buntanetap** or any future product candidates ultimately receives marketing approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company with the marketing, sale or distribution of biopharmaceutical products and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Even if we obtain FDA approval for ~~Buntanetap~~ **buntanetap** or any other product candidates in the United States, we may never obtain approval for or commercialize ~~Buntanetap~~ **buntanetap** or any other product candidates in any other jurisdiction, which would limit our ability to realize their full market potential. Our future growth may depend, in part, on our ability to develop and commercialize ~~Buntanetap~~ **buntanetap** and any future product candidates in foreign markets. We are not permitted to market or promote any product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for ~~Buntanetap~~ **buntanetap** or any future product candidates. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials ~~47conducted~~ -- **conducted** in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries

and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. If we obtain regulatory approval of product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including: ● different regulatory requirements for approval of drugs in foreign countries ; ● reduced protection for intellectual property rights ; ● the existence of additional third- party patent rights of potential relevance to our business ; ● unexpected changes in tariffs, trade barriers and regulatory requirements ; **42** ● economic weakness, including inflation, or political instability in particular foreign economies and markets ; ● compliance with export control and import laws and regulations ; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad ; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country ; ● foreign reimbursement, pricing and insurance regimes ; ● workforce uncertainty in countries where labor unrest is common ; ● differing regulatory requirements with respect to manufacturing of products ; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad ; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. Even if we obtain regulatory approval for ~~Buntanetap~~ **buntanetap** or any product candidates, we will still face extensive and ongoing regulatory requirements and obligations and any product candidates, if approved, may face future development and regulatory difficulties. Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding ~~48the~~ -- **the** distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post- approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on manufacturing such products; ● restrictions on the labeling or marketing of products; ● restrictions on product distribution or use; **43** ● requirements to conduct post- marketing studies or clinical trials; ● warning letters or untitled letters; ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our products; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. Further, the FDA' s policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially ~~49delay~~ -- **delay** , the FDA' s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA' s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as ~~Buntanetap~~ **buntanetap** or any future product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other

regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval for ~~Buntanetap~~ **buntanetap** or any future product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of ~~Buntanetap~~ **buntanetap** or any future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. ~~We~~ **44We** may seek a Breakthrough Therapy designation for ~~Buntanetap~~ **buntanetap** from the FDA in PD and AD ~~at the end of the first Phase 3 study in PD, and at the end of the Phase 2 / 3 study in AD, respectively~~ . However, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. We may seek a Breakthrough Therapy designation for ~~Buntanetap~~ **buntanetap** or one or more of our other product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs 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 the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit, delay or cease commercialization of any products that we may develop. The use of ~~Buntanetap~~ **buntanetap** or any other product candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. This risk will be even greater if we commercialize our product candidates, especially if our products are prescribed for off- label uses (even if we do not promote such uses). For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. Claims could also be asserted under state consumer protection acts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs or be required to limit, delay ~~50or~~ **or** cease the commercialization of our products. Even a successful defense would require significant financial and management resources. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● impairment of our business reputation and significant negative media attention; ● withdrawal of participants from our clinical trials; ● significant costs to defend the litigation; ● distraction of management' s attention and our resources from our primary business; ● substantial monetary awards to patients or other claimants; ● inability to commercialize ~~Buntanetap~~ **buntanetap** or any other product candidate; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● decreased market demand for any product; **45** ● significant negative financial impact; and ● a decline in our stock price. The product liability insurance coverage we carry or acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. In connection with all our clinical studies, we carry insurance for product liability claims in the United States and in Europe. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of ~~Buntanetap~~ **buntanetap** or any future product candidates. Although we maintain such insurance, a successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, **cyber security liability,** employment benefits liability, workers' compensation, products liability, and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. Risks Related to CommercializationWe face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain

