

## Risk Factors Comparison 2025-04-15 to 2024-04-02 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

The following is a summary of the principal risks that could adversely affect our business, operations and financial results:

- Risks Related to Our Financial Position and Capital Needs ~~oWe-~~ **We** have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future. ~~oWe-~~ **We** currently have very limited product revenue and may never achieve or maintain profitability. ~~oWe-~~ **We** will require additional capital to finance our operations to continue as a going concern, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates and have substantial doubt about our ability to continue as a going concern. **We have identified material weaknesses in ~~oOur-~~ our internal control over financial reporting that could impair our ability to produce timely and accurate financial statements or comply with applicable laws and regulations. The restatement of previously issued financial statements may affect stockholder and investor confidence or harm our reputation.** **Our** ability to use net operating loss and credit carryforwards may be limited as a result of the effects of changes in tax laws and regulations. ~~oWe-~~ **We** may not be able to pay our liabilities and obligations when due.
- Risks Related to Our Business and Industry ~~oOur-~~ **Our** product candidates are in preclinical development or the early stages of clinical development. We cannot predict if we will meet safety and efficacy endpoints in clinical trials, if our preclinical studies and clinical trials will produce positive results, or if we will receive regulatory approval to commercialize and market any of our product candidates. ~~oWe-~~ **We** depend heavily on the success of our lead product candidate, pepinemab, and if we had to cease developing pepinemab, it would have material adverse effects on our business and future prospects. ~~oIf-~~ **If** we experience any continued delays in clinical testing or difficulties enrolling patients in clinical trials, it will delay any potential approvals of our product candidates. ~~oWe-~~ **We** may not successfully identify, develop or commercialize new product candidates or new applications of our existing product candidates. ~~oOur-~~ **Our** product candidates may have properties that could prevent their regulatory approval, limit their commercial scope, or result in significant negative consequences following any marketing approval. ~~oWe-~~ **We** may be required to suspend, repeat or terminate our clinical trials. ~~oWe-~~ **We** are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. ~~oThe-~~ **The** regulatory review processes are lengthy, time - consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business. ~~oEven-~~ **Even** if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties such as ongoing regulatory compliance and obligations. ~~oOur-~~ **Our** failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates in those jurisdictions and hurt our prospects. ~~oOur-~~ **Our** product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success. ~~oOur-~~ **Our** competitors may develop and market products or services which may diminish or eliminate the commercial success of any products or services we commercialize. ~~oWe-~~ **We** may not be able to achieve continued observable effects or the benefits or synergistic effects of pepinemab in combination with other immunotherapies that we have observed in preclinical studies of pepinemab in combination with the anti-CTLA-4 antibody ipilimumab. ~~oWe-~~ **We** may need to develop or obtain additional capabilities, or enter into arrangements with third parties, to commercialize any product candidates that obtain regulatory approval, and we may encounter unexpected costs or difficulties in doing so. ~~oEven~~ if we commercialize a product candidate, it or any other product candidates that we develop may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business. ~~oCurrent~~ and future legislation may increase the difficulty and cost for commercialization of our product candidates and affect the prices we or our partners may obtain. ~~oIf~~ we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. ~~oProduct~~ liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates. ~~oOur~~ relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, the violation of which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. ~~oOur~~ internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches. ~~oOur~~ employees may engage in misconduct or other improper activities which could have a material adverse effect on our business, which may result in penalties and liabilities under certain healthcare laws. ~~oWe~~ depend on key personnel for our continued operations and future success and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.
- Risks Related to our Dependence on Third Parties ~~oWe-~~ **Parties** ~~oWe-~~ rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost- effective manner. ~~oWe~~ depend on third- party manufacturers as well as on third parties for our supply chain. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates, which could harm our results of operations. ~~oWe~~ may not succeed in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize product candidates. ~~oCollaborations~~ may require us to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.
- Risks Related to Intellectual Property ~~oIf~~ **Property** ~~oIf~~ we are unable to obtain, maintain or protect

