Risk Factors Comparison 2025-03-20 to 2024-03-21 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report, including our consolidated financial statements and their related notes included elsewhere in this Annual Report and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " before making an investment decision. If any of the following risks actually occurs, our business, prospects, operating results, and financial condition could suffer materially, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results, and financial condition. Summary of Selected Risk Factors Associated with Our Business Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in this " Risk Factors " section, including the following: • We are a clinical- stage biopharmaceutical company with a limited operating history and no history of commercializing products and have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability. • Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates. • We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts. • We rely heavily on the biomarker data gathered from our Platform. We currently anticipate that certain of our therapeutic product candidates will require us to develop and obtain FDA approval of a companion diagnostic for such therapeutic product candidates. We expect to initiate discussions with the FDA concerning the development of companion diagnostics at our end of Phase 2 meetings with respect to ALTO- 100 and ALTO- 300. If the FDA does not agree with our biomarker- based approach, or if we are unable to successfully develop and obtain regulatory approval for certain companion diagnostic tools needed to leverage our Platform, or experience significant delays in doing so, our business will be materially harmed. • Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time- consuming, and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of our product candidates, and additional time may be required to obtain marketing authorization for any of our product candidates that we develop as drug / device combination products. • Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, **third- party payors** and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable. • The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue. • Our business depends on the success of our product candidates. If we are ultimately unable to successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. • We rely on, and intend to continue to rely on, our internal clinical development expertise to conduct our current and future clinical trials, including internal teams and systems as well as external vendors and CROs. If our team is unable to execute according to our strategy, comply with regulatory requirements, or run trials effectively, our ability to obtain regulatory approval may be delayed and our business could be materially harmed. • The terms of our **Amended** Loan **Agreement and the Convertible Grant** Agreement place restrictions on our operating and financial flexibility and may cause dilution to our stockholders. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business or result in further dilution to investors in our common stock. • Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our current products may be adversely affected. • We are dependent on the services of our management and other clinical and scientific personnel, including our internal clinical operations team, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer. • If we are unable to obtain and maintain sufficient intellectual property protection for our Platform, technologies, and product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected. Further, our issued composition of matter patents covering our pharmaceutical product candidates may expire at such a date that our patents may not prevent competitors from developing, making, and marketing a product that is identical to our product candidates after expiration of any applicable regulatory exclusivities. For example, our composition of matter patents ~~in~~ **covering** ALTO- 100 ~~are due to expire~~ **expired** ~~in 2024~~ and patents covering its method of manufacturing are due to expire in 2030 ~~,~~ **;** our **composition of matter patents in ALTO- 202 (compound) expired (in foreign countries) and are due to expire in 2026 (in the United States), and our polymorph** composition of matter

patents in ALTO- 202 are due to expire in ~~2024 (compound) and~~ 2035 **;** ~~(polymorph),~~ and our composition of matter patents in ALTO- 203 are due to expire in 2027, in all cases without taking into account patent term extensions or adjustments, and assuming payment of all applicable maintenance, renewal, and annuity fees. • Our rights to develop and commercialize our product candidates, our Platform, or other technologies are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Stanford, Sanofi, and MedRx. The terms of these licenses may be inadequate to protect our competitive position on products or product candidates for a sufficient amount of time. For example, our patent rights under the terms of our exclusive license agreement with Stanford are only exclusive until December 2029, at which time such rights will become nonexclusive, and our rights under certain technology relating to the inventions covered by such patents are ~~non- exclusive~~ **nonexclusive** . Further, if we fail to comply with our obligations in the agreements under which we in- license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business. • Patent terms may be inadequate to protect our competitive position on products or product candidates for a sufficient amount of time. • We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates. Risks Related to Our Limited Operating History, Financial Position, and Need for Capital We are a clinical- stage biopharmaceutical company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of product candidates and the prospects for our future viability. We are a clinical- stage biopharmaceutical company with a limited operating history. We were formed in 2019 and our operations to date have been limited to organizing, staffing, and financing our company, in- licensing our technology, and conducting research and development activities, including developing our Platform, conducting clinical trials for our product candidates, and establishing our intellectual product portfolio. If we are successful in achieving regulatory approval for our product candidates, we will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. Our approach to the discovery and development of product candidates based on our Platform is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. Moreover, as an organization, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization, or generate revenues. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical- stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable, have incurred substantial losses in each period since our inception, and we expect to incur significant losses for the foreseeable future. For the years ended December 31, **2024, and** 2023 **,** ~~and 2022~~ our net losses were approximately $ **61. 4 million and $** 36. 3 million ~~and $ 27. 7 million~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of approximately $ ~~77~~ **138** . ~~0~~ **4** million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and Platform, research and development, and clinical trial costs, and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates. We anticipate that our expenses will increase substantially if, and as, we: • conduct further clinical trials for ALTO- 100, ALTO- 300, ALTO- 101, ALTO- 203, ALTO- 202, and advance our preclinical programs into the clinic; • identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials; • procure the manufacturing of preclinical, clinical, and commercial supply of our current and future product candidates; • seek regulatory approvals for our **current** product candidates or any future product candidates; • commercialize our current product candidates or any future product candidates, if approved; • take steps toward our goal of being an integrated biopharmaceutical company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure; • attract, hire, and retain qualified clinical, scientific, operations, and management personnel; • add and maintain operational, financial, and information management systems; • protect, maintain, enforce, and defend our rights in our intellectual property portfolio; • defend against third- party interference, infringement, and other intellectual property claims, if any; • address any competing therapies and market developments; • experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates due to macroeconomic conditions, geopolitical conflicts, or other global events ~~, including residual effects of the COVID- 19 pandemic~~ ; and • incur additional costs, including legal, accounting, and other expenses, associated with operating as a public company. We have no product candidates approved for commercial sale and have not generated any revenue from the sale of products. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, one of our product candidates for our initial and potential additional indications, or any other product candidates we may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing approval for these product

candidates, manufacturing, marketing, and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post- marketing requirements, and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses, or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the FDA or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings, or continue our operations. If we continue to suffer losses as we have in the past, you may not receive any return on your investment and may lose your entire investment. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies, and clinical trials of our current and future product candidates, to seek regulatory approvals for our **current** product candidates, and to launch and commercialize any products if we receive regulatory approval. As of December 31, ~~2023~~ **2024**, we had $ ~~82~~ **168**. ~~5~~ **7** million of cash ~~and ,~~ cash equivalents **and restricted cash**. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of the date of filing of this ~~Annual~~ **Quarterly** Report ~~, including funds raised from the IPO~~, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our programs and product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including: • the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current or future product candidates; • the number of clinical trials required for regulatory approval of our current or future product candidates; • the costs, timing, and outcome of regulatory review of any of our current or future product candidates; • the costs associated with acquiring or licensing additional product candidates, technologies, or assets, including the timing and amount of any milestones, royalties, or other payments due in connection with our acquisitions and licenses; • the cost of manufacturing clinical and commercial supplies of our current or future product candidates; • the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property- related claims, including any claims by third parties that we are infringing upon their intellectual property rights; • the effectiveness of our Platform in identifying target patient populations and utilizing our approach to enrich our patient population in our clinical trials; • our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement; • the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; • expenses to attract, hire, and retain skilled personnel; • the costs of operating as a public company; • our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third- party and government payors; • our ability to mitigate the impact of adverse macroeconomic conditions or **other** geopolitical events ~~, including the residual effects of the COVID- 19 pandemic~~, the ongoing conflicts between Ukraine and Russia and in the Middle East, ~~recent bank failures~~ **geopolitical tensions in China**, inflation ~~and increased~~ **, fluctuating** interest rates **, tariffs**, or other factors on our preclinical and clinical development or operations; • the effect of competing technological and market developments; and • the extent to which we acquire or invest in business, products, and technologies. We will require substantial additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long- term business strategy. Market volatility resulting from adverse macroeconomic conditions or geopolitical events, including the ongoing conflicts between Ukraine and Russia and in the Middle East, ~~recent bank failures~~ **geopolitical tensions in China**, inflation ~~and increased~~ **, fluctuating** interest rates **, proposed tariffs**, or other factors may further adversely impact our ability to access capital as and when needed. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future 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, selling or licensing our assets, making capital expenditures, declaring dividends, or encumbering our assets to secure future indebtedness. Such restrictions

could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional funds through future collaborations, licenses, and other similar arrangements, we may have to relinquish valuable rights to our 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 or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The obligations from our license and asset acquisition agreements may cause dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations. Under the terms of certain of our license and acquisition agreements, the counterparties to such agreements are entitled to substantial contingent payments upon the occurrence of certain events. For example, under the terms of our license agreement with Sanofi, we will be required to pay Sanofi up to an aggregate amount in the low- mid double digit millions upon the achievement of certain one- time development and regulatory approval milestones with respect to ALTO- 101, and, if regulatory approval is achieved, up to an aggregate amount of $ 102. 0 million in commercial milestone payments and a tiered royalty on aggregate annual worldwide net sales at percentages ranging from the mid- to- high single digits. Under the terms of our license agreement with Cerecor, we will be required to pay Cerecor or Merck, depending on the milestone, up to an aggregate of $ 59. 1 million if we achieve certain development, regulatory, and first commercial sale milestones for ALTO- 202. If we successfully commercialize ALTO- 202, we will be required to pay Merck sales milestones in an amount of up to $ 15. 0 million. Beginning on the date of our first commercial sale of ALTO- 202, we will also be obligated to pay Merck and Cerecor tiered royalties on aggregate annual worldwide net sales at percentages in the high single digits, in addition to potential payments in respect of a companion diagnostic product. Pursuant to our asset purchase agreement with Teva, pursuant to which we acquired the rights to ALTO- 203, we may be required to pay up to an aggregate of $ 27. 0 million upon the achievement of certain development and regulatory approval milestones **($ 0. 5 million of which was paid to Teva in connection with the initiation of our Phase 2 POC trial evaluating ALTO- 203)** , and up to $ 35. 0 million for the achievement of certain tiered sales milestones, as well as tiered royalties on worldwide annual net sales at percentages ranging from the mid- single- digit to ten percent. Pursuant to our joint development and license agreement with MedRx, we are required to pay MedRx up to an aggregate of $ 11. 0 million for the achievement of certain development and first commercial sale milestones for ALTO- 101 with respect to a first indication, an additional milestone in the mid single digit millions for each additional approved distinct indication for ALTO- 101, as well as sales milestones based on the achievement of specified levels of aggregate annual worldwide net sales of up to $ 110. 0 million in the aggregate and a mid- single digit royalty on annual, worldwide net sales. **In April 2024, we achieved a milestone under the MedRx Agreement and paid MedRx approximately $ 0. 8 million in cash and issued MedRx 46, 875 shares of our common stock.** If we achieve certain development and regulatory approval milestones for a product that contains ALTO- 100 or is otherwise derived from assets we acquired from Palisade we will be required to pay Palisade up to an aggregate of $ 4. 5 million. See ~~the section titled~~ " ~~Business~~ **Item 7. Management' s Discussion and Analysis of Financial Condition and Results of Operations** — ~~License~~ **Liquidity** and ~~Other Agreements~~ **Capital Resources — Contractual Obligations and Commitments** " ~~elsewhere~~ in this Annual Report for additional information regarding these agreements. In order to satisfy our obligations to make these payments, if and when they are triggered, we may need to issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash and cash equivalents or incur debt obligations to satisfy the payment obligations in cash, which may adversely affect our financial position. In addition, these obligations may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third- party line of credit. Risks Related to Product Candidate Development and Commercialization All of our product candidates are in preclinical or clinical development and their risk of failure is high. In particular, our approach to utilizing our Platform to identify biomarkers and conducting clinical trials in patient populations expressing certain biomarkers has not been validated and may not prove to be successful. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in patient populations identified by our Platform for the relevant indication. Preclinical and clinical testing can take many years to complete, and its outcome is inherently uncertain. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the preclinical study or clinical trial process, despite promising preclinical or clinical results. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials, and results in one indication may not be predictive of results to be expected for the same product candidate in another indication **. For example, in October 2024, we reported that our Phase 2b trial of ALTO- 100 in patients with MDD did not meet its primary endpoint** . Differences in trial design between early- stage clinical trials and later- stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Certain of our product candidates were previously subject to all- comer population studies and were not progressed for further development or did not achieve statistically significant outcomes. For example, ALTO- 100 demonstrated numerical improvements in MADRS scores but did not achieve statistically significant outcomes in a prior all- comer population study. There can be no assurance that our results to date for these product candidates in our biomarker- characterized patient populations will continue or that the results of our trials will continue to differ from the outcomes of prior all- comer studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates achieved promising results have nonetheless failed to obtain marketing approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. In addition, our approach of identifying biomarkers and conducting