marketing approval for new products on a cost- effective basis and to market them successfully. If ~~Buntanetap~~ **buntanetap** is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater ~~51resources~~ -- **resources** than we do and may conduct similar research ~~;~~**,** seek patent protection ~~;~~and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us. Our competitors may, among other things: ● have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors; ● develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe **side** effects; ● obtain quicker regulatory approval; ● implement more effective approaches to sales and marketing; or ● form more advantageous strategic alliances. ~~Smaller~~ **46Smaller** 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; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, or are more convenient or are less expensive than ~~Buntanetap~~ **buntanetap** . Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ~~Buntanetap~~ **buntanetap** , which could result in our competitors establishing or strengthening their market position before we are able to enter the market. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competing products may render ~~Buntanetap~~ **buntanetap** or any future product candidates we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. The successful commercialization of ~~Buntanetap~~ **buntanetap** and any other product candidates we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford prescription medications such as ~~Buntanetap~~ **buntanetap** , if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Assuming we obtain coverage for our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. ~~52Third~~ -- **Third** - party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. 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. ~~No~~ **47No** uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost- containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States 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. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Even if ~~Buntanetap~~ **buntanetap** or any product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success, which would adversely affect our business. Buntanetap and any future product candidates may not be commercially successful. If ~~Buntanetap~~ **buntanetap** or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to: ● the efficacy and potential advantages compared to alternative treatments; ~~53~~ ● the indications for which our product candidates are approved; ● the limitation of our targeted patient population and other limitations or warnings contained in any FDA- approved labeling; ● effectiveness of sales and marketing efforts; ● the cost of treatment in relation to alternative treatments, including any similar generic treatments; ● our ability to offer our products for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the strength of marketing and distribution support; **48** ● the availability of third- party coverage and adequate reimbursement; ● the willingness of patients to pay all, or a portion of, out- of- pocket costs associated with our products in the absence of sufficient third- party coverage and adequate reimbursement ; ● the prevalence and severity of any side effects; ● any restrictions on the use of our product together with other medications; ● potential product liability claims; ● the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs; and ● unfavorable publicity relating to the product. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. Our efforts to educate the medical community and third- party payors regarding the benefits of our products may require significant resources and may never be successful. If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing ~~Buntanetap~~ **buntanetap** , if approved. We do not have any infrastructure for the sales, marketing or distribution of ~~Buntanetap~~ **buntanetap** , and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market and successfully commercialize our drug or any product candidate we develop, if approved, we must build our sales, distribution, marketing, managerial and other non- technical capabilities or collaborate with third parties to perform these services. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator' s strategic interest in a product and such collaborator' s ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of ~~Buntanetap~~ **buntanetap** , if approved, for certain markets overseas; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. ~~54If~~ **If** we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of ~~Buntanetap~~ **buntanetap** , we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for ~~Buntanetap~~ **buntanetap** we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for ~~Buntanetap~~ **buntanetap** at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects. If we are unable to establish adequate sales, marketing and distribution capabilities, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. ~~A~~ **49A** variety of risks associated with operating internationally could materially adversely affect our business. We currently have no international operations, but our business strategy includes potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to: ● the burden of

complying with multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; ● failure by us to obtain and maintain regulatory approvals for the use of our products in various jurisdictions; ● additional potentially relevant third- party patent rights; ● complexities and difficulties in obtaining protection and enforcing our intellectual property; ● difficulties in staffing and managing foreign operations; ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● limits in our ability to penetrate international markets; ● financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; ● natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; ● certain expenses including, among others, expenses for travel, translation and insurance; and ● regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its books and records provisions, or its anti- bribery provisions. Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations. ~~55Risks~~ -- **Risks** Related to Our Dependence on Third PartiesOur employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. Our employees and independent contractors, including principal investigators, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, 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~~ **50subject** to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. 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 such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. We currently rely on third- party contract manufacturing organizations (" CMOs ") ~~,~~ for the production of clinical supply of ~~Buntanetap~~ **buntanetap** and intend to rely on CMOs for the production of commercial supply of ~~Buntanetap~~ **buntanetap** , if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position. We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of ~~Buntanetap~~ **buntanetap** and any product candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of ~~Buntanetap~~ **buntanetap** drug substance to enable us to complete our clinical trials, and we have also engaged two CMOs to provide clinical and commercial supply of the drug product. The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also ~~56terminate~~ -- **terminate** or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another

acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. We rely on and will continue to rely on CMOs to purchase from third- party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. ~~Finding~~ **51Finding** new CMOs or third-party suppliers involves additional cost and requires our management' s time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. As part of their manufacture of our product candidates, our CMOs and third- party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third- party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third- party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. We currently rely and in the future intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business. We rely, and will continue to rely, on CROs, CRO- contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, yet we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards. We and our CROs will be required to comply with the Good Laboratory Practice **(" GLP ")** requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP requirements, 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 marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully ~~57commercialize~~ **commercialize** any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management' s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. Additionally, working with collaborators presents risks, including but not limited to: ● the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; and ● the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business. ~~If~~ **52If** any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all. In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to

attract new collaborators and the perception of our business and our stock price could be adversely affected. We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, 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 elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected. Risks Related to Healthcare Laws and Other Legal Compliance MattersEnacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the " ACA ") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. ~~58Since~~ -- **Since** its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there may be additional challenges and amendments to the ACA in the future. It is uncertain the extent to which any such changes may impact our business or financial condition. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring ~~more~~ **53more** 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. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include: ● the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return