intellectual property rights, both in the U. S. and throughout the world, we may not be able to compete effectively in our market or globally. Changes in patent law and legal precedent concerning patents could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. We may become involved in lawsuits to protect or enforce our intellectual property rights and could have a materially adverse impact on the success of our business and financial condition. We may be involved in legal proceedings initiated by third parties regarding infringement, validity or scope of intellectual property rights, the outcome of which would be uncertain, and an adverse determination could have a materially adverse effect on the success of our business and financial condition. The terms of our patents may not be sufficient to effectively protect our drug candidates and business. If we do not obtain additional legislative protection extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed. If we fail to comply with our obligations in our license agreements, we could be required to pay monetary damages or could lose license rights that are important to our business. Our inability to protect our confidential information and trade secrets would harm our business.

**Risks Related to Our Securities**

**Our Common Stock was delisted from trading on Nasdaq and is currently not in compliance with available for quotation on the OTCBK continued listing standards of the Nasdaq Capital Market, and if we are unable to regain compliance, being listed on a national securities exchange. The relatively low trading volume of our common stock may limit your ability to sell your shares. Our common stock is subject to the penny stock rules, which makes our common stock less liquid. The Series A Preferred Stock ranks senior to the Company's common stock with respect to rights on the distribution of assets upon liquidation, dissolution and winding up. Shares of common stock issuable upon conversion of our Series A Preferred Stock will be delisted from dilutive to our existing stockholders upon conversion and adversely affect the exchange market price of our common stock.**

Certain members of our management, including the chief executive officer and chairman of our board, and their affiliates, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. For a more complete discussion of the material risks facing our business, see below.

**Risks Related to Our Financial Position and Capital Needs**

**We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future.** We are a clinical-stage biotechnology company with a limited operating history. Investment in biotechnology 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, obtain regulatory approval or become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2001. For the years ended December 31, **2024, and 2023, and 2022**, we reported a net loss of \$ **18.6 million, \$20.3 million, \$19.8 million**, respectively. As of December 31, **2024, and 2023, and 2022**, we had an accumulated deficit of \$ **358.6 million, and \$339.9 million, and \$319.7 million**, respectively. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We 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 revenues, if any. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations.

**We currently have very limited product revenue and may never achieve or maintain profitability.** To date, we have only generated very limited revenue from our ActivMAb product and have not generated any revenue from our product candidates in our SEMA4D Antibody Platform. Our ability to generate product revenue and become profitable depends on a number of factors, including, but not limited to, our ability to:

- successfully complete research and clinical development of current and future product candidates;
- timely commence, enroll, conduct and complete clinical trials;
- secure and maintain collaborations, licensing or other arrangements for the future development and / or commercialization of our product candidates, as well as the terms of those arrangements;
- complete and submit applications to, and obtain regulatory approval from, the FDA and foreign regulatory authorities;
- identify and develop additional product candidates;
- achieve market acceptance for our product candidates if and when they are approved;
- develop a commercial organization capable of sales, marketing and distribution in our core strategic markets, or enter into relationships with third parties to do the same;
- obtain coverage and adequate product reimbursement from third-party, including government, payors;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain additional qualified personnel.

In addition, due to the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of expenses, or when or if we will generate revenue and ultimately be able to achieve or maintain profitability. Even if we are able to complete the process described above, we anticipate incurring significant costs associated with commercializing these products. Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

**We will require additional capital to finance our operations to continue as a going concern, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product**