clinical trials in patient populations expressing those biomarkers is unique, unproven, and does not have significant precedent with the FDA and the FDA has, thus far, not affirmatively adopted our approach. Commencing any future clinical trials is subject to finalizing the trial protocol and submitting an IND to the FDA or similar application to initiate a clinical study to a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials, which may lead to delays and increase the costs of our preclinical development programs. The FDA also has the authority to require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, could have a significant impact on our ability to obtain approval of any product candidates. Similar decisions may also be made by foreign regulatory authorities and have similar impact. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates. We expect to continue to rely on our clinical trial sites and clinical trial teams to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. In addition, we may in the future enter into collaboration agreements pursuant to which our collaborator would be responsible for clinical development. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including: • regulators, such as the FDA or comparable foreign regulatory agencies, Institutional Review Boards, or IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or regulators may disagree as to the design or implementation of our clinical trials and require that we modify or amend our clinical trial protocols; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms with clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites; • delays in identifying, recruiting, and training suitable clinical investigators; • IRBs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; • changes or amendments to the clinical trial protocol; • clinical trial sites may deviate from the trial protocol or drop out of a trial; • failure by any of our third-party contractors to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries; • the number of participants required for clinical trials may be larger than we anticipate, we may experience difficulty in finding and enrolling sufficient qualified patients for our biomarker- guided trials, enrollment in clinical trials may be slower than we anticipate, or participants may drop out or fail to return for post- treatment follow- up at a higher rate than we anticipate; • subjects may fail to enroll or remain in our trials at the rate we expect, or fail to return for post- treatment follow-up, including subjects failing to remain in our trials due to movement; • patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials; • the cost of clinical trials may be greater than we anticipate; • the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial; • we may experience difficulties in manufacturing, or fail to manufacture, sufficient quantities of our product candidates for use in clinical trials; • we may experience delays in developing and validating our companion diagnostics to be used in a clinical trial, if applicable; • subjects experiencing severe or serious unexpected drug- related adverse effects; • reports from clinical testing conducted by other companies of other therapies in the same class of agents that could be considered similar to our product candidates may raise safety, tolerability, or efficacy concerns about our product candidates; • we may lack adequate funding to initiate or continue one or more of our clinical trials; • selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data; • a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or cross- contaminations of product candidates in the manufacturing process; • changes to our manufacturing processes may be necessary or desired; • third-party clinical investigators may lose the licenses or permits necessary to perform our clinical trials and may fail to perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements; • third- party contractors being unwilling or unable to satisfy their contractual obligations to us in a timely or accurate manner; • third- party contractors could ~~become~~ **be** debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and • clinical trials of our product candidates may fail to show appropriate safety, tolerability, or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations, and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA or comparable foreign regulatory authorities, or the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, adverse findings from inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to establish or

achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial. ~~Clinical trials may also be delayed or~~ **For** ~~terminated as~~ **example, recently the FDA informed us of** a ~~result~~ **partial clinical hold related to a limit on the exposure level** of ~~ambiguous~~ **ALTO- 101 in** ~~or~~ **our** ~~negative interim results~~ **ongoing Phase 2 POC trial, which we subsequently resolved by amending the dosing paradigm to evaluate broader exposure levels of ALTO- 101** . Many of the factors that cause, or lead to, a delay in the commencement or completion of, or the termination or suspension of, clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. We currently conduct preclinical testing of our patch formulation drug / device combination product candidate with our collaborator MedRx and may in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical, and biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties, and may increase our future costs and expenses. In addition, certain of our primary or secondary endpoints in our clinical trials, including our currently ongoing Phase 2b clinical trials of ALTO- 100 **in patients with bipolar depression** and ALTO- 300 **, our currently ongoing Phase 2 clinical trial of ALTO- 101 in patients with CIAS, and our currently ongoing Phase 2 clinical trial of ALTO- 203** in patients with MDD, involve subjective assessments by physicians and / or patients, which can increase the uncertainty of clinical trial outcomes. For example, primary endpoints include the change in MADRS score from baseline to week six, which requires patients or examiners to undertake a questionnaire regarding ten symptoms at the beginning and end of the trial. This and other assessments are inherently subjective, which can increase the variability of clinical results across clinical trials and create a significant degree of uncertainty in determining overall clinical benefit **. Such subjectivity may cause the indications we study to be more difficult to evaluate than indications for which clinical trials are structured with more objective endpoints, as such indications are often subject to high placebo effect which may make it more challenging to isolate the beneficial effects of our product candidates** . Accordingly, these subjective assessments can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement, and generally adversely impact a clinical development program by introducing additional uncertainties. Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations, and prospects. We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Patient enrollment is a significant factor in the timing of clinical trials, and 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. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials to such trial' s conclusion as required by the FDA or comparable foreign regulatory authorities. Subject enrollment is affected by many factors including the size and nature of the patient population, competing clinical trials in the same or similar indications or at the same trial site, the severity of the disease or condition under investigation, the availability and efficacy of approved drugs and diagnostics for the disease or condition under investigation, the number and location of clinical sites, the proximity of patients to clinical sites, willingness of patients to participate in a decentralized clinical trial, **should we conduct future trials in this manner,** the eligibility and exclusion criteria for the trial, perceived risks and benefits of the product candidate under study, the design of the clinical trial, continued enrollment of prospective patients by clinical trial sites, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for, or any product candidates under investigation for, the indications we are investigating. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Utilizing our Platform, we plan to focus our development activities on patients characterized by a biomarker that we believe will be most likely to respond to our product candidates. As a result, the potential patient populations for our clinical trials may be narrowed, and we may experience difficulties in identifying and enrolling a sufficient number of patients in 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 subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing subjects may prove costly. We have in the past and may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials, including participants in any control groups, may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials, and delays in enrollment may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development

of our product candidates. Additionally, participants with neuropsychiatric disorders, including MDD **, BPD,** and schizophrenia, constitute a vulnerable patient population and may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues relating to their underlying disease or condition or otherwise **. Further, subjects in MDD trials historically have been documented to show varying levels of medication compliance in such trials. If subjects are not compliant within a trial, the outcome of such trial may not properly reflect the actual effect of the relevant product candidate** . Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from similar patient populations, which may make it more difficult to fully enroll any clinical trials. Our inability to enroll a sufficient 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. In addition, we expect to rely on clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines. Use of our product candidates could be associated with adverse side effects, adverse events, or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved product, or result in other significant negative consequences that could severely harm our business, prospects, operating results, and financial condition. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post- approval requirements. Any treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly. If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, we may need to interrupt, delay, or abandon their development or limit 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. Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. If such significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition, and prospects. Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals, or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences associated with adverse events include: • we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace; • regulatory authorities may withdraw or change their approvals of a product; • regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; • we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post- marketing studies; • we may be required to change the way a product is administered; • we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and • a product may become less competitive, and our reputation may suffer. In addition, participants with neuropsychiatric disorders, including MDD **, BPD,** and schizophrenia, constitute a vulnerable patient population and any adverse side effects or adverse events may be exacerbated in such patient population. Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities. We rely heavily on the biomarker data gathered from our Platform. We currently anticipate that certain of our therapeutic product candidates will require us to develop and obtain FDA approval of a companion diagnostic for such therapeutic product candidates. If the FDA does not agree with our approach, or if we are unable to successfully develop and obtain regulatory approval for certain companion diagnostic tools needed to leverage our Platform, or experience significant delays in doing so, our business will be materially harmed. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, along with the companion diagnostic tools needed to leverage our Platform. Our development programs contemplate the use of our Platform, which uses machine learning to identify appropriate patient populations. Our Platform measures biomarkers by analyzing factors such as brain activity patterns detected via EEG readings, cognitive assessment

scores, and sleep structure and circadian rhythms captured by wearable data. Analyzing a broad range of biomarkers allows our scientists to develop a comprehensive understanding of the underlying mechanisms of mental health conditions, and target these accordingly. Companion diagnostics, which come in many forms, are the tests needed to identify these biomarkers and, thus, identify an appropriate patient population for our product candidates. The process of obtaining or creating such diagnostic is time consuming and costly. Absent an exemption, these companion diagnostics will be subject to regulation and marketing approval or clearance as medical devices by the FDA and comparable foreign regulatory authorities before we may commercialize our product candidates. In the United States, the laws and regulations governing the marketing of companion diagnostics are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. We currently anticipate that certain of our therapeutic product candidates will require us to develop and obtain FDA approval of a companion diagnostic for such therapeutic product candidates. This includes certain software applications, such as software that we are developing to identify biomarkers, that may meet the definition of a medical device and be subject to FDA premarket authorization, depending on its classification and software function. The approval or clearance of the therapeutic with a labeled limitation on use in only those patients who receive certain results using a companion diagnostic will limit the marketing of the product candidate, if approved, to only those patients who express the biomarker detected by the companion diagnostic. We expect to initiate discussions with the FDA concerning the development of companion diagnostics at our end of Phase 2 meetings with respect to ALTO- 100 and ALTO- 300. See ~~the section titled~~ “ **Item 1.** Business — Government Regulation — FDA Regulation of Companion Diagnostics and Clinical Decision Support Software ~~.~~ ” **in this Annual Report.** Moreover, even if data from early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and / or third- party collaborators may encounter difficulties in developing, obtaining regulatory approval or clearance for, manufacturing, and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving marketing authorization, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we or any third parties we may engage are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so: • we may be unable to identify appropriate patients for enrollment in our clinical trials, which may adversely affect the development of our product candidates; • our product candidates may not receive marketing approval if the FDA or other regulators determine that the safe and effective use of our product candidates, if any, depends on the companion diagnostic; and • we may not realize the full commercial potential of any therapeutics that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines, if any. If we are unable to develop and obtain regulatory approval or clearance for the companion diagnostic tools needed to leverage our Platform, our business, financial condition, results of operations, and prospects could be materially and adversely affected. Our approach to the discovery and development of precision medicines based on our Platform is unproven, and we do not know whether we will be able to develop any therapeutics or companion diagnostics of commercial value, or if competing technological approaches will limit the commercial value of our product candidates and Platform. We have concentrated our research and development efforts on the application of precision medicine to the diagnosis and treatment of psychiatric disorders, including MDD **, BPD,** and schizophrenia, and our future success depends on the discovery of biomarkers through our Platform and the continued development of this Platform. However, neither we nor any other company has received regulatory approval to market therapeutics targeting specific subpopulations of patients with psychiatric disorders based on biomarker identification. The success of our business depends primarily upon our ability to identify, develop, and commercialize precision medicine products based on our Platform, which leverages a novel and unproven approach of applying data analytics and machine learning to the thousands of samples available to us through data collected from both our trials and third party trials. We have not yet succeeded and may not succeed in demonstrating efficacy for any product candidates in clinical trials **(e. g., we reported negative topline results in October 2024 with regard to our Phase 2b trial of ALTO- 100 in MDD)** or in obtaining marketing approval thereafter. Our research methodology and novel approach to precision medicine for MDD **, BPD, and** ~~(or other indications such as~~ schizophrenia ~~)~~ may be unsuccessful in identifying biomarkers that lead to effective selection of a specific subpopulation of patients for whom a product candidate would be effective. Further, even if we successfully identify biomarkers that can be used to identify a specific subpopulation of patients for whom a product candidate would be effective, we may not be able to test potential patients for biomarkers on a commercial scale. Additionally, the FDA may not agree with our biomarker- based approach, which would present additional risks to the potential for successful development. Moreover, because all of our product candidates and development programs utilize our Platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs. In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position for our Platform, which relies on our ability to establish predictive biomarkers and segment patients into biomarker- characterized populations corresponding to product candidates in our pipeline. If our Platform is compromised, it may materially and adversely affect our ability to create and develop product candidates and identify biomarkers, and compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our product candidates and identified biomarkers, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. We have never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining, or fail to obtain, regulatory approval for our product candidates. We have never obtained regulatory approval for, or commercialized, a drug. Our clinical trial results may not