for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order ~~59to~~ **to** have committed a violation. The U. S. federal Anti- Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand; ● the U. S. federal false claims and civil monetary penalties laws, including the civil False Claims Act (" FCA ") which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes " any request or demand " for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims; **54** ● Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or 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 a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH ") and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure 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; ● the Federal Food, Drug and Cosmetic Act (" FDCA "), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; ● the U. S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and ● analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. ~~60Because~~ -- **Because** of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and 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 the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to ~~operate~~ **55operate** our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are 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, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming and may require significant 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. Any clinical trial programs we conduct or research collaborations we enter into in the EEA may subject us to the General Data Protection Regulation. If we conduct clinical trial programs or enter into research collaborations in the EEA, we may be subject to the General Data Protection regulation (" GDPR "). The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the European Union (" EU ") to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third- party processors in connection with the processing of personal data. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to € 20 million or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls and anti- corruption and anti- money laundering laws and regulations, including the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for ~~61the --~~ **the** corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Furthermore, U. S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U. S. sanctions. U. S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain. ~~We~~ **56We** are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. We and any contract manufacturers and suppliers we engage are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. While the materials we use require operations involving the use of hazardous and flammable materials, including chemicals and biological materials, we do not produce any materials ourselves and contract with third parties for the manufacture and the disposal of these materials and wastes. As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third- party manufacturers or our development efforts may be interrupted or delayed. Recent U. S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (" CARES Act ") was enacted in response to the COVID- 19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100 % of taxable income for taxable years beginning before 2021. Previously, NOLs generated after December 31, 2017 were limited to 80 % of taxable income in future years. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The NOL carryback provision of the CARES Act had no impact on us due to our tax losses generated during all prior years. U. S. tax legislation enacted in 2017 has significantly changed the U. S. federal income taxation of U. S. corporations, including by reducing the U. S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. The legislation could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U. S.

Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is remains unclear how these U. S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. ~~62Risks~~ -- **Risks** Related to Our Intellectual PropertyIf we are unable to obtain, maintain and enforce patent or other intellectual property protection for ~~Buntanetap~~ **buntanetap , Posiphen Form B** or any future product candidates or technology or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, our ability to successfully commercialize ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidates may be adversely affected and we may not be able to compete effectively in our markets. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain and defend patent protection in the United States and other countries with respect to ~~Buntanetap~~ **buntanetap , Posiphen Form B,** and any future product candidates. Because we have not conducted a formal freedom to operate analysis for patents related to ~~Buntanetap~~ **buntanetap** since 2008, we may not be aware of patents issued since then that a third- party might assert are infringed by ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidates, which could materially impair our ability to commercialize ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidates. We generally seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to ~~Buntanetap~~ **buntanetap , Posiphen Form B,** and any future product candidates, manufacturing processes, and methods of use. If we are unable to obtain, maintain or enforce patent protection, our business, financial condition, results of operations and prospects could be materially harmed. ~~Changes~~ **57Changes** in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue will issue as patents in any particular jurisdiction, will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, will be found to be invalid, unenforceable, or not infringed. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection before public disclosures are made. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third- party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with ~~Buntanetap~~ **buntanetap , Posiphen Form B,** and any future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent **or file on** the inventions claimed in any of our licensed patents or pending patent applications, or that we or our licensors were the first to make the inventions claimed in those owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. Furthermore, even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. If we are unable to obtain additional patent protection to prolong the patent life of our product candidates, we may not be able to continue development of our product ~~candidate~~ **candidates** . We seek to protect and prolong our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. If the patent applications we own with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, ~~63and~~ -- **and** threaten our ability to commercialize future product candidates. Any such outcome could have a materially adverse effect on our business and our company could cease to exist. Annovis has filed ~~ten~~ **fourteen** families of patent applications to prolong the patent life of ~~Buntanetap~~ **buntanetap , Posiphen Form B** . Unless these applications are approved by the U. S. and international patent offices, the patent life of using ~~Buntanetap~~ **buntanetap , and Posiphen Form B** is limited. The first patent application family we filed, which would be expected to expire in 2031, **before any patent term adjustments or extensions,** covers the use of ~~Buntanetap~~ **buntanetap in** ~~at much lower doses and expands its use to~~ the treatment of AD, PD and other neurodegenerative disorders such as Huntington' s disease, prion diseases, amyotrophic lateral sclerosis, tauopathies ~~and~~ **,** frontotemporal dementia **, Lewy bodies disease, and chronic traumatic encephalopathy** , based on our preclinical research. In August 2019, the **U. S. Patent and Trademark Office (“** USPTO **”)** granted the first of our Annovis patents from this family covering **treatment of** PD and Lewy body diseases. Subsequently **,** the USPTO also granted patents covering ~~tau~~ **treatment frontotemporal dementia** and **Prion' s disease,** tauopathies, chronic traumatic encephalopathy, prion diseases, amyotrophic lateral sclerosis, Alzheimer' s