**candidates or develop new product candidates and have substantial doubt about our ability to continue as a going concern.** These financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of \$ ~~17.16~~ 2 million and \$ ~~19.21~~ ~~1.4~~ million for the years ended December 31, ~~2024, and 2023~~ and ~~2022~~, respectively, and an accumulated deficit of \$ ~~358.6 million and \$~~ 339.9 million ~~and \$ 319.7 million~~ as of December 31, ~~2024, and 2023~~ and ~~2022~~, respectively. **In addition, the Company has been delisted from the NASDAQ Capital Market due to its inability to comply with continued listing standards, is currently listed on the OTCPK, and filed a Form 15 to deregister its securities under Section 12 (g) of the Securities Act on March 27, 2025, which is expected to be effective no later than 90 days from when it was filed.** These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. To date, the Company has relied on equity and debt financing to fund its operations, in addition to capital contributions from noncontrolling interests and a limited amount of service revenue from collaboration agreements. In September 2020, we filed a prospectus supplement related to open market sale agreement (the "Open Market Sale Agreement" or "ATM") with Jefferies, LLC ("Jefferies") pursuant to which we may sell up to \$ 113.0 million of shares of our common stock through Jefferies. On May 19, 2023, the Company filed a prospectus supplement under which the Company may offer and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$ 4,391,000 through the Open Market Sale AgreementSM. In ~~2024 and 2023~~ and ~~2022~~, **the Company sold 208 and 3,409 and 15,188 shares, respectively, were sold** through the Open Market Sale Agreement for proceeds of \$ ~~2,077 and \$~~ 0.3 million ~~and \$ 3.6 million~~, respectively, net of commission. **No further sales can** ~~During the year ended December 31, 2022, the Company recorded as revenue \$ 175,000 in proceeds from its \$ 750,000 grant from the Alzheimer's Association under its 2020 Part the Cloud Program. As of December 31, 2022, this award was fully funded. On May 8, 2020, we received a loan for approximately \$ 1.1 million under the Small Business Administration's Paycheck Protection Program (the "PPP Loan"). However, the PPP Loan was only sufficient to fund our payroll and other eligible expenses for a limited period of time. On November 8, 2021 we were granted loan forgiveness of \$ 876,171 by the SBA. The remaining balance of the loan will be made pursuant~~ paid in monthly installments of \$ 6,333 through April 2025. During the year ended December 31, 2023 the Company completed private placements of our common stock and warrants to purchase common stock to various investors for gross proceeds of \$ 6.3 million. During the **Open Market Sale Agreement** year ended December 31, 2022 the Company completed private placements of our common stock to various investors for gross proceeds of \$ 13.5 million. Even with the **equity financing** arrangements described above **we have completed in the past**, we will need to complete additional financing transactions in order to continue operations. These arrangements may also not be sufficient in the near-term. Given, among other things, the current economic uncertainty associated with the inflationary environment, and our recent stock price performance, our ~~arrangement with Jefferies and other~~ financing strategies we may pursue may not be sufficient to fund our operations in the near term. There can be no assurances that we will be able to secure additional financing, or if available, that it will be sufficient to meet our needs or on favorable terms. Circumstances may also cause us to consume capital even more rapidly than we currently anticipate. For example, as we move our lead product candidate through clinical trials and submit Investigational New Drug applications for new indications or other product candidates, we may have adverse results requiring us to alter our development plans and anticipate clinical trial design or find new product candidates. Additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our operations and the development or commercialization of one or more of our product candidates or the range of indications for which they are developed. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, and / or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. Our future capital requirements will depend on many factors, including, among others: • the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities; • the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates we may develop or in-license; • the number and characteristics of product candidates that we develop or in-license, if any; • the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; • the effect of competing technological efforts and market developments; • our ability to establish collaborative arrangements to the extent necessary; • the economic and other terms, timing and success of any collaboration, licensing, distribution or other arrangements into which we may enter in the future; • revenues received from any product candidates that are approved; and • payments received under any current or future strategic partnerships. If a lack of available capital prevents us from expanding our operations or otherwise capitalizing on our business opportunities, our business, financial condition and results of operations could be materially adversely affected. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our operations and the development of one or more of our product candidates or cease operations. We **have identified material weaknesses in our internal control over financial**