support regulatory approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or the use of biomarkers to identify patient populations who will benefit from our product candidates; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications; • negative or ambiguous results from our clinical trials, or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country; • serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • 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 sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; • such authorities may disagree with us regarding the formulation, labeling, and / or the product specifications of our product candidates; • approval may be granted only for indications that are significantly more limited than those sought by us, and / or may include significant restrictions on distribution and use; • additional time may be required to obtain marketing authorization for any of our product candidates that are regulated as a drug / device combination product; • such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; and • the FDA or comparable foreign regulatory authorities may find deficiencies in or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies. In addition, the product candidate we are developing as ALTO- 300 is already an approved antidepressant in Europe and Australia with the International Nonproprietary Name agomelatine. While we are developing ALTO- 300 solely in the United States, if there is a recall, safety concern, or adverse regulatory action with respect to agomelatine in Europe or Australia, it could adversely affect our ability to obtain regulatory approval for ALTO- 300 in the United States. Finally, the FDA and comparable foreign regulatory authorities may change their approval policies and new regulations may be enacted, which could delay or prevent our ability to obtain approval. If any of our product candidates fail to achieve regulatory approval due to the above factors, or otherwise, any such failure would adversely affect our business, results of operations, and financial condition. In addition, difficulties in obtaining approval of a product candidate in any of the initial indications for which we are developing it could adversely affect our efforts to seek approval from regulatory authorities for other indications. Additional time may be required to obtain marketing authorizations for any of our product candidates that we develop as drug / device combination products. We are developing one of our product candidates, ALTO- 101, as a drug / device combination product candidate. While we have not had conversations to date with the FDA regarding whether ALTO- 101 would be regulated as a combination product, we anticipate that, if successfully developed, ALTO- 101 would be regulated as a combination product by the FDA and other regulatory authorities. Combination products require coordination within the FDA and within comparable regulatory agencies for review of their drug and device components. For example, the FDA' s review of a marketing application for ALTO- 101 may include the participation of both the FDA' s Center for Drug Evaluation and Research and the FDA' s Center for Devices and Radiological Health. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying drug component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device which may delay the approval of the combination product. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time- consuming, and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of our product candidates. Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, import, export, marketing, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable foreign regulatory authorities. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals. Although we believe that we have the capabilities to conduct preclinical studies and clinical trials and complete these applications using our internal resources, we selectively employ and may in the future rely on third- party contract research organizations, or CROs, or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the

United States and abroad, is expensive, often takes many years following the commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved, as well as the target indications and patient populations. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Prior to obtaining approval to commercialize a product candidate in the U. S. or abroad, we must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may delay, limit, or deny approval of a product candidate for many reasons, or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods, and agreements with pricing authorities. Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and / or the implementation of REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates, including for other indications, may be harmed, and our ability to generate revenues will be materially impaired. Interim, " topline, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses 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 preclinical study or clinical trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. **For example, in February 2025, we reported the results of an interim analysis of our clinical trial of ALTO- 300 in MDD.** Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects **and may cause the trading price of our common stock to fluctuate significantly** . 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 program, the approvability or commercialization of the particular product candidate or product and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. 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, our product candidates may be harmed, which could harm our business, financial condition, results of operations, and prospects. Further, disclosure of interim, topline, or preliminary data by us or by our competitors could result in volatility in the price of our common stock. Furthermore, if we fail to replicate the positive results from our preclinical studies or clinical trials in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for, and commercialize our current or future product candidates. If we fail to develop and commercialize our current product candidates for additional indications or fail to discover, develop, and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. Although the development and commercialization of our current product candidates for the treatment of MDD **, BPD,** and schizophrenia are our primary focus, as part of our longer- term growth strategy, we plan to **potentially** evaluate our current product candidates in other indications ~~(such as bipolar disorder, Parkinson' s disease, and PTSD)~~ and develop other product candidates. We intend to evaluate internal opportunities from our current product candidates or other potential product candidates, and also may choose to in- license or acquire other product candidates as well as commercial products to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time- consuming development efforts prior to commercial sale, including preclinical studies, clinical trials, and approval by the FDA and / or comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products, if approved, will be manufactured or produced

economically, successfully commercialized, or widely accepted in the marketplace, or be more effective than other commercially available alternatives. 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: • the research methodology used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates obsolete; • product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights; • a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community, or third- party payors. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired. We may expend our resources to pursue a particular product candidate or indication and forgo the opportunity to capitalize on product candidates or indications that may ultimately be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. We may seek regulatory approval for our product candidates outside the United States. Foreign regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions also must approve the manufacturing, marketing, and promotion of the product candidate in those jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In some jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products also is subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive and maintain applicable marketing 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 our product candidates will be harmed, which could adversely affect our business, results of operations, and financial condition. We may conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business. We may conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, to accept data from a clinical trial that was conducted only at sites outside of the United States and not subject to an IND, the FDA requires such clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on- site inspection if the FDA deems such inspection necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. For studies not subject to an IND, the FDA generally does not review clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design, protocol, and / or results from a non- U. S. clinical trial were inadequate for the purposes we intend, which could require us to conduct additional clinical trials. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept data from our clinical trials of our product candidates, it may result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our therapeutic product candidates. Conducting clinical trials outside the United States also exposes us to additional risks, including

risks associated with: • additional foreign regulatory requirements; • foreign exchange fluctuations; • compliance with foreign manufacturing, customs, shipment, and storage requirements; • cultural differences in medical practice and clinical research; and • diminished protection of intellectual property in some countries. We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, testing for biomarkers and pairing biomarker identification with our product candidates may not gain acceptance among physicians, patients, third- party payors, and others in the medical community. If both our approach to precision psychiatry and product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable. Further, the number of patients with the relevant biomarkers that our product candidates are designed to treat may be smaller than expected. The degree of market acceptance of both our approach to precision psychiatry and our product candidates will depend on a number of factors, some of which are beyond our control, including: • the pricing and cost- effectiveness of our product candidates, as well as the ease of administration, time burden, and market acceptance of testing for biomarkers in relation to alternative treatments and therapies; • the safety, efficacy, and tolerability of our product candidates; • acceptance of our approach to precision psychiatry by patients, the medical community, and third- party payors; • changes in the standard of care for targeted indications and the reluctance of physicians to switch their patients' current standard of care; • the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products and the ability to test for identified biomarkers; • the clinical indications for which the products are approved and the approved claims that we may make for the products; • any restrictions on the use of our products, and the prevalence and severity of any adverse effects; • distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan; • the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid; • 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 extent and strength of our marketing and distribution of such product candidates; • the timing of market introduction of such product candidates, as well as competitive products; • our ability to offer our product candidates for sale at competitive prices; • adverse publicity about our product or favorable publicity about competitive products; and • potential product liability claims. In addition, the product candidate we are developing as ALTO- 300 is already an approved antidepressant in Europe and Australia with the International Nonproprietary Name agomelatine. While we are developing ALTO- 300 solely in the United States, if there is a recall, safety concern, or adverse regulatory action with respect to agomelatine in Europe or Australia, it could prevent us from achieving or maintaining market acceptance of ALTO- 300 or otherwise adversely affect our ability to successfully commercialize ALTO- 300 in the United States. Our efforts to educate the medical community and third- party payors as to the benefits of both our approach to precision psychiatry and our product candidates may require significant resources and may never be successful. Even if the medical community accepts the ability to test for identified biomarkers and that our products, if approved, are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment for the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third- party payors, we may not generate meaningful revenue from our product candidates and may never become profitable. The availability of coverage and the adequacy of 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 our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third- party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the **EU** ~~European Union~~ , or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that third- party payors may not see the benefit of using biomarkers to identify patient populations who will benefit from our product candidates. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop. There is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. Regulatory approvals, pricing, and reimbursement for new drug products vary widely from country to country. 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 will be covered. 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 products. Obtaining and maintaining reimbursement status is time consuming, costly, and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. **Thus, even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.** Some or all of our companion diagnostic tests may require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical products. If any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medicinal 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, if approved. 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. See " — ~~EU drug~~ **Drug** marketing and reimbursement regulations **in the EU** may materially affect our ability to market and receive coverage for our products in the EU member states " below for further discussion of risks related to foreign marketing and reimbursement regulations. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. Risks Related to Our Business and Operations We were founded with a mission to redefine neuropsychiatric drug development, a field that has seen very limited success. The ability to successfully develop drugs in this field is extremely difficult and is subject to a number of unique challenges. Drug development in the field of neuropsychiatry and CNS disorders has seen very limited success historically, with a 7. 3 % and 6. 2 % likelihood of approval from Phase 1 in psychiatry and neurology, respectively. Clinical success depends on a number of factors and employing a patient selection biomarker approach does not guarantee that our product candidates will be approved and commercialized. Developing a product candidate for treatment of CNS disorders is extremely difficult and subjects us to a number of unique challenges **. For example** , ~~including~~ **clinical trials focused on neuropsychiatric diseases rely on subjective patient- reported outcomes as key endpoints. This makes them more difficult to evaluate than indications with more objective endpoints. Furthermore, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. There can be no guarantee that we will successfully overcome these challenges in our ongoing or any future clinical trials of our product candidates or that we will not encounter other challenges in the development of our product candidates. Moreover,** obtaining regulatory approval from the FDA and other regulatory authorities who **only** have ~~only~~ a limited set of precedents to rely on **augments challenges in neuropsychiatric drug development** . We intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation in an effort to obtain regulatory approval for our product candidates; however, the process of developing our product candidates may be more complex and time- consuming relative to other more well- known approaches to drug development. We cannot be certain that our approach will lead to the development of product candidates that effectively and safely address CNS disorders. Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by us or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the market price of our common stock. We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development, and expect that we will continue to invest heavily in these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur. If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to: • scale our ability to test potential patients for biomarkers so that we can identify patients for whom we believe our product candidates would be effective; • demonstrate the superiority of pairing biomarker identification with our product candidates compared to the standard of care, as well as other therapies in development; • achieve market acceptance of our Platform by patients, the medical community, and third- party payors; • create market demand for our product candidates through our ~~own~~ marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish; • receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing; • price our products competitively such that third- party and government reimbursement permits broad product adoption; • effectively commercialize any of our products that may receive regulatory approval; • manufacture or otherwise have access to EEG testing mechanisms that can be used by physicians and patients to test for identified biomarkers; • manufacture product candidates through ~~contract manufacturing organizations, or~~ CMOs ~~,~~ in sufficient quantities and at acceptable quality and manufacturing