and Huntington' s disease. The second patent application family covers ANVS405' s use in acute brain and nerve trauma and would be expected to expire in 2036, before any patent term adjustments or extensions. In December 2020, the EPO approved the whole patent ~~,~~ and it has since been approved in **most** ~~number of other~~ countries **filed claiming** ~~. However, the USPTO entered~~ a ~~species restriction~~ **method of treating acute nerve and brain injuries by administering ANVS405 before and after the injury. The US patent office instead** ~~as~~ **has asked us** to **separate** the **application into four divisional applications covering stroke,** ~~condition being treated and we are therefore currently pursuing claims directed to~~ traumatic brain injury ~~. We intend to file additional divisional applications when we have successfully reached a conclusion to the pending application, assuming we are not able to cover the remaining acute conditions (stroke~~ , nerve injury and spinal cord injury ~~) for which patent coverage is being sought in the pending application~~ . The third patent application family relates to the use of the mechanism of action of ~~Buntanetap~~ **buntanetap** and ANVS405 to prevent and treat neurodegenerative diseases and would be expected to expire in 2038, before any patent term adjustments or extensions. The first divisional of this application was approved in December 2022 ~~;~~ **,** it covers the prevention of neurodegenerative diseases. **The fourth** ~~In May 2020, we filed a~~ patent application family **relates to** ~~with the USPTO concerning~~ a method of inhibiting, preventing, or treating neurological injuries due to viral, bacterial, fungal, protozoan, or parasitic infections in humans and in animals via administration of ~~Buntanetap~~ **buntanetap or related 58compounds. In May 2020, we filed a patent application with the USPTO concerning a method of inhibiting, preventing, or treating neurological injuries due to viral, bacterial, fungal, protozoan, or parasitic infections in humans and in animals via administration of buntanetap** or related compounds **,** which would be expected to expire in 2041, before any patent term adjustments or extensions ~~;~~ **.** The fifth patent family application is directed to a method of maintaining heavy metal homeostasis avoiding the effect of toxic levels of a heavy metal in cells in a healthy human or restoring heavy metal homeostasis in a sick human patient. The USPTO granted the first patent in this family on March 7, 2023, which is expected to expire in 2039 **, before any patent term adjustments or extensions** . The sixth patent application family relates to treating brain metastasis via administration of ~~Buntanetap~~ **buntanetap** or related compounds. In September 2023, we filed a U. S. nonprovisional patent application directed to treatment of brain metastasis via administration of ~~Buntanetap~~ **buntanetap** or related compounds with the USPTO, which, if allowed, would be expected to expire in 2043 **, before any patent term adjustments or extensions** . The seventh patent application family relates to treatment of mental illness via administration of ~~Buntanetap~~ **buntanetap** or related compounds. In January 2024, we filed an International (PCT) application and a U. S. nonprovisional patent application directed to treatment of mental illness via administration of ~~Buntanetap~~ **buntanetap** or related compounds with the USPTO, which, if allowed, would be expected to expire in 2044 **, before any patent term adjustments or extensions** . The eighth patent application family relates to treatment of neurodegenerative diseases **and other diseases** via co- administration of ~~Buntanetap~~ **buntanetap** or related compounds and an **antidiabetic** ~~additional therapeutic~~ agent. In ~~January~~ **September** 2024, we filed **an International (PCT) application and** a ~~provisional~~ U. S. **nonprovisional** patent application directed to treatment of neurodegenerative **diseases and other** diseases via administration of this combination. The ninth patent application family relates to treatment of neurodegenerative diseases **and other diseases** via co- administration of ~~Buntanetap~~ **buntanetap** or related compounds and **a phosphodiesterase inhibitor. In September 2024, we filed an International (PCT) application and a U. S. nonprovisional patent application directed to treatment of neurodegenerative diseases and** ~~another~~ ~~-~~ **other diseases via administration of this combination. The tenth patent application family relates to treatment of neurodegenerative diseases and other diseases via co- administration of buntanetap or related compounds and an antihypertensive agent. In September 2024, we filed an International (PCT) application and a U. S. nonprovisional patent application directed to treatment of neurodegenerative diseases and other diseases via administration of this combination. The eleventh patent application family relates to treatment of neurodegenerative diseases and other diseases via co- administration of buntanetap with two additional** therapeutic ~~agent~~ **agents . In August 2024** , ~~which is different from~~ **we filed a provisional U. S. Patent application directed to treatment of neurodegenerative diseases and** ~~the~~ **other diseases via administration of this combination. The twelfth patent application family relates to treatment of neurodegenerative diseases and other diseases via co- administration of buntanetap or related compounds and an** additional therapeutic agent ~~in the seventh patent application family~~ . In ~~April~~ **February** ~~2023~~ **2025** , we filed a provisional U. S. ~~patent~~ **Patent** application directed to treatment of neurodegenerative **diseases and other** diseases via administration of this combination. The ~~tenth~~ **thirteenth** patent application family relates to the new Form B of Posiphen (ANVS402); it demonstrates that it can be used instead of ~~Buntanetap~~ **buntanetap** , including in the foregoing uses of ~~Buntanetap~~ **buntanetap** of the Company' s patent portfolio. Posiphen Form B may be the compound of choice in current uses of ~~Buntanetap~~ **buntanetap** , because it may have advantageous properties such as better stability and higher purity. ~~The~~ **In 2023, the** Company ~~has~~ filed with the USPTO two **provisional** patent applications as to Posiphen Form B **. In 2024, the Company filed an International (PCT) as to Posiphen Form B and uses thereof. The International Search Report and ' Written Opinion " issued by the USPTO in the prosecution of the PCT application was favorable, indicating that the search claims directed to Posiphen Form B are novel and inventive** . The Company expects to further file patent applications **in the U. S. and outside the U. S.** as **National** ~~to Posiphen Form B~~ and ~~uses thereof~~ **Regional Phase patent applications of the PCT application** . As to this family of patent applications involving Posiphen Form B and uses thereof, patents would be expected to expire in 2044 **, before any patent term adjustments or extensions. The Company also expects to seek New Chemical Entity status for Posiphen Form B before the US Food and Drug Administration (FDA), and to seek additional regulatory exclusivity based thereon. The fourteenth patent application family relates to new, improved and commercially advantageous methods for preparing buntanetap and Posiphen Form B. The Company sees this patent application family as providing further protection as to methods that use buntanetap or Posiphen Form B, and for Posiphen form B. More in particular, in 2024 the Company filed with the USPTO a provisional patent application directed to new methods of preparing buntanetap and Posiphen Form B. The Company expects in 2025 to further file at least an International (PCT) application, claiming**