reporting, and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired. In the course of our financial close process audits for the year ended December 31, 2024, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified relate to our control environment based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The material weaknesses related to (1) a lack of segregation of duties within our financial reporting controls that are relevant to our preparation of financial statements, including the ability to create, approve and post journal entries within our general ledger system and the ability to prepare and approve account reconciliations, and (2) not having effectively designed and implemented controls to review the statement of cash flows at an appropriate level of precision, which resulted in the restatement of the Company's Statement of Cash Flows for fiscal year ended December 31, 2023 as described in Note 18 to the financial statements included in this Form 10-K. If we are unable to remediate the identified material weaknesses or further implement and maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods could be adversely affected. Furthermore, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or may result in a restatement of financial statements for prior periods. The restatement of certain previously issued financial statements may affect stockholder and investor confidence or harm our reputation, and may subject us to additional risks and uncertainties, including increased cost and the increased probability of legal proceedings, regulatory inquiries, sanctions, or investigations. In the course of our financial close process audits for the year ended December 31, 2024, our management determined that due to a material weakness in our internal controls over financial reporting, the statement of cash flows for our 2023 financial statements did not appropriately present cash used in operating activities and cash provided by financing activities. As a result, the 2023 statement of cash flows has been restated from the amounts previously reported. As a result of the restatement, the Company has incurred unanticipated costs for accounting and legal fees in connection with, or related to, such restatement. In addition, such restatement could subject us to several additional risks and uncertainties, including the increased possibility of legal proceedings and inquiries, sanctions or investigations by the SEC or other regulatory authorities. Any of the foregoing may adversely affect our reputation, the accuracy and timing of our financial reporting, or business, results of operations, liquidity and financial condition, or cause stockholders and investors to lose confidence in the accuracy and completeness of our financial reports or cause the price of our common stock to decline. Our ability to use net operating loss and credit carryforwards may be limited as a result of the effects of changes in tax laws and regulations. We plan to use our current year operating losses to offset taxable income from any revenue generated from operations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss, or NOL, carryforwards to offset income that would otherwise be taxable. However, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended, the amount of benefits from our NOL and credit carryforwards may be limited if we incur a cumulative ownership change of more than 50 %, as interpreted by the U. S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL and credit carryforwards could be limited depending upon the timing and amount of additional equity securities that we issue. State NOL carryforwards may be similarly limited. As of December 31, 2023-2024, we had federal NOLs of \$ 297-312.7 million that could be limited by our past and any future ownership change, which could have an adverse effect on our future results of operations. Similar limitations will apply to our ability to carry forward any unused tax credits to offset future taxable income. The Tax Cuts and Jobs Act of 2017, or the Tax Act, among other things, generally limited utilization of losses generated after 2017 to 80 % of future annual taxable income. Any such limitations or disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow. We may not be able to pay debt and obligations when due. On May 8, 2020, we received the PPP Loan for approximately \$ 1.1 million under the Paycheck Protection Program. On November 8, 2021, we were granted loan forgiveness of \$ 876,171 by the SBA. The remaining balance of the loan will be paid in monthly installments of \$ 6,333-334 through April 2025. Our business is not expected to generate sufficient cash flow from operations in the future sufficient to pay our debt at maturity, or earlier, if certain events of default occur. Accordingly, we expect to have to raise additional capital in the future, either through restructuring debt, or obtaining additional equity capital, or pursuing other alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to make payments on our indebtedness depends on our future performance and capital raising activities, which are subject to economic, financial, competitive and other factors beyond our control. **We Risks Related to Our Business and Industry** We may choose not to continue to pursue our clinical trial evaluating pepinemab for the treatment of Alzheimer's Disease and, if we do continue to pursue trials for the treatment of Alzheimer's Disease, the development pathway is uncertain, which may make development more unpredictable or difficult than we currently expect. We initiated a clinical study of pepinemab as a potential treatment for AD in late 2020. In