cost to meet commercial demand at launch and thereafter; • establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms; • obtain, maintain, protect, and enforce patent and other intellectual property protection and regulatory exclusivity for our products; • maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies; and • assure that our products, if approved, will be used as directed and that additional unexpected safety risks will not arise. We rely on, and intend to continue to rely on, our internal clinical development expertise to conduct our current and future clinical trials. This model includes internal teams and systems as well as external vendors and CROs to comprise a full clinical trial team. If our clinical trial team does not comply with applicable regulatory requirements, meet expected deadlines, or run trials effectively, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed. We conduct much of our clinical trial work (e. g., clinical and medical monitoring, data management, and project management) with internal personnel, though we selectively employ CROs when conducting our Phase 1 pharmacodynamic trials and use certain CRO and / or vendor services (e. g., biostatistics, pharmacovigilance, central raters, and rater training and remediation services) to augment our internal expertise. We also rely on our internal, proprietary systems for some data, Spectra, Altoscope, and TechCheck. See ~~the section titled~~ " **Item 1.** Business — Our ~~Differentiated Approach and Capabilities — Our Precision Psychiatry~~ Platform ~~— Computerized Neurocognitive Battery, " and " — EEG~~ . " Moreover, some of our trials **have included in the past, and may** include **in the future,** a decentralized clinical trial component supported by our internal personnel wherein clinical trial activity occurs in the participant' s home or at a local health care facility and includes virtual elements of care, exposing us to increased risk of variability and lack of control of the clinical trial. ~~See the section titled " Business — Our Differentiated Approach and Capabilities — Our Internal Clinical Development Expertise and Decentralized Clinical Trial Infrastructure. "~~ Although we believe that we have the capabilities to conduct clinical trials through our insourced model, we may need to rely on third party CROs to conduct clinical trials if our internal capabilities cannot scale as we work to progress our current product candidates through development, as we potentially expand our product candidate portfolio, or if we do not have sufficient **or applicable** personnel to support ~~our~~ **any future potential** decentralized clinical ~~trial~~ **trials** ~~model~~ . Moreover, without the use of an experienced CRO, our insourced team is responsible for the coordination of drug supply through various shipping vendors **,** ~~as well as~~ the supply of certain equipment (e. g., EEG devices) for our trials, and **the management of potential future decentralized clinical trials;** our failure to coordinate such matters in an effective and efficient manner could have a material adverse effect on our trials **, including our ability to execute upon any future potential decentralized clinical trials** . Our failure or the failure of any CROs we may employ to conduct the trials in compliance with FDA regulations could result in a delay or failure in obtaining FDA approval and could require us to repeat any preclinical studies or clinical trials we or the CRO administered. Our insourced personnel could fail to meet deadlines or run less effectively than a CRO, which could delay development of our product candidates and our ability to seek or obtain regulatory approval or marketing approval for our product candidates. Further, under our ~~insource~~ **insourced** model we presently contract directly with all of our clinical trial sites, and therefore have to negotiate budgets and contracts with each trial site, which may result in delays to our development timelines and increased costs. If any of our relationships with trial sites terminate, we may not be able to enter into arrangements with alternative trial sites or do so on commercially reasonable terms. Switching or adding additional trial sites can also involve additional costs and requires time and focus of our clinical trial operations management team. Additionally, if we ever transition to relying on a CRO to manage the conduct of any of our clinical trials, we will also have to negotiate budgets and contracts with such CRO, which may similarly lead to delays and increased costs. There is a natural transition period when a new CRO begins work which could result in delays that could materially impact our ability to meet our desired clinical development timelines. The terms of our **Amended** Loan **Agreement and our Convertible Grant** Agreement place restrictions on our operating and financial flexibility and may cause dilution to our stockholders. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business or result in further dilution to you. In December 2022, we entered into a loan and security agreement, or the **Original** Loan Agreement, with K2 HealthVentures, as a lender and the other lenders from time to time party thereto, or collectively, the Lender, K2 HealthVentures, as administrative agent for the Lender, and Ankura Trust Company, LLC, as collateral agent for the Lender. ~~The~~ **In January 2025, we entered into an amendment to this facility, or the Amendment (and collectively with the Original Loan Agreement, the Amended Loan Agreement), pursuant to which the** Lender has agreed to make available to us term loans in an aggregate principal amount of up to $ ~~35~~ **75** . 0 million ~~under the Loan Agreement~~ , including a $ ~~10~~ **20** . 0 million **tranche** ~~term loan facility~~ funded on ~~December 16~~ **January 13** , ~~2022~~ **2025 (approximately $ 10. 0 million of which was used to refinance all obligations under the Original Loan Agreement and pay fees and expenses incurred in connection with the Amendment)** . Based upon the terms of the **Amended** Loan Agreement **,** ~~we could potentially access~~ up to **an additional** $ ~~10~~ **30** . 0 million **is available at our request until December 15, 2025, subject to our achievement** of **certain milestones as more fully described in** the ~~remaining~~ **Amended Loan Agreement, and up to an additional** $ 25. 0 million ~~of~~ **is available at our request subject to** the ~~credit facility~~ **Lender' s approval** . Our obligations under the **Amended** Loan Agreement are secured by a security interest in substantially all of our assets, other than intellectual property assets. The **Amended** Loan Agreement includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on our ability to transfer collateral, incur additional indebtedness, engage in mergers or acquisitions, pay cash dividends or make other distributions, make investments, create liens, sell assets, and make any payment on subordinated debt, in each case subject to certain exceptions **. In addition, following an initial period with no financial covenants, beginning January 1, 2026, we must maintain a cash runway of at least five months, provided that this covenant will be waived during any period in which our market capitalization exceeds $ 700. 0 million** . These restrictive covenants could limit our

flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial and failure to comply with these restrictive covenants would make us ineligible to receive future additional funding under the **Amended** Loan Agreement. In ~~addition~~ **July 2024** , **we entered into a convertible loan agreement, or** the **Convertible Grant Agreement, with The Wellcome Trust Limited, or Wellcome. The Convertible Grant Agreement provides for an unsecured convertible loan, or the Convertible Loan, from Wellcome of up to approximately $ 11. 7 million, payable in six tranches, $ 1. 3 million of which was funded upon the execution of the Convertible Grant Agreement, and the remainder of which will be funded upon draw down of the remaining initiation payment or the completion of certain milestones as set forth in the Convertible Grant Agreement, subject to certain conditions described therein which may or may not be met in a timely manner or at all. Proceeds from the Convertible Loan may be used by the Company solely to advance development of ALTO- 100 in bipolar depression. The Convertible Grant Agreement also includes customary covenants, representations and warranties, including with respect to the conduct of our Phase 2b clinical trial evaluating ALTO- 100 in patients with bipolar depression and certain information and audit rights of Wellcome in connection therewith, as well as with respect to our efforts to develop and exploit ALTO- 100. The** Lender could declare a default upon the occurrence of any event that it interprets could have a material adverse effect, as defined in the **Amended** Loan Agreement **,** ~~. Upon the occurrence~~ and ~~continuance of~~ **Wellcome may declare** an event of default **upon the occurrence of certain specified events set forth in the Convertible Grant Agreement. Upon the occurrence and continuance of an event of default** , the Lender **or Wellcome, as applicable,** may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the **Amended** Loan Agreement **and the Convertible Grant Agreement, respectively** . Any declaration ~~by the Lender~~ of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. In addition, **pursuant to the Amended Loan Agreement,** the Lender may, at its option, elect to convert up to $ ~~4~~ **9** . 0 million of the then outstanding term loan amount into shares of our common stock. The Lender also has ~~a warrant~~ **warrants** to purchase shares of our common stock, and we may be required to issue additional warrants to the Lender in the future **. At any time after the second anniversary of the date of the Convertible Grant Agreement, Wellcome has the right, from time to time, to convert some or all of the Convertible Loan into shares of our common stock at a 20 % discount to the 30- day volume- weighted average price on the New York Stock Exchange at the date of conversion** . Any conversion of debt into equity by the Lender **or Wellcome pursuant to the Amended Loan Agreement or the Convertible Grant Agreement, respectively,** or exercise of any warrants held by the Lender now or in the future would cause dilution to our stockholders. The biopharmaceutical industry is characterized by the rapid innovation and intense competition. While we believe that our innovative precision psychiatry approach and pipeline of clinical assets provide us with competitive advantages, we face competition from multiple biopharmaceutical and biotechnology companies that are similarly working to develop therapeutics targeting neuropsychiatry and CNS disorders, as well as from academic institutions, governmental agencies, and public and private research institutions. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals and commercializing their products. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available. ~~We~~ **In particular we** are ~~currently~~ developing **our** ~~ALTO- 100, ALTO- 300 and ALTO- 203 for the treatment of MDD. Patients with MDD have historically been treated with a variety of anti- depressant medications and, accordingly, we believe these~~ product candidates **in the areas of major depressive disorder** , ~~if~~ **bipolar depression, and schizophrenia. Notable examples of companies with either** approved ~~, would~~ **therapies or product candidates in development in areas that may be** ~~compete~~ **competitive in our areas of focus are AbbVie Inc.;** ~~with several currently approved therapeutics, including: Auvelity (marketed by~~ Axsome Therapeutics, Inc. ~~)~~ ; ~~Prozac (marketed by Eli Lilly and Company); Rexulti (marketed by Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A / S); Trintellix (marketed by Takeda Pharmaceuticals Company Limited and H. Lundbeck A / S); Vraylar and Viibryd (marketed by AbbVie Inc.); Wellbutrin (marketed by GSK plc); and Zoloft and Effexor (marketed by Pfizer Inc.). We are also aware of several companies developing compounds for the treatment of MDD, including Biogen Inc., Minerva Neurosciences, Inc.,~~ Neumora Therapeutics, Inc. ~~, Relmada Therapeutics~~ **; Neurocrine Biosciences** , Inc. **;** ~~, Sage Therapeutics, Inc.,~~ and Xenon Pharmaceuticals **,** Inc., **among** ~~as well as other~~ **others** ~~earlier stage competitors. We are also developing ALTO- 101 for the treatment of schizophrenia. While there remains significant unmet need in schizophrenia, we believe ALTO- 101, if approved, may face competition from product candidates also being developed for negative or cognitive symptoms of schizophrenia, including by: Boehringer Ingelheim, Cerevel Therapeutics Holdings, Inc., Karuna Therapeutics, Inc., Merck & Co. Inc., Minerva Neurosciences, Inc., and Neurocrine Biosciences, Inc., as well as other earlier stage competitors~~ . We believe the key competitive factors affecting the success of our product candidates that we develop to address MDD **, BPD** , schizophrenia, and other CNS disorders, if approved, are likely to be efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third- party payors. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace. We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business. As of December 31, ~~2023~~ **2024** , we had ~~63~~ **76** total employees. As our development and commercialization plans and strategies develop, and as we transition into **fully** operating as a public company, we expect to expand our employee base for managerial, operational, financial, and other resources. In addition, we

have limited experience in manufacturing and commercialization. As our product candidates enter and advance through clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems and procedures, which may lead to significant costs and may divert management attention. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations, and prospects. We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer. Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. We are highly dependent upon our Founder, President, and Chief Executive Officer, Amit Etkin, M. D., Ph. D., and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We maintain " key person " life insurance for Dr. Etkin, but the insurance proceeds may not be sufficient to compensate for the adverse effects that we expect would arise from the loss of Dr. Etkin and the costs associated with recruiting a new Chief Executive Officer. Additionally, in light of our insourced clinical trial model, we are heavily reliant on the expertise of our clinical trial team, and the loss of even a small number of those employees could have a significant adverse impact on our ability to conduct our clinical trials in a compliant and timely manner. Additionally, as we expand our clinical trial operations, or if we experience turnover within our clinical trial team, even if we are able to recruit qualified personnel to support ~~out~~ **our** insourced clinical trial model, the onboarding and integration process takes time and can result in delays to our clinical development timeline. We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology, and other businesses, particularly in the greater San Francisco Bay Area. If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy. Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, commercial partners, CROs, CMOs, and vendors. Misconduct by these parties could include intentional, reckless, and / or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, European Medicines Agency, and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the **EU** ~~European Union~~, United Kingdom and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing, and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets

and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations, and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting, and legal requirements, and reduced protection of intellectual property rights in some foreign countries. Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations, and prospects. As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing, and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval for, and ~~marketing~~ --- **market, our** products, such claims could result in an investigation by the FDA, comparable foreign regulatory authorities, or other regulators of the safety and efficacy of our future product candidates, our manufacturing processes and facilities, or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management' s time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations, and prospects. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, clinical trials, cybersecurity, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations, and prospects. We may seek Breakthrough Therapy Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek Breakthrough Therapy Designation for our product candidates where we believe the clinical data support such designation. A " Breakthrough Therapy " designation may be available for a drug candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or 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, increased 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 also receive the same benefits associated with Fast Track Designation, including eligibility for rolling review of a submitted NDA, if the relevant criteria are met. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review, or approval 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 the product candidates we develop qualify as Breakthrough Therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation, or otherwise decide that the time period required for FDA review or approval will not be reduced. We may seek Fast Track Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process, and would not increase the likelihood that our product candidates will receive marketing approval. We may seek Fast Track Designation for the product candidates we develop. The Fast Track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, if a new drug is intended for the treatment of a serious or life- threatening disease or condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition, the drug sponsor may apply for Fast Track Designation. Fast Track Designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this

designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that any product candidate that may be granted Fast Track Designation will receive regulatory approval in the **United States** ~~U. S~~. Many product candidates that have received Fast Track Designation have ultimately failed to obtain approval. If our telecommunications or information technology systems, or those used by our collaborators, CROs, CMOs, clinical sites, third- party logistics providers, distributors, or other contractors, consultants, or third party service providers upon which we rely, are or were compromised, become unavailable, or suffer security breaches, loss, or leakage of data or other disruptions, we could suffer adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences. In the ordinary course of our business, we, and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** , collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") sensitive data and as a result, we and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** face a variety of evolving threats that could cause security incidents and other disruptions to such information technology systems. If any of our sensitive or proprietary data is compromised, including our Platform and our internal, proprietary systems for data collection, it may materially and adversely affect our ability to create and develop product candidates and identify biomarkers, and compete effectively. Our Platform, our internal, proprietary systems for data collection, and our information technology systems and those of our collaborators, CROs, CMOs, clinical sites, third- party logistics providers, distributors, and other contractors and consultants upon which we rely are vulnerable to attack, damage, and interruption from cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including ransomware, and as a result of advanced persistent threat intrusions), **model poisoning,** and other attacks by computer hackers, nation- state and nation- state- supported actors, cracking, application security attacks, social engineering (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), supply chain attacks and vulnerabilities through our third- party service providers, denial- or degradation- of- service attacks **,** ~~(such as~~ credential stuffing ~~)~~ **attacks** , credential harvesting, personnel misconduct or error, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications or electrical failures, natural disasters (e. g., earthquakes, fires, and floods), terrorism, war, **attacks enhanced or facilitated by artificial intelligence,** and other similar threats. Such systems ~~could~~ **are** also ~~be~~ vulnerable to intentional or inadvertent acts or lack of action by those with authorized access to our systems that **could** lead to exposure or exploitation of those systems. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation- states, and nation- state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive information), loss of income, significant extra expenses to restore data or systems, reputational loss, and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Some actors also now engage and are expected to continue to engage in cyber- attacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell, and distribute our goods and services. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. **Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with the use by our personnel or vendors of generative artificial intelligence, or AI, technologies.** Additionally, remote ~~work has become more common with approximately 50 % of our employees working remotely. Remote~~ work has increased risks to our information technology systems and data, as ~~more of~~ our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We and certain of our service providers are from time to time subject to system failures, cyberattacks, and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, and take steps to detect and remediate vulnerabilities, we may not be able to detect, adequately investigate, or remediate all vulnerabilities or breaches because the tools and techniques used to exploit such vulnerabilities change frequently are often sophisticated in nature, and are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred or for an extended period. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. We rely on third- party service providers and technologies to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third- party service providers to assist with our