priority from that provisional patent application, and directed to the new, improved and commercially advantageous methods for preparing buntanetap and Posiphen Form B, and thereafter patent applications in the U. S. and outside the U. S. as National and Regional Phase patent applications of the PCT application. As to this family of patent applications, patents would be expected to expire in 2045, before any patent term adjustments or extensions . It is possible that we will fail to identify further patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that provide further coverage of ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any other product candidate in the United States or in other foreign countries. ~~Our~~ **59Our** patents may be challenged in courts, in patent offices or before other administrative bodies which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio, along with the unpredictable nature of patent prosecution, may not provide us with sufficient rights to similarly challenge other parties or exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents further cover ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidate, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Our patent rights may be subject to such priority, validity, inventorship, scope and enforceability disputes. Legal ~~64proceedings~~ -- **proceedings** relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time- consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. If we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of U. S. Supreme Court cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic methods are considered ineligible for patenting because they are directed to a " law of nature. " Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit our ability to stop others from using or commercializing similar or identical technology and products. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our patent rights, any potential trade secrets, or other intellectual property as an inventor, co-inventor or owner of any potential trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, any potential trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates or put our patents and other proprietary rights at risk. Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property- dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U. S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have ~~substantially~~ **60substantially** greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We may be subject to third- party claims including infringement, interference or derivation proceedings, post- grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe ~~65third~~ -- **third** party infringement claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the

applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Proceedings challenging our patents or those that we license may also result in our patent claims being invalidated or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third- party is entitled to certain patent ownership rights instead of us. Further, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages, if we are found to be infringing a third party' s patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third- party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. Modifying our product candidates to design around third- party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of eligibility, lack of novelty, obviousness or non- enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing on our patents or other intellectual property rights. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Finally, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of ~~their~~ **61their** substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope, or expiration of a third- party patent, which might adversely affect our ability to develop, manufacture and market our product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States, Europe and ~~66elsewhere~~ -- **elsewhere** that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. From time to time we may identify patents or applications in the same general area as our products and product candidates. We may determine these third- party patents are irrelevant to our business based on various factors including our interpretation of the

scope of the patent claims and our interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe on the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time- consuming and inherently uncertain. In addition, the America Invents Act (" AIA ") which was passed in September 2011, resulted in significant changes to the U. S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent with the USPTO. This applies to all of our ~~U~~ **62U** . S. patents, even those issued before March 16, 2013. Because of a ~~lower~~ **possibly different** evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs ~~67surrounding~~ -- **surrounding** the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. 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 and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions 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 such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' 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 and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide

to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. For example, unlike other countries, China has a heightened requirement for patentability, and ~~specifically~~ **63specifically** requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it ~~68difficult~~ -- **difficult** for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Prosecution of patent applications in other jurisdictions is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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. We may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and ~~in foreign countries~~ under similar legislation **in foreign countries** , thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments and similar legislation in the EU. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension 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, the period during which we can enforce our patent rights for that product will be shortened and our competitors may ~~obtain~~ **64obtain** approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO, referred to as Patent Term Adjustment (" PTA "). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third- party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering ~~69pharmaceutical~~ -- **pharmaceutical** products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated. Intellectual property rights do not address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our