April 2023, we reached our enrollment target for the Phase 1b / 2 SIGNAL- AD study evaluating pepinemab as a potential treatment for people with **Mild Cognitive Impairment (MCI) or** mild dementia due to AD. **It is anticipated that all 49- On April 25, the Company provided an update regarding plans for analysis of biomarkers and clinical outcome measures during a presentation at 12th Annual Alzheimer's & Parkinson's Drug Development Summit. All 50 participants will have completed 12- months of treatment by on June 30, 2024, and SIGNAL- AD topline data was will be reported in the second half by Eric Siemers, MD, Principal Investigator of the SIGNAL- AD trial at the Alzheimer's Association International Conference in Philadelphia on July 31, 2024. Based- Additional efficacy data for SIGNAL- AD was reported by Elizabeth Evans, PhD, Senior VP Discovery and Translational Research and Chief Operating Officer on October 31, 2024, at the Phase 1b / 2- results we may not continue to pursue clinical- Clinical development for this indication- Trials on Alzheimer's Disease Conference in Madrid, Spain .** If we cease to pursue the AD indication, we may pursue clinical development of our other indications for pepinemab, which require significant additional development resources. Pursuing these other indications will take a significant amount of time and capital to pursue and may not ultimately be successful. This may require that we seek an early partnership or license selected assets to advance our business efforts . **Our product candidates are in preclinical development or the early stages of clinical development. We cannot predict if we will meet safety and efficacy endpoints in clinical trials, if our preclinical studies and clinical trials will produce positive results, or if we will receive regulatory approval to commercialize and market any of our product candidates .** All of our product candidates are in early stages of development, and they will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit a biologics license application, or BLA, for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our target indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials. If our clinical trial results are not positive, we may terminate the clinical trials for a product candidate and abandon any further research or testing of that product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the submission of any BLAs to the FDA and, ultimately, our ability to obtain approval for and commercialize our product candidates and generate product revenues. In addition, before obtaining marketing approval from regulatory authorities for the sale of our future product candidates, we or our collaborators must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Despite the results reported in our Phase 1 and Phase 2 clinical trials for pepinemab and in preclinical studies for pepinemab and our other product candidates, we do not know whether the clinical trials we or our collaborators may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later- stage clinical trials do not produce favorable results, our or our collaborators' ability to achieve regulatory approval for any of our product candidates may be adversely impacted. **We depend heavily on the success of our lead product candidate, pepinemab, and if we had to cease developing pepinemab, it would have material adverse effects on our business and future prospects.** Pepinemab is our most advanced product candidate, and we are focused on developing it for AD, **and as our resources allow also developing pepinemab for** HNSCC, and PDAC. Additionally, third party investigators are studying pepinemab investigator- sponsored trials, or ISTs, is evaluating pepinemab in breast cancer and melanoma as well as in "window of opportunity" studies in other indications. We do not have control over how the ISTs are conducted or designed. These ISTs may identify adverse reactions associated with our product candidates. Any problems that arise in development of pepinemab for one indication, or in one trial, may have an adverse effect on the development of pepinemab for other indications and could cause us to cease development of pepinemab altogether. Similarly, as part of our SEMA4D antibody platform strategy, we intend to also develop pepinemab in additional neurodegenerative disease and cancer indications. Any adverse result or event that causes us to cease developing or limits our development of pepinemab would have adverse effects on our existing business, as well as our future prospects. If we experience any continued delays in clinical testing, it will delay any potential approvals of our product candidates, our costs may increase, and our business may be harmed. 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. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Numerous circumstances may result in a delay or failure in attaining successful completion of clinical development, including but not limited to: • delays or failure in obtaining approval from institutional review boards, or IRBs, or ethics committees, or ECs, to begin clinical trials at study sites; • imposition of a clinical hold by the FDA, or a decision by the FDA, other regulatory authorities, IRBs, ECs, or recommendation by a data safety monitoring board to suspend or terminate clinical trials at any time for safety issues or for any other reason; • delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites; • deviations from the trial protocol by clinical trial sites and investigators, or failure to conduct the trial in accordance with regulatory requirements; • failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines; • delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites; • for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the development, transfer and validation of assays or tests to be used to identify selected patients; • delays in enrolling and having patients complete participation in a trial or return for post- treatment follow- up; • delays caused