~~mental health research registry and our~~ clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption **, as some in the past have** , we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third- party information technology systems that support us and our services. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services including clinical trials. **For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future.** The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our collaborators, CROs, CMOs, clinical sites, third- party logistics providers, distributors, and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from financial, legal, business, or reputational losses or to mitigate other liabilities arising out of an interruption or breach of our systems, or deficiencies in our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. If any such incidents were to occur and cause interruptions in our operations, it could result in a material disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or unauthorized disclosure of personal, confidential, or proprietary information, we could incur liability, including litigation exposure, penalties, and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of any product candidates could be delayed. Such incidents could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could cause management distraction and the obligation to devote significant financial and other resources to mitigate such problems, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical, and technical safeguards, further training of employees, changing third- party vendor control practices, and engaging third- party subject matter experts and consultants and reduce the demand for our technology and services. Applicable data privacy and security obligations may require us to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security incidents **, or to take other actions, such as providing credit monitoring and identity theft protection services** . The costs associated with the investigation, remediation, and potential **related obligations could be** ~~requirement to make such notifications are~~ material, and the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory investigations, and enforcement actions, including significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates and materially and adversely affect our business, results of operations, or financial condition. Many of our operations are concentrated in California, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our current corporate and IT infrastructure operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic ~~such as the COVID- 19 pandemic~~ , power shortage, telecommunication failure, or other natural or ~~manmade~~ **man-made** accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or ~~manmade~~ **man- made** disasters on our current or future third- party CMOs and CROs located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage, or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third- party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our current or future CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and

losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations, and prospects. Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate. The precise incidence and prevalence for all the conditions we aim to address with our 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 our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, if any, the ability to scale testing for identified biomarkers, the ability of our product candidates to improve on the safety, convenience, cost, and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, 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 through biomarker identification, and 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, results of operations, and prospects. Our business could be adversely affected by the effects of health pandemics or epidemics, ~~such as the COVID- 19 pandemic,~~ which could cause significant disruptions in our operations and those of our current or future CMOs, CROs, and other third parties upon whom we rely. Health pandemics or epidemics ~~,~~ ~~such as the COVID- 19 pandemic,~~ have in the past and could again in the future result in quarantines, stay- at- home orders, remote work policies, or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third- party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators, and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs, and other third- party service providers to assist us in managing, monitoring, and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics ~~, such as the COVID- 19 pandemic,~~ may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and / or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and adversely affect our business, financial condition, results of operations, and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. Risks Related to Collaborations, Intellectual Property, and Related Agreements We rely upon a combination of patents, know- how, trade secrets, and confidentiality agreements, to protect the intellectual property related to our Platform, technologies, and product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. We also rely on protection afforded by in- licensed intellectual property rights and proprietary technology of third parties. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating, or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we own and in- license issued patents, our pending and future patent applications, and those licensed to us by third party licensors, may not result in patents being issued. Even if our patent applications result in issued patents, we cannot assure you that such issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or that they will effectively prevent others from commercializing competitive technologies, products, or product candidates. Obtaining and enforcing patents is expensive and time- consuming, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications or maintain and / or enforce patents that may issue based on our patent applications at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. We do not have exclusive control over the preparation, filing, and prosecution of patent applications under certain of our in- license agreements, and although we may have the right to have some input in connection with such activities, we may not have the right to control the preparation, filing, and prosecution of patent applications that are licensed to us by third parties, or to control prosecution and maintenance of patents

that we out- license to third parties. Therefore, patents and applications that are relevant to our product candidates may not be prosecuted and enforced in a manner consistent with the best interests of our business. 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, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in any of our or our collaborators' or licensors' patent applications directed to composition of matter of our product candidates will be considered patentable by the ~~United States Patent and Trademark Office, or the~~ USPTO ~~,~~ or by patent offices in foreign countries, or that the claims in any of our or our licensors' issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Further, our issued composition of matter patents covering our pharmaceutical product candidates may expire at such a date that our patents may not prevent competitors from developing, making and marketing a product that is identical to our product candidates after expiration of any applicable regulatory exclusivities. For example, our composition of matter patents in ALTO- 100 **expired and patents covering its method of manufacturing** are due to expire in **2030; our composition of matter patents in ALTO- 202 (compound) expired in May** 2024 **(in foreign countries) and are due to expire in 2026 (in the United States)** , **and** our **polymorph** composition of matter patents in ALTO- 202 are due to expire in ~~2024 (compound) and~~ 2035 **;** ~~(polymorph),~~ and our composition of matter patents in ALTO- 203 are due to expire in 2027, in all cases without taking into account patent term extensions or adjustments, and assuming payment of all applicable maintenance, renewal, and annuity fees. Similarly, patents for pharmaceutical formulations containing pharmaceutical product candidates may provide an additional form of intellectual property protection, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our or our collaborators' or licensors' pending patent applications directed to pharmaceutical formulations containing our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our or our licensors' issued patents will be considered valid and enforceable by courts in the United States or foreign countries. In addition, we cannot be certain that the claims of such patents, if granted, will be sufficiently broad to effectively prevent competitors from working around our claimed inventions by developing an alternative formulation and thereby competing with us without infringing our patent rights. Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside methods of use included in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their product for indications that are covered by our patents, clinicians may prescribe these competitor products " off- label. " Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute. Like method of use patents, patents relating to our Platform protect the platform for the method specified in the patent claims. This type of patent does not prevent a competitor from developing alternative technologies to identify biomarkers or target patient populations. Even if competitors copy our Platform, infringement may be difficult to determine, prevent, or prosecute. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability, and commercial value of any patent rights are highly uncertain. Our pending and future owned and in- licensed patent applications may not result in patents being issued that protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third- party intellectual property upon our freedom to operate, is highly uncertain. 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 know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we 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 patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability, and commercial value of our or our licensors' patent rights are highly uncertain. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third- party pre- issuance submissions of prior art to the USPTO, and our issued patents and those

of our licensors may be subject to post- grant review, proceedings, oppositions, derivations, reexaminations, interferences, inter partes review proceedings, or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. Such submissions may also be made prior to a patent' s issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in- licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products, or product candidates without infringing third- party patent rights. In addition, 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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations, and prospects. Issued patents covering our product candidates, or the method of use of our product candidates or associated companion diagnostics could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering our product candidates or companion diagnostics associated with our product candidates, or our other proprietary technologies, including our platform technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, 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, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In addition to such counterclaims, third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights in such a way that they no longer cover our product candidates, therapeutic and diagnostic programs, and other proprietary or platform technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection provided to our product candidates, companion diagnostics, proprietary platform technologies, or other components of our therapeutic and diagnostic programs, as applicable. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects. We may not be successful in obtaining or maintaining necessary rights to third party patents for our product candidates through acquisitions and in- licenses. The growth of our business may depend in part on our ability to acquire, in- license, or use third- party intellectual property and proprietary rights. A number of our existing product candidates are the subject to in- licenses from third parties. Other pharmaceutical companies and academic institutions may own patents or may have filed, or be planning to file, patent applications potentially relevant to our business. In order to avoid infringing such patent rights, we may find it necessary or prudent to obtain licenses to such patent rights from such third parties. For example, we may be required by the FDA or comparable foreign regulatory authorities to provide a specific companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use patents or know how owned or controlled by third parties. In addition, with respect to any patent or other intellectual property rights we may co- own with third parties, we may require licenses to such co- owners' interest to such patent or other intellectual property rights. We may be unable to acquire or in- license any compositions, methods of use, processes, or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe, misappropriate, or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types

of negotiations and ultimately acquire the rights to the intellectual property related to the products or product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer. We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. Our rights to develop and commercialize our product candidates, our Platform, or other technologies are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Stanford, Sanofi, and MedRx. The terms of these licenses may be inadequate to protect our competitive position on products or product candidates for a sufficient amount of time. Further, if we fail to comply with our obligations in the agreements under which we in- license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business. We are heavily reliant upon licenses to certain patent rights and other intellectual property that are relevant to our Platform or are important or necessary to the development of ALTO- 101 or our other current or future biomarker platform and product candidates. For example, we depend on licenses from Sanofi and MedRx for certain intellectual property relating to the development and commercialization of ALTO- 101. Although we conduct diligence on intellectual property that is the subject of our in- licenses at the time of entry into the applicable agreements, these third party licensors may have relied upon, and any future licensors may rely upon, third- party companies, consultants, or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize ALTO- 101 or our other current or future product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of ALTO- 101 and development of any future product candidates may, require us to enter into additional license or collaboration agreements. Additionally, under the terms of ~~our exclusive license agreement with equity, or~~ the Stanford Agreement ~~, with Stanford~~ , we obtained a worldwide, royalty- bearing license, with the right to sublicense during the exclusive term only, under certain patent rights in five patent families relating to brain stimulation, electroencephalogram and functional MRI that are applicable to guiding treatment of psychiatry patients in our Platform, or the **Stanford** Licensed Patents, and under certain technology relating to the inventions covered by the **Stanford** Licensed Patents, or **Stanford** Licensed Technology, to make, have made, use, import, offer for sale and sell licensed products for use in any indication. Our rights under the **Stanford** Licensed Patents are only exclusive until December 2029, at which time such rights will become non- exclusive, and our rights under the **Stanford** Licensed Technology are non- exclusive. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our product candidates in the future. These existing license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, or other obligations on us. If we breach any of our obligations under our license agreements, including diligence obligations with respect to development and commercialization of product candidates covered by the intellectual property licensed to us, or use the intellectual property licensed to us in an unauthorized manner or we are subject to bankruptcy- related proceedings, we may be required to pay damages and the licensor may have the right to terminate the respective agreement or materially modify the terms of the license, such as by rendering currently exclusive licenses non- exclusive. License termination or modification may result in our inability to develop, manufacture, and commercialize platforms, product candidates and other technology covered by the licensed intellectual property under such license agreements. If such in- license agreements are terminated or modified, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in- licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Further, we or our licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our in- licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors fail to establish, maintain, or protect such in- licensed patent rights or any other in- licensed intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any in- licensed patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our in- licensed patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent

competition from third parties, which may have an adverse impact on our business, financial conditions, results of operations, and prospects. Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications that we license from third parties. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs. If our licensors and future licensors fail to prosecute, maintain, enforce, and defend patents we may license, or lose rights to such patents or patent applications, our licensed rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our platforms, products, or product candidates that is the subject of such licensed rights could be materially adversely affected. Even where we have the right to control prosecution of in- licensed patents and patent applications under license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution. Our technology acquired or licensed currently or in the future from various third parties is or may be subject to retained rights. Our predecessors or licensors do and may retain certain rights under their agreements with us, including the right to use the underlying technology for non- commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • our financial or other obligations under the license agreement; • the extent to which our platforms, product candidates, or other technology infringe, misappropriate, or violate intellectual property rights of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights to third parties, including the terms and conditions thereof; • our diligence obligations under the license agreement and what activities satisfy those obligations; • our right to transfer or assign the license; • the inventorship or ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects. Our current or future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating, or otherwise violating the licensor' s intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in- licensed technology, we may be unable to successfully develop, out- license, market, and sell our product candidates, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies and licensed technology into commercial product candidates. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out- license, or market and sell our product candidates. We may form or seek collaborations or strategic alliances, enter into additional licensing arrangements or other business transactions in the future, and we may not realize the benefits of such transactions. We have entered into licensing arrangements and strategic transactions to acquire and advance new assets or product candidates and may consider similar or other types of business arrangements in the future, including strategic partnerships, in- licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, acquisitions of companies, asset purchases, business combinations, and investments. Any future transactions that we enter into may not be successful. In particular, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that: • collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates; • a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; • we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or

invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates; • collaborators may own or co- own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and • a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings. In addition, any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses, or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity, and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky, and costly endeavor for which we may never realize the full benefits of the acquisition. 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 adversely affect our business, financial condition, results of operations, and prospects. We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or 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. These competitor 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. Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our proprietary rights. Various countries outside the United States 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. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. 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. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor to try to protect our technologies and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive, and unpredictable. In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement, or defense of our issued patents or those of any current or future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Intellectual property rights do not necessarily 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. For example: • others may be able to make product candidates that are similar to ours, identify different biomarkers or target patient populations, or use product candidates similar to ours with similar biomarker discovery methodologies, but that are not covered by the pending patent applications that we own or the patents or patent applications that we license; • we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our biomarker or patient population discovery methodologies without infringing or otherwise violating our owned or licensed intellectual property rights; • it is possible that noncompliance with the USPTO and foreign governmental patent agencies' requirements for a number of procedural, documentary, fee payment, and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; • issued patents, if any arise in the future, that we either own or have exclusively licensed may be revoked, modified, or

held invalid or unenforceable, as a result of legal challenges by our competitors; • others may have access to the same intellectual property rights licensed to us in the future on a non- exclusive basis; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • we cannot predict the scope of protection of any patent issuing based on our and our licensors' patent applications, including whether the patent applications that we own, presently in- license, or, in the future, in- license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates; • the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; • if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable, and infringed; • we may need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • we may choose not to file a patent application in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property; • we may fail to adequately protect and police our trademarks and trade secrets; and • the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications. Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations, and prospects. 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 and market our product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate, or otherwise violate existing or future third- party patents or other intellectual property rights. Identification of third- party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including 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 and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Numerous U. S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically 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. Certain United States applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates, or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidates or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and 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. For example, 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 or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. We cannot provide any assurances that third- party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our biomarker discovery methodologies, product candidates, their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors or other third parties may infringe, misappropriate, or violate our patents, trademarks, or other intellectual property. To counter infringement, misappropriation, or unauthorized use, we or one of our licensing partners may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or our licensors' patents are invalid

or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement, insufficient written description, or failure to claim patent- eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or our licensors' patent claims do not cover the invention, or decide that the other party' s use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § ~~27~~ **271** (e) (1). An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, misappropriation, or violation, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the **share** price ~~of shares~~ of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement, misappropriation, or violation claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates or any future product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or misappropriation or violation of our other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms. Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed, misappropriated, or otherwise violated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting 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 perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution 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 greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot be certain that our product candidates will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third- party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such ~~United States~~ **U. S.** patent or find that our technologies or product candidates do not infringe any such claims. If we are found to infringe, misappropriate, or otherwise violate a third party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non- infringing manner, which may not be commercially feasible. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing, or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could

require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our technologies or product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, could be found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such ~~United States~~ **U. S.** patent. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could adversely affect our business and operations. 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 litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. We may choose to challenge the enforceability or validity of claims in a third party' s ~~United States~~ **U. S.** patent by requesting that the USPTO review the patent claims in an ex- parte re- exam, inter partes review, or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO, or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates. Our product candidates licensed from various third parties may be subject to retained rights. Our licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. It is difficult to monitor whether any of our licensors limit their use of the product candidates to these permitted uses, and we could incur substantial expenses to enforce our rights to our licensed product candidates in the event of misuse. In addition, we may license certain rights under the relevant agreements on a non- exclusive basis or we may license exclusive rights that may become nonexclusive after a period of time. For example, under the terms of the Stanford Agreement, our rights under the **Stanford** Licensed Patents relating to certain Platform patents are exclusive until December 2029, at which time it will become non- exclusive, and our rights under the **Stanford** Licensed Technology are non- exclusive. Further, the ~~United States~~ **U. S.** federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or Bayh- Dole Act. For examples, certain patents and patent applications licensed from Stanford may have been made with financial assistance from the federal government. The federal government retains a " nonexclusive, nontransferable, irrevocable, paid- up license " for its own benefit. The Bayh- Dole Act also provides federal agencies with " march- in rights. " March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a " nonexclusive, partially exclusive, or exclusive license " to a " responsible applicant or applicants. " If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and it is our policy to avoid engaging, university partners in projects concerning our product candidates in which there is a risk that federal funds may be commingled, we cannot be sure that any co- developed intellectual property will be free from government rights pursuant to the Bayh- Dole Act. If, in the future, we co- own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining, and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual

property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy- Smith America Invents Act, or the Leahy- Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy- Smith Act includes a number of significant changes to ~~United States~~ **U. S.** patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post- grant proceedings compared to the evidentiary standard in ~~United States~~ **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 or our licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' future issued patents, all of which could adversely affect our business, financial condition, results of operations, and prospects. After March 2013, under the Leahy- Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third- party was the first to invent the claimed invention. Consequently, if a third party that files a patent application in the USPTO before we file an application covering the same invention, the third party could therefore be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations, and prospects. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. 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. Depending on future actions by the ~~United States~~ **U. S.** Congress, the ~~United States~~ **U. S.** courts, the USPTO, and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in 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. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court, or the UPC, for litigation involving such patents. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC' s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt- out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan- European injunction. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. We cannot predict how future decisions by the courts, the ~~United States~~ **U. S.** Congress, or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations, and prospects. We may become subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property. We may be subject to claims that former employees, collaborators, or other third parties have an interest in our or our licensors' patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates, or as a result of questions regarding co- ownership of potential joint inventions. For example, we co-

own a patent application with MedRx, which names inventors from our company and MedRx. It is possible that MedRx could challenge the inventorship of the individuals from our company. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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 of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our current or future licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the ~~United States~~ **U. S.** government, such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects. 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. Such claims could adversely affect our business, financial condition, results of operations, and prospects. 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 ~~United States~~ **U. S.** non- provisional or international patent application 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 products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing, and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. For example, issued patents covering the composition of ALTO- 100 ~~are due to expire~~ **expired** ~~in 2024,~~ and patents covering the method of its manufacturing are due to expire in 2030 ~~,~~**; our composition of matter** patents ~~covering~~ **in ALTO- 202 (compound) expired in May 2024 (in foreign countries) and are due to expire in 2026 (in** the **United States), and our polymorph** composition of **matter patents in** ALTO- 202 are due to expire in ~~2024 (compound) and~~ 2035 **;** ~~(polymorph),~~ and patents covering the composition of ALTO- 203 are due to expire in 2027, in all cases without taking into account patent term extensions or adjustments, and assuming payment of all applicable maintenance, renewal, and annuity fees. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension for our product candidate, our business may be materially harmed. Depending upon the timing, duration, and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued ~~United States~~ **U. S.** patents or issued ~~United States~~ **U. S.** patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as the EU Regulation (EC) No 469 / 2009 concerning the Supplementary Protection Certificate for medicinal products. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in- license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel, third party vendors, or our licensing partners to pay these fees due to ~~United States~~ **U. S.** and non- ~~United States~~ **U. S.** patent agencies. The USPTO and various non- ~~United States~~ **U. S.** government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations, and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In

addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know- how, information, or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know- how, and if the license is not available on commercially- viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know- how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed, whether inadvertently or through intentional acts of current or departing employees, or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations, and prospects could be adversely affected. 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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. 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. 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. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. 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 the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to 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 name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects. We may be subject to claims asserting that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees, consultants, or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, we or our licensors may in the future be subject to claims by former employees, consultants, or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment

to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects. Risks Related to Our Reliance on Third Parties We have relied and expect to continue to rely on third parties to conduct certain aspects of our clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our development programs could be delayed, more costly, or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates. Although we rely on our internal, proprietary systems for data collection and our own clinical trial team to conduct our clinical trials (~~see~~ **See** " — We rely on, and intend to continue to rely on, our internal clinical development expertise to conduct our current and future clinical trials. This model includes internal teams and systems as well as external vendors and CROs to comprise a full clinical trial team. If our clinical trial team does not comply with applicable regulatory requirements, meet expected deadlines, or run trials effectively, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed. "), we rely or may rely in the future on third- party clinical investigators, medical institutions, and clinical data management organizations to conduct, supervise, and monitor clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality, and other aspects of clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs and harm our competitive position. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, and prospects. We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors **, such as a failure to adhere to contractually obligated protocols regarding storing, packaging and distributing drug supplies,** could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory, and scientific standards, and our reliance on clinical trial sites and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies are conducted in accordance with good laboratory practices, or GLPs, and clinical trials are conducted in accordance with **good clinical practices, or** GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre- approval inspections once an NDA is submitted to the FDA) of trial sponsors, clinical investigators, clinical trial sites, and IRBs. If we, our clinical trial sites, or other third parties fail to comply with applicable GLP, GCP, or other regulatory requirements, we or they may be subject to enforcement or other legal actions, 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, if ever. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Moreover, our business may be significantly impacted if our clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates. If our third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third- party service providers in the future, our business may be materially and adversely affected. If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we work to carefully manage our relationships with our third- party investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. In addition, if an agreement with any

of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator' s technology or intellectual property or require us to stop development of those product candidates completely. We rely on third- party manufacturers and suppliers to supply our product candidates. The loss of our third- party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business. We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing and have no current plans to develop our own clinical or commercial- scale manufacturing capabilities. We currently rely, and expect to continue to rely, on third- party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials, samples, patch technology, components, and other materials for our product candidates and delivery devices, as well as for commercial manufacture if any of our product candidates receive regulatory approval. Reliance on third- party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our clinical development product supplies will not be limited, interrupted, terminated, or will be of satisfactory quality or be available at acceptable prices. We typically order raw materials and services on a purchase order basis and do not enter into long- term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements. The manufacturing process for our product candidates is subject to the FDA' s review and, in the future, may be subject to comparable foreign regulatory authority review. We, and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and, in the future, comparable foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure and / or maintain regulatory approval for the use of their manufacturing facilities. Moreover, we do not conduct the manufacturing process ourselves and are completely dependent on our CMOs for manufacturing our product candidates in compliance with cGMP. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing, or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget, or obtain regulatory approval for or market our product candidates. We expect to continue to rely on third- party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and comparable foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance, and corresponding maintenance of records and documents. If we are unable to obtain or maintain third- party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party' s failure to execute on our manufacturing requirements, comply with cGMPs, or maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities could adversely affect our business in a number of other ways, including: • an inability to initiate or complete clinical trials of product candidates in a timely manner; • delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates; • subjecting third- party manufacturing facilities to additional inspections by regulatory authorities; • loss of the cooperation of existing or future collaborators; • requirements to cease development or to recall batches of our product candidates; and • in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products. Reliance on third- party manufacturers entails additional risks such as limitations on supply availability resulting from capacity and scheduling constraints of third parties; the possible breach of manufacturing agreements by third parties because of factors beyond our control; the possible termination or non- renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; failure to manufacture our product according to our schedule or at all; and the possible misappropriation of our proprietary information, including our trade secrets and know- how. Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes ~~or ,~~ unstable political environments **, or geopolitical tensions such as geopolitical tensions in China** . If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in clinical trials, or to provide product for treatment of patients if approved, would be jeopardized. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement, which would have a material adverse impact on our financial position. If any third- party manufacturer of our product candidates

is unable to increase the scale of its production of our product candidates, and / or increase the product yield of its manufacturing, then our costs to manufacture product candidates may increase and commercialization may be delayed. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our products, our third- party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the output. The transition to larger scale production could prove difficult. In addition, if our third- party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation. We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer- term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed. We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates **. For example, active pharmaceutical ingredients, or API, and drug product for ALTO- 101 and ALTO- 203 are manufactured by our supplier in China** . We do not currently have long- term supply contracts with any of our CMOs and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long- term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long- term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations, and prospects. Furthermore, **the climate of geopolitical tensions in China affecting global supply chains could impact our ability to continue to source API and drug product for ALTO-101 and ALTO- 203 from our supplier in China. Certain Chinese biotechnology companies and CMOs may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such restrictions could cause delays, disruptions, and cost increases in our studies for ALTO- 101 and ALTO- 203 or have other adverse effects on the development of our product candidates and our business operations. In addition,** any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations, and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise. The operations of our suppliers that are located outside of the United States are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations, and prospects. Currently, some of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including: • political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured; • the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate **(including tariffs proposed by the current administration)** ; • greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities; • reduced protection for intellectual property rights, including trademark protection, in some countries, particularly China **as suggested by recent disclosure allegations against certain Chinese CMOs** ; • disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters; • disruptions or delays in shipments; and • changes in local economic conditions in countries where our manufacturers or suppliers are located. In addition, certain Chinese biotechnology companies and CMOs may become subject to trade restrictions, sanctions, and other regulatory requirements by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of certain materials. These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations, and prospects. The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide supply