business, or permit us to maintain our competitive advantage. The following examples are illustrative: ● others may be able to make products that are similar to ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or our future product candidates but that are not covered by the claims of the patents that we own or license from others; ● others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights; ● we or any of our collaborators might not have been the first to conceive and reduce to practice **or file on** the inventions covered by the patents or patent applications that we own, license or will own or ~~license; ● we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a~~ license; ● it is possible that our pending patent applications will not lead to issued patents; ● issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● ownership of our patents or patent applications may be challenged by third parties; and ● the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. In addition to seeking patent protection for our product candidates and proprietary technologies, we may also rely on trade secret protection and confidentiality agreements to protect our unpatented know- how, technology, and other proprietary information and to maintain our competitive position. We consider proprietary trade secrets or confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets or confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture ~~Buntanetap~~ **buntanetap , Posiphen Form B,** and any future product candidates, and we expect to collaborate with third parties on the development of ~~Buntanetap~~ **buntanetap , Posiphen Form B,** and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know- how can be difficult to maintain as confidential. ~~To~~ **65To** protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. ~~70However~~ -- **However** , current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Furthermore, we cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to any potential trade secrets or proprietary technology and processes. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know- how is expensive, time- consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. If any of our potential trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We have not yet registered our trademarks in the United States or other jurisdictions. Failure to secure such registrations could adversely affect our business. We have not yet registered our trademarks in the United States or other jurisdictions. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace. We have also not yet registered trademarks for any of our product candidates in any jurisdiction. When we file registration applications for trademarks relating to our product candidates, those applications may be rejected, and registered trademarks may not be obtained, maintained or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties may oppose pending trademark registration applications or seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In addition, any proprietary name we may propose to use with ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidate in the United States must be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative

body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. 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 unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market ~~confusion~~ **66confusion** . In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. There could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Furthermore, in many countries, owning and maintaining a trademark registration may not ~~71provide~~ -- **provide** an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. In response to an inability to enforce our patent rights, or in the event of successful litigation against us by third parties, or in the normal course of future business operations, we may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. Furthermore, if we or our licensors are unsuccessful in any proceedings sought to enforce our patent rights, such patents and patent applications may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties. Although at this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize ~~Buntanetap~~ **buntanetap , or Posiphen Form B** , a third party may also hold intellectual property, including patent rights that are important or necessary to the future development or commercialization of ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or our future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or our product candidates, in which case we would be required to obtain a license from these third parties. If any of these situations were to occur, such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, contractors, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and 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 confidential information of our employees' former employers or other third parties. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against any of the foregoing claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership or right to use. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Our proprietary information may be lost, or we may suffer security breaches. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our ~~operations~~ **67operations** . Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Certain federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from breaches experienced by us or by our vendors,

contractors, or organizations with which we have formed strategic relationships. Although, to our knowledge, we have not experienced any such material security breach to date, any ~~72such~~ -- **such** breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disruption of our operations, delays in our regulatory approval efforts, damage to our reputation, costs to recover or reproduce the data and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. If any security breach or other incident, whether actual or perceived, were to occur, it could impact our reputation and / or operations, cause us to incur significant costs and liabilities, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture ~~Buntanetap~~ **buntanetap , or Posiphen Form B** , and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security breach affects our systems (or those of our third- party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of ~~Buntanetap~~ **buntanetap , Posiphen Form B,** or any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities. In addition, a security failure could result in violations of applicable privacy and other laws. If this information is inappropriately accessed and used by a third party or a team member for illegal purposes, such as identity theft, we may be responsible to the affected individuals for any losses they may have incurred as a result of misappropriation. In such an instance, we may also be subject to regulatory action, investigation or liable to a governmental authority for fines or penalties associated with a lapse in the integrity and security of our team members' or patients' information. We may be required to expend significant capital and other resources to protect against and remedy any potential or existing security breaches and their consequences. In addition, our remediation efforts may not be successful **,** and we may not have adequate insurance to cover these losses. Security breaches could also significantly damage our brand and our reputation with existing and prospective clients and third parties with whom we do business. Any publicized security problems affecting our businesses and / or those of such third parties may negatively impact the market perception of our products and discourage third parties from doing business with us. Risks Related to Our Employees, Managing Our Growth and Our OperationsOur future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel. We are highly dependent on the development, regulatory, commercialization and business development expertise of Maria L. Maccecchini, PhD, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and 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 successfully develop product candidates, gain regulatory approval, and commercialize new products. 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. ~~Other~~ **68Other** pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may ~~73experience~~ -- **experience** constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We expect to expand our development, regulatory, and sales and marketing capabilities, 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 our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the

percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day- to- day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. We may seek to enter into collaborations, license agreements and other similar arrangements in the future, and may not be successful in doing so. We may seek to enter into collaborations, joint ventures, licensing arrangements or other similar arrangements with third parties for the development or commercialization of ~~Buntanetap~~ **buntanetap** and any future product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. These relationships or those like them may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish or maintain a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate ~~them~~ **69them** with our existing operations and company culture. In addition, 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 revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, ~~74we~~ **we** will achieve the revenues or specific net income that justifies such transaction. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. Collaborations involving ~~Buntanetap~~ **buntanetap** or any future product candidates would pose significant risks to us, 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 or at all ; ● we could grant exclusive rights to our collaborators that would prevent us from collaborating with others ; ● collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval 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 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours ; ● product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates ; ● a collaborator with marketing and distribution rights to any product candidate that achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such products ; ● a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings ; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in 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 enforce, maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation ; **70** ● collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability ; ● collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, ~~75accurately~~ **accurately** forecast financial results or provide timely information to our stockholders regarding our out- licensed product candidates ; ● we may be required to invest resources and attention into such collaboration, which could distract from other business objectives ; ●

disputes may arise between the collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations ; ● collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all ; ● if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated ; and ● collaborations may be terminated, including for the convenience of the collaborator, prior to or upon the expiration of the agreed upon terms and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to ~~Buntanetap~~ **buntanetap** or any future product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and **future commercial** prospects. Our business and operations would suffer in the event of failures involving our information technology systems, or those of any of our service providers. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), team member misconduct, human error, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of ~~Buntanetap~~ **buntanetap** or any other product candidate could be delayed. It is not possible to prevent all threats or to our information technology systems and information and those of our third- party service providers, over which we exert less control, and any controls we implement to do so may prove to be ineffective. Disruption, failure or cybersecurity breaches affecting or targeting computers and infrastructure used by us or our business partners may adversely impact our business and operations. We use computers and telecommunication systems to analyze and store financial and operating data and to communicate within our company, with outside business partners, and across international borders. These systems can be subject to technical system flaws; power loss; cyber attacks, including viruses, malware, phishing, ransomware, terrorism, and surveillance **;,** unauthorized access **;,** malicious software **;,** intentional or inadvertent data privacy breaches by employees or others with authorized access **;,** hacktivism **;,** ransomware **;,** physical or electronic break- ins **;,** fires or natural disasters **;,** supply chain attacks **;,** and other cybersecurity issues. We have no assurance that our systems are appropriately redundant to withstand these events. Accordingly, such events could cause adverse ~~effects~~ **71effects** and material disruptions to our operations or systems or those of our business partners; compromise the security, integrity, availability, and confidentiality of customer information, employee information, strategic projects, product formulas and other trade secrets, other business or personal sensitive data, including third party confidential information in our possession. Release of third party confidential information could materially harm our reputation, affect our relationships with such parties and expose us to liability. Although we have introduced many security measures, including firewalls and information technology security policies and training, these measures may not offer the appropriate level of security. A security breach or other compromise of our information ~~76security~~ **security** safeguards could expose our confidential information, including third party confidential information in our possession (such as customer information) to theft and misuse, which could in turn adversely affect our relationships with such third parties and have an adverse effect on our business, financial condition, results of operations and cash runway. The cash and cash equivalents that we use to meet our working capital and operating expense needs are held in deposit accounts at two financial institutions. If one or both financial institutions fail, our deposit accounts could be adversely affected due to the loss of or delay in obtaining access to all or a portion of our uninsured funds. The cash and cash equivalents that we use to meet our working capital and operating expense needs are held in deposit accounts at two financial institutions. The balance held in these accounts regularly exceeds the Federal Deposit Insurance Corporation (" FDIC "), standard deposit insurance limit or similar government guarantee schemes. If one or both of the financial institutions in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. For example, on March 10, 2023, Silicon Valley Bank (" SVB ") and Signature Bank, were closed by state regulators and the FDIC was appointed as the receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the U. S. Department of the Treasury, the Federal Reserve and the FDIC. If one or both of the financial institutions in which we hold our funds for working capital and operating expense needs were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner. Risks Related to Our Common StockThe market price of our common stock has been volatile and fluctuated substantially in the past and may continue to experience volatility and substantial fluctuations in the future, which could result in substantial losses for purchasers of our common stock. The market price of our common stock is highly volatile. For example, from ~~August~~ **July** 1, ~~2023~~ **2024** to ~~March~~ **February** 28, ~~2024~~ **2025**, the ~~sale~~ **closing** price of our common stock on the New York Stock Exchange ranged from as low as $ ~~5~~ **1**. ~~42~~ **74** to as high as $ ~~22~~ **15**. ~~49~~ **46** and daily trading volume ranged from ~~7~~ **67**, 300 shares to ~~2~~ **40**, ~~141~~ **734**, ~~300~~ **200** shares. The market price of our common stock may be subject to wide fluctuations in response to a variety of factors, including the following: ● results of our clinical trials, and the results of trials of our competitors or those of other companies in our market sector ; ● our ability to enroll subjects in our future clinical trials ; ● delays or unanticipated developments in the completion of our planned clinical trials; ● any delay in submitting an NDA and