of our products for participants, if approved, could be delayed or halted. Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time- consuming, highly regulated, and subject to multiple risks. Our CMOs must comply with legal requirements, including cGMPs, and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products. Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. If any such drug product loss occurs, the impact to our business could be compounded by the long lead times needed to procure additional drug product due to plant capacity limitations, or other restrictions, at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered at our third- party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Moreover, if the FDA or any other regulatory authority determines that our third- party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny approval until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is able to ensure compliance of the product being manufactured. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMPs, lot consistency, and timely availability of raw materials. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations, and prospects. Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task. If our third- party manufacturers are unable, or decide not, to adequately validate or scale- up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale- up the manufacturing process for our product candidates with CMOs, we will in most cases still need to negotiate with such CMOs an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. We cannot assure you that any stability or other issues relating to the manufacture of any of our current or future product candidates or products, if approved, will not occur in the future. If our third- party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to participants in clinical trials and products to participants, if approved, would be jeopardized. Any delay or interruption in clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products, if approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write- offs and incur other charges and expenses for product candidates or products, if approved, that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations, and prospects. As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product candidate used in earlier clinical phases or at earlier portions of a trial to the product candidate used in later clinical phases or later portions of the trial. We are currently party to license and collaboration agreements with parties such as Sanofi, MedRx, and Cerecor, and we expect to enter into similar strategic transactions in the future. We may have conflicts with our current or future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the interpretation of a biomarker derived from our Platform, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations, or the ownership of intellectual property developed during our collaboration. Moreover, a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those

activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement. Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. We have historically relied on an affiliated third party to provide certain business services and the replacement of such services could adversely affect our business operations. We engage a professional employment organization, or PEO, to provide us with payroll services, benefit services, and human resources support. As we continue to transition to operate as a standalone entity, we intend to hire additional qualified personnel to provide certain of these functions internally in the future. Upon the termination of the PEO relationship, such services will be provided internally or by unaffiliated third parties, and we expect that in some instances, we will incur higher costs to obtain such services than we incurred under the terms of such agreement. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or 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 and despite our efforts to protect our trade secrets, a competitor' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations, and prospects. Risks Related to Government Regulation Our relationships with healthcare providers and physicians and third- party payors may be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third- party payors, and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, and if approved, sell, market, and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales, and marketing of our product candidates is subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring, and commission (s), certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state, and foreign healthcare laws and regulations laws that may affect our ability to operate now or in the future include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The 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; • the federal civil and criminal false claims laws, including the federal ~~False Claims Act, or~~ FCA ~~,~~ which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to " cause " the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery; • ~~the federal Health Insurance Portability and Accountability Act of 1996, or~~ HIPAA ~~,~~ which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact, or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity can be found guilty of violating the health care fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans,

healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors; • the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program (with certain exceptions) to report annually to ~~the United States Department of Health and Human Services, or~~ HHS ~~,~~ information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; ~~and~~ state and local laws that require the registration of pharmaceutical sales representatives **; and state laws that protect consumer privacy or require notice to customers about how personal information is used and collected. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment** . The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state, and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties, and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and may divert our management' s attention from the operation of our business. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages, and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management' s attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations, and financial condition. ~~EU drug~~ **Drug** marketing and reimbursement regulations **in the EU** may materially affect our ability to market and receive coverage for our products in the EU member states. We intend to seek approval to market our product candidates in the United States and we may also seek to do so in selected foreign jurisdictions, including the **EU** ~~European Union~~ . If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the **EU** ~~European Union~~ , the pricing of medicinal products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some countries provide that products may be marketed only after a reimbursement decision has been taken by the relevant regulatory authority. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for our product candidates and may be affected by existing and future health care reform measures. Much like the federal Anti- Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians **and other healthcare professionals** to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is also prohibited in the **EU** ~~European Union~~ . **Interactions between pharmaceutical companies and healthcare professionals are** ~~The provision of benefits or advantages to physicians is~~ governed by the national anti- bribery laws of EU member states ~~and the~~ **, national sunshine rules, regulations,** industry codes of conduct ~~. Infringement~~ **, any physicians' codes** of **professional conduct. Failure to comply with** these **requirements** ~~laws or codes of conduct~~ could result in **reputational risk, public reprimands, administrative penalties** substantial fines and imprisonment. Payments made to healthcare professionals, healthcare organizations, students, or patient organizations in EU member states must increasingly be publicly disclosed. Moreover, agreements with healthcare professionals must be the subject of a prior written agreement between the parties and often must be the subject of prior notification and / or approval by the healthcare professional' s employer, his or her competent professional organization, and / or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public

reprimands, administrative penalties, or fines. In addition, in most foreign countries, including the EU member states, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, EU member states may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced EU member states, can further reduce prices. An EU member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the **EU** ~~European Union~~ do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected. **Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. This Health Technology Assessment (" HTA ") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.** In December 2021, Regulation No. 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. This regulation **,** which ~~will~~ **began to** apply ~~from~~ **on** January 12, 2025 **, through a phased implementation, is** ~~intends~~ **intended** to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three- year transitional period **.** Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. Entry into application of the HTA regulation is anticipated to increase reliance by competent national authorities on reference pricing mechanisms, the mechanism whereby countries reflect the reimbursement price in other EU member states. This has the potential to result in a decrease in reimbursement price in a number of EU member states to reflect the price fixed in the EU member state with the lowest reimbursement price. Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates is approved, ~~they~~ **it** will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMPs and similar requirements outside the United States and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs or similar regulations. As such, we and our contract manufacturers will be subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities to assess compliance with cGMPs or similar requirements and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with which we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may be subject to significant limitations on the approved indicated uses for which the product may be marketed (e. g., use restrictions for specified age groups, warnings, precautions or contraindications), and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS program as a condition of approval of our product candidates or similar risk management measures, which could entail requirements for long- term patient follow- up, a medication guide, physician training and communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA or comparable foreign regulatory authorities may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on that product, the manufacturing facility or us, including revisions to the approved labeling to add new safety information or a " black box " warning, imposition of post- market studies or clinical trials to assess

new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters, or holds on clinical trials; • refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals; • product seizure or detention or refusal to permit the import or export of our products; and • injunctions or the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. **Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent change in presidential administration. The current administration is pursuing policies to reduce regulations and expenditures across the U. S. government including at FDA and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business.** The policies of the FDA and comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. **For example, the U. S. Supreme Court' s June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations.** We cannot predict the likelihood, nature, or extent of government regulation that may arise from **current or** future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and our business, results of operations, and financial condition could be adversely affected. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA and comparable foreign regulatory authorities strictly regulate marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards and restrictions for direct- to- consumer advertising, industry- sponsored scientific and educational activities, promotional activities involving the internet, and off- label promotion. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. 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 FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, results of operations, and financial condition. Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations, and financial condition. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA, as amended by the Health Care and Education Reconciliation Act of 2010, was passed by Congress, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. Since its enactment, certain provisions the ACA have been subject to executive, judicial, and congressional challenges **and amendments** . For example, on ~~June 17, 2021, the U. S. Supreme Court dismissed a challenge to the ACA on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. On~~ August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or the IRA, ~~into law~~ **was enacted** , which among other things extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and by creating a newly established manufacturer discount program. It is unclear how ~~other~~ healthcare reform measures of the ~~Biden~~ **current** administration ~~, if any,~~ will impact our business. 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 several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs covered under Medicare **that have been on the market for at least seven years** and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list of~~ **agreed- upon prices for** the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. ~~It is currently unclear how the IRA~~ **On January 17, 2025, HHS selected fifteen additional drugs covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D**

products will **become subject** ~~be implemented but it is likely~~ to ~~have a significant effect on~~ the ~~pharmaceutical industry~~ **Medicare drug price negotiation program** . Further ~~, in response to the Biden administration' s October 2022 executive order~~ , on February 14, 2023, HHS released a report outlining three new models for testing by the ~~Centers for Medicare & Medicaid Services, or~~ CMS ~~,~~ Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, at the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Disruptions at the FDA and other national and foreign government authorities caused by funding shortages ~~or ,~~ global health concerns, **or additional regulatory changes** ~~such as COVID- 19,~~ could hinder their ability to hire, retain, or deploy key leadership and other personnel, or prevent new or modified products from being developed, reviewed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability **and propensity** of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s and comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, **social movements promoting alternatives to the use of drugs to treat certain neuropsychiatric conditions,** and other events that may otherwise affect the FDA' s and comparable foreign regulatory authorities' ~~ability to perform~~ **performance of** routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result **. Moreover, the current administration is pursuing policies to reduce expenditures across the U. S. government which may include directives to reduce agency workforce, including at the FDA. Such policy changes could create additional uncertainty for our business if key personnel are not in place to support the review, approval, and commercialization of our products** . In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at **and funding of the U. S. Department of Veterans Affairs, which we partner with for certain clinical trials,** the FDA **,** and other national and foreign authorities ~~also~~ may **reduce resources, increase internal costs incurred to counteract the potential reduction in resources, and** slow the time necessary for review and / or approval by necessary government authorities, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities and the federal government ~~is currently~~ **may, from time to time,** ~~operating~~ **operate** under a continuing resolution that could result in a shutdown if Congress is unable to timely pass an appropriations bill. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. **We and the third parties with whom we work are subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security.** Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards, and other requirements could adversely affect our business, results of operations, and financial condition. We maintain a large quantity of sensitive information, including confidential business and health- related information in connection with the conduct of our clinical trials, and personal information related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect **, and in certain cases has affected,** our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations ~~could~~ apply to our operations or the operations of our partners, including state and federal data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health- related and other personal information. Among these regulations are: Section 5 of the Federal Trade Commission Act, which prohibits unfair or deceptive commercial practices ~~; new rules adopted by the SEC in July 2023, which require public companies to disclose material cybersecurity incidents they experience and to disclose on an annual basis material information regarding their cybersecurity risk management, strategy, and governance~~ ; and HIPAA, as amended by HITECH, and the regulations promulgated thereunder. We may obtain health information from third parties, including information submitted by potential clinical trial participants through our internal, proprietary systems for data collection that are subject to privacy and security requirements under 21 CFR Part 11 governing the electronic storage of records that are required by the FDA' s regulations to be maintained or submitted to the FDA. Actual or perceived failure to comply with any such law or regulation by either us or our third - party vendors could adversely affect our business, results of operations, and financial condition. In addition, **numerous U. S.** states **have enacted comprehensive privacy** ~~are adopting comparable laws or amending existing~~ laws that ~~govern the~~ **impose certain obligations on covered businesses, including providing specific disclosures in** privacy **notices and affording residents with certain rights concerning their personal data. As applicable** , **such rights may include the right to access, correct, or delete**

certain personal data, and to opt- out of certain data processing **activities** , **such as targeted advertising, profiling,** and **automated decision** ~~protection of health- related~~ **making. The exercise of these rights may impact our business** and ~~other~~ **ability to provide our products and services. Certain states also impose stricter requirements for processing certain** personal **data, including sensitive** information ~~., Such~~ **such as conducting data privacy impact assessments. These state** laws **allow** ~~and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues~~ for **statutory fines for noncompliance** ~~us and our future customers and strategic partners and requiring greater attention to frequently changing regulatory requirements~~ . For example, the California Consumer Privacy Act of 2018, or CCPA, ~~went into effect on January 1~~ **applies to personal data of consumers** , ~~2020. The CCPA gives~~ **business representatives, and employees who are** California residents ~~expanded~~ **, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy** rights ~~related to their personal information and imposes increasing obligations on companies processing that personal information.~~ The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation ~~. Further, the California Privacy Rights Act, or CPRA, which became effective on January 1, 2023, significantly amended the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required~~ . Similar comprehensive privacy laws have been enacted and are continuing to be proposed in numerous other states and at the federal level reflecting a trend toward more stringent privacy legislation in the United States. ~~If passed, these bills may have potentially conflicting requirements that would make compliance challenging.~~ In addition, several states have enacted laws that provide additional protection to consumer health data such as the state of Washington, which ~~recently~~ enacted a comprehensive privacy bill, called the My Health My Data Act ~~. Effective March 2024~~ , **which broadly defines** ~~this new law will impose strict requirements on the collection, use and processing of~~ consumer health **data** ~~information that is not subject to HIPAA~~ , ~~and~~ **places restrictions on processing consumer health data (including imposing stringent requirements for consents),** provides **consumers certain rights with respect to their health data, and creates** a private right of action to **allow individuals to sue for violations of the** ~~consumers whose health information is collected in Washington State. Nevada and Connecticut have enacted similar laws~~ **law.** ~~, and other~~ **Other** states are considering ~~bills with~~ **and may adopt** similar ~~requirements~~ **laws** . While certain of these laws **, such as the CCPA,** exempt data regulated by HIPAA and certain clinical trial data, if passed and applicable to us, these laws may add additional complexity to our existing compliance obligations and may require us to modify our policies and practices and may increase our potential liability and adversely affect our business **. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU' s General Data Protection Regulation (" EU GDPR ") and the United Kingdom' s GDPR (" UK GDPR ") (collectively, " GDPR ") impose strict requirements for processing personal data. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In the ordinary course of business, we have transferred, and may in the future transfer, personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. In**

addition to data privacy and security laws, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences . Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition, and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. **Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty.** With the CCPA, and other laws, regulations, and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules, or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business **. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations** . Additional laws and regulations governing international operations could adversely affect our business, results of operations and financial condition. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or the FCPA, prohibits any U. S. individual or business from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate, and other related parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations, and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. We are subject to U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws. Among other things, Trade Laws prohibit companies and their employees, agents, clinical research organizations, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government- affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase over time. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or

partners, even if we do not explicitly authorize or have prior knowledge of such activities. Risks Related **to** Ownership of Our Common Stock and Our Status as a Public Company An active and liquid trading market for our common stock may not continue to develop or be sustained. Prior to the IPO, there was no public market for our common stock. Although our common stock is listed on The New York Stock Exchange, an active trading market for our shares may not continue to develop or be sustained. If an active trading market for our common stock does not continue developing or is not sustained, you may not be able to sell your shares at an attractive price or at all. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration. Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including: • variations in the level of expense related to the ongoing development of ALTO- 100, ALTO- 300, ALTO- 101, ALTO- 203, and our other product candidates or future development programs; • results and timing of preclinical studies and ongoing and future clinical trials, or the addition **, suspension,** or termination of any such clinical trials; • the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof; • our execution of any strategic transactions, including acquisitions, collaborations, licenses, or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions; • any intellectual property infringement lawsuit or opposition, interference, or cancellation proceeding in which we may become involved; • recruitment and departures of key personnel; • if any of our product candidates receives regulatory approval, the terms of such approval, and market acceptance and demand for such products; • regulatory developments affecting our product candidates or those of our competitors; • global or regional public health emergencies, ~~including any residual effects of the COVID- 19 pandemic,~~ natural disasters, or major catastrophic events; • adverse macroeconomic conditions or geopolitical events, including ~~any residual effects of the COVID- 19 pandemic~~ , the conflict between Ukraine and Russia, the conflict in the Middle East, **geopolitical tensions in China,** high levels of inflation, ~~heightened~~ **fluctuating** interest rates, and **proposed tariffs** ~~recent bank failures~~ ; • the impacts of inflation and rising interest rates on our business and operations; and • changes in general market and economic conditions. If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our stock price may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of shares of our common stock. The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to: • volatility and instability in the financial and capital markets; • **adverse macroeconomic conditions or geopolitical events, including the conflict between Ukraine and Russia, the regional conflict in the Middle East, geopolitical tensions in China, high levels of inflation, fluctuating interest rates, and proposed tariffs; •** announcements relating to our product candidates, including the results of clinical trials by us or our collaborators **, such as our announcement regarding our Phase 2b trial of ALTO- 100 in MDD in October 2024** ; • announcements by competitors that impact our competitive outlook; • negative developments with respect to our Platform, our product candidates, or similar products or product candidates with which we compete; • developments with respect to patents or intellectual property rights; • announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors; • announcements relating to strategic transactions, including acquisitions, collaborations, licenses, or similar arrangements; • actual or anticipated variations in our operating results due to the level of development expenses and other factors; • changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates; • announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business; • sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions; • expiration of market standoff or lock- up agreements ~~described in the section titled " Underwriters " section~~ ; • conditions and trends in the pharmaceutical, biotechnology, and other industries; • regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems; • litigation or arbitration; • general economic, political, and market conditions and other factors; and • the occurrence of any of the risks described in this section titled " Risk Factors ~~.~~ " **.** In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the research, development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The **Amended** Loan Agreement **and the Convertible Grant Agreement** ~~contains~~ **contain** , and any future debt or other financing arrangements may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders therefore will be limited to the appreciation in the price of our common stock. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of March 1, ~~2024~~ **2025** , our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially held, in the aggregate, approximately 35 % of our outstanding common stock. These stockholders, acting together, would be able to significantly influence all matters requiring

stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This level of control may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an " emerging growth company " as defined in the 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 to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this Annual Report and our future periodic reports and proxy statements, and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. We could be an emerging growth company for up to five years following the year in which we completed the IPO, although circumstances could cause us to lose that status earlier. 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 completion of the IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion and (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Investors may 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 stock price may be more volatile. Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards. We also are a " smaller reporting company " as defined in the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our ~~annual~~ **Annual** ~~report~~ **Report** on ~~Form~~ **Form10** ~~10-~~ K ~~, including this Annual Report,~~ and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders. Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Sales of a substantial number of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March ~~1~~ **17** , ~~2024~~ **2025** , we had outstanding ~~26~~ **27** , ~~883~~ **072** , ~~988~~ **129** shares of common stock. Of these shares, substantially all of the 9, 246, 000 shares sold in the IPO (excluding any shares sold in the directed share program implemented in connection with the IPO) are freely tradable and, subject to the restrictions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, substantially all of our additional shares of common stock **became** ~~will be~~ available for sale in the public market on July 30, 2024, which ~~is~~ **was** 180 days after the date of the final prospectus filed in connection the IPO, following the expiration of lock- up agreements between some of our stockholders and the underwriters and / or market stand- off provisions ~~. Jefferies LLC, Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated may release these stockholders from their lock- up agreements with the underwriters at any time and without notice, which, subject to the restrictions of Rule 144, would allow for earlier sales of shares in the public market~~ . In addition, we filed a registration statement on Form S- 8 under the Securities Act registering the issuance of 5, 721, 134 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under the registration statement on Form S- 8 will be available for sale in the public market subject to vesting arrangements and exercise of options, and the restrictions of Rule 144 in the case of our affiliates. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the holders of ~~15~~ **2** , ~~601~~ **032** , ~~885~~ **595** shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act as provided under the terms of our amended and restated investors' rights agreement between us and various of our stockholders, subject to the restrictions described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. We have broad discretion in the use of our cash and cash equivalents ~~, including the net proceeds from the IPO,~~ and may not use them effectively, which could affect our results of operations and cause our stock price to decline. Our management has considerable

discretion in the application of our cash and cash equivalents, including the net proceeds from the IPO. We may use our cash and cash equivalents for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management, and limit the market price of our common stock. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our board of directors and management. Our amended and restated certificate of incorporation and amended and restated bylaws includes provisions that: • authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock; • require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent; • specify that special meetings of our stockholders can be called only by directors representing a majority of the total authorized size of our board of directors, the chairperson of our board of directors, or our chief executive officer; • establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; • establish that our board of directors is divided into three classes, with each class serving three- year staggered terms; • prohibit cumulative voting in the election of directors, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; • provide that our directors may be removed for cause only upon the vote of at least 66 2 / 3 % of our outstanding shares of voting stock; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and • require the approval of our board of directors or the holders of at least 66 2 / 3 % of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation. 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, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that holders of our common stock would receive a premium for their shares of our common stock in an acquisition. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district court for the District of Delaware of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action asserting a breach of fiduciary duty; • any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; • any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws; • any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and • any action asserting a claim against us that is governed by the internal- affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, results of operations, and financial condition. This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. General Risk Factors Our ability to use our net operating loss carryforwards and certain other tax attributes to offset

taxable income or taxes may be limited. We have incurred significant losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, ~~2023~~ **2024**, we had federal gross net operating loss, or NOL, carryforwards of $ ~~24~~ **42**. ~~8~~ **2** million and state gross NOL carryforwards of $ ~~66~~ **33**. 6 million. **Portions of** ~~These~~ **these** NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Internal Revenue Code of 1986, as amended, or the Code, federal NOL carryforwards arising in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in **a** taxable ~~years~~ **year** ~~beginning after December 31, 2020~~ is limited to no more than 80 % of ~~current year~~ taxable income **in such year** (with certain adjustments) ~~. It is uncertain if and to what extent various states will conform to federal law~~. In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and certain other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. **These ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.** We ~~have not~~ completed a ~~Section 382~~ study to assess whether an ownership change has occurred ~~or whether~~ **through December 31, 2024. Based on** ~~there~~ **these analyses, an ownership change was identified in 2019, 2021 and 2023 as a result of the completion of certain preferred stock financings. As a result of the ownership shifts that** have ~~been multiple ownership~~ **occurred, we determined that $ 24. 0 million of our gross federal NOLs and tax credit carryforwards are subject to an annual utilization limitation, which can be increased in the five year period post** ~~changes~~ **change date for any realized built- in gain.** ~~since our formation, due to the complexity and cost associated with such~~ **Such limitations expire no later than December 31, 2029 and the related gross federal NOLs and tax credit carryforwards are subject to** a ~~study~~ **full valuation allowance as of December 31, 2024. We will continue to monitor equity movement** and ~~the fact that~~ **its impact on** ~~there~~ -- **the** ~~may be~~ **utilization of the NOLs and credits as we could experience** additional ownership changes ~~in the future as a~~ **subsequent to December 31, 2024, which may** result ~~of changes~~ in ~~our stock ownership, some~~ **additional limitations on the utilization** of ~~which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre- change~~ NOL carryforwards and ~~other pre- change tax attributes (such as research tax~~ credits ~~) to offset our post- change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations~~. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows. As a result of the foregoing, we have a full valuation allowance for deferred tax assets, including our NOL carryforwards. In addition, we have received, and may receive, research and development tax credits in certain jurisdictions, including Australia, from time to time. To the extent such tax credits are reduced or eliminated or we no longer qualify for such tax credits in the future, our ability to offset our taxable income or taxes in such jurisdictions will be limited. Recent and future changes to tax laws could materially adversely affect our company. The tax regimes we are subject to or operate under, including with respect to income and non- income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the IRA enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the Tax Cuts and Jobs Act requires the capitalization and amortization of certain research and experimental expenses ~~incurred in tax years beginning after December 31, 2021~~ over five years if incurred in the United States and fifteen years if incurred outside the United States, rather than deducting such expenses currently. Although there have been legislative proposals to repeal or defer the capitalization requirement, there can be no assurance that such requirement will be repealed, deferred, or otherwise modified. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business. Unstable economic and market conditions may have serious adverse consequences on our business, financial condition, and stock price. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia- Ukraine conflict ~~and~~ **,** conflict in the Middle East **, and geopolitical tensions in China**). The financial institutions in which we hold our cash and cash equivalents are **also** subject to risk of failure ~~. For example, recent events surrounding certain banks, including Silicon Valley Bank, First Republic Bank, and Signature Bank, created temporary uncertainty on their customers' cash deposits in excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. As of December 31, 2023, we have no direct exposure to such banks. While we do not expect further developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk~~. Any such loss or limitation on our cash and cash equivalents would adversely affect our business. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well

as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property, or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, 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 public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, 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. Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected. As a public company, we are required to comply with the SEC' s rules implementing Sections 302 and 404 of the Sarbanes- Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting ~~. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our annual report on Form 10- K for the fiscal year ending December 31, 2024~~ . However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. When we lose our status as an " emerging growth company " and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. There may 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 New York Stock Exchange, the 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. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the

objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new **and / or close** relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock is likely to be volatile **, and has been volatile following our announcement regarding our Phase 2b trial of ALTO- 100 in MDD in October 2024** . The stock market in general, and the New York Stock Exchange and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time- consuming, damage our reputation, and divert our management' s attention from other business concerns, which could seriously harm our business.