any adverse development or perceived adverse development with respect to the FDA' s review of that NDA; ● our ability to obtain and maintain regulatory approval of ~~Buntanetap~~ **buntanetap** or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process ; ● failure to successfully develop and commercialize ~~Buntanetap~~ **buntanetap** or any future product candidates; **72** ● the degree and rate of physician and market adoption of any of our current and future product candidates ; ● inability to obtain additional funding or obtaining funding on unattractive terms; ~~77~~ ● regulatory or legal developments in the United States and other countries applicable to ~~Buntanetap~~ **buntanetap** or any other product candidates; ● adverse regulatory decisions; ● changes in the structure of healthcare payment systems; ● manufacturing, supply or distribution delays or shortages, including our inability to obtain adequate product supply for ~~Buntanetap~~ **buntanetap** or any other product candidates, or the inability to do so at acceptable prices; ● the success or failure of our efforts to identify, develop, acquire or license additional product candidates ; ● introduction of new products, services or technologies by our competitors; ● failure to meet or exceed financial projections we provide to the public; ● failure to meet or exceed the estimates and projections of the investment community; ● changes in the market valuations of companies similar to ours; ● market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations; ● announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; ● any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners ; ● significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● additions or departures of key scientific or management personnel; ● sales of our common stock by us or our stockholders in the future; ● changes in our capital structure, such as future issuances of securities and the incurrence of additional debt ; ● changes in accounting standards, policies, guidelines, interpretations or principles; ● trading volume of our common stock; ● actual or anticipated fluctuations in our financial condition and results of operations ; ● publication of news releases by other companies in our industry, and especially direct competitors, including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls ; **73** ● announcement or progression of geopolitical events (including in relation to the conflict between Russia and Ukraine **or Isreal and Hamas**) ; and ● the other factors described in this " Risk Factors " section. ~~78In~~ **In** addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock may decline, and our stockholders may lose some or all of their investment. Our failure to meet the New York Stock Exchange' s continued listing requirements could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of the New York Stock Exchange, such as the corporate governance requirements **, market capitalization** or the minimum closing bid price requirement, the New York Stock Exchange may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non- compliance with the listing requirements of the New York Stock Exchange. We have been subject to securities class action litigation in the past and could be subject to such litigation in the future. In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. During the year ended December 31, 2021, two securities class action complaints were filed against us and our executive officers following disclosure of interim results from the AD / PD Trials. Both complaints were voluntarily dismissed without prejudice by the plaintiffs. If we again face such litigation in the future, it could result in substantial costs, a diversion of management' s attention and resources, and damage to our reputation, which could have a material adverse effect on our business, financial condition and results of operations and prospects. Our directors, executive officers and certain stockholders own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant control over matters subject to stockholder approval. Our directors, executive officers, and stockholders affiliated with our directors and executive officers own ~~25~~ **14** . ~~6~~ **3** % of the current voting power of our outstanding common stock. Therefore, acting together, they have the ability to substantially influence all matters submitted to our board of directors or stockholders for approval. For example, these holders may be able to control the appointment of our management, elections and removal of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which our stockholders may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. So long as they continue to own a significant amount of our equity, these holders will be able to strongly influence or effectively control our decisions. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common

stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to ~~regularly~~ **74regularly** publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. ~~79Because --~~ **Because** we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock would be our stockholders' sole source of gain on an investment in our common stock for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. See " Dividend Policy " for additional information. We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses. The Sarbanes- Oxley Act of 2002 (" SOX "), the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the New York Stock Exchange, and other applicable securities rules and regulations impose various requirements on U. S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of SOX, we are required to furnish a report by our senior management on our internal control over financial reporting. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with Section 404, we are required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan 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 maintain a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We have had a material weakness in our internal control over financial reporting in the past, and cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NYSE, SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We are an " emerging growth company, " and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act (" JOBS Act "). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are ~~applicable~~ **75applicable** to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute ~~80payments --~~ **payments** not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering (" IPO ") on January 31, 2020, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of our prior second fiscal quarter, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our restated

certificate of incorporation and our amended and restated bylaws that became effective upon the closing of our IPO may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing advance notice bylaw provisions for proposals from stockholders for presentation at annual meetings and forum selection bylaw provisions. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our restated certificate of incorporation that became effective upon the closing of our IPO specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. Our bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders with respect to our company and our directors. This choice of forum provision may limit a stockholder' s ability to bring a claim in a **76** ~~judicial forum that the stockholder believes is favorable for disputes with us or our directors, which may discourage meritorious claims from being asserted against us and our directors. Alternatively, if a court were to find this provision of our charter inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs~~ 81