by patients dropping out of a trial due to side effects, disease progression or other reasons; • withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or • changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials. Any inability by us or our collaborators to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments, or royalties on product sales. ~~If we or our collaborators encounter any continued difficulties enrolling patients in clinical trials, the clinical trials could be delayed or otherwise adversely affected.~~ **We may not successfully identify, develop our or commercialize new product candidates** ~~collaborators encounter any continued difficulties enrolling patients in clinical trials, the clinical trials could be delayed or otherwise adversely affected.~~ The timely completion of clinical trials largely depends on patient enrollment. Many factors affect patient enrollment, including: • the nature and size of the patient population; • the number and location of participating clinical sites; • competition with other companies for ~~or clinical sites~~ **new applications of or our existing product candidates** ~~patients; • design of the trial protocol; • ability to obtain informed consents from patients; and • clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any drugs that may already be approved for the indications we are investigating.~~ ~~If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.~~ The success of our business depends primarily upon our ability to identify and validate new biotherapeutics and / or applications, including through the use of our SEMA4D antibody platform and our ActivMAB antibody discovery platform, and identify, develop and commercialize antibodies and product candidates, which we may develop ourselves or develop on behalf of or out- license to others. Our research efforts may initially show promise in discovering potential new targets or biotherapeutic product candidates, yet fail to result in product candidates for clinical development for a number of reasons, including: • our research methodology may not successfully identify potential antibodies that can serve as biotherapeutic product candidates to the targets that we or our collaborators believe are medically important; • we identify and select from our ActivMAB platforms novel, untested antibodies for the particular targets we are pursuing, which we may fail to validate after further research work; • we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable; • our product candidates may not demonstrate a meaningful benefit to patients; and • our collaborators may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product. 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, operating results and prospects and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval, limit the commercial scope of their approved uses, or result in significant negative consequences following any marketing approval. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal unacceptable side effects or unexpected characteristics. In such an event, we could suspend or terminate our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such products, a number of potentially significant negative consequences could result, including: • we may suspend marketing of, or withdraw or recall, such product; • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require additional warnings on the label or otherwise seek to limit the scope of the approved uses reflected in the label of such product; • the FDA may require the use of or modification of a Risk Evaluation and Mitigation Strategy, or REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose other implementation requirements on us; • regulatory authorities may require that we conduct post- marketing studies; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects. We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, the trials are not well designed, or a regulator may request or require additional trials. The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost- effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. Clinical trials must be conducted in accordance with the FDA' s current Good Clinical Practices requirements, or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, and IRBs or ECs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, or us, or by an IRB or EC with respect to a particular clinical trial site, for various reasons, including: • deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols; • deficiencies in the clinical trial operations or trial sites; • unforeseen adverse side effects or the emergence of undue risks to study subjects; • deficiencies in the trial design necessary to demonstrate efficacy; • the product candidate may not appear to

offer benefits over current therapies; or • the quality or stability of the product candidate may fall below acceptable standards.

**We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.**

The process of manufacturing biologics, including our product candidates, is complex and subject to several risks, including: • product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. 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 in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination; • the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and • any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. The regulatory review processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. Our inability to obtain regulatory approval, in the timelines we anticipate or at all, for our product candidates would substantially harm our business. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is difficult to predict but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval even if our preclinical studies or clinical trials initially appear to be successful. Our product candidates could fail to receive approval from the FDA or comparable foreign regulatory authorities for many reasons, including: • disagreement with the design or implementation of our clinical trials, including the endpoints used to assess effectiveness and / or safety; • failure to demonstrate that a product candidate is safe and effective for its proposed indication; • failure of clinical trials' endpoints to meet the level of statistical significance required for approval; • failure to demonstrate that a product candidate' s benefits outweigh its risks; • disagreement with our interpretation of data from preclinical studies or clinical trials; • the insufficiency of data collected from clinical trials of our product candidates to support a BLA or other submission or to obtain regulatory approval; or • changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership . **Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties such as ongoing regulatory compliance and obligations .**

Even if we obtain regulatory approval for a product candidate, it will be subject to ongoing regulation by the FDA and comparable foreign, state and local regulatory authorities, including requirements governing the manufacture, quality control, further development, labeling, packaging, tracking, storage, distribution, safety surveillance, import, export, advertising, promotion, record keeping and reporting of safety and other post- market information. The FDA and other applicable foreign regulatory authorities continue to closely monitor the safety and effectiveness profile of any product even after approval. If we receive an approval, we will be required to submit periodic reports to the FDA and notify it of adverse events of which we become aware. If the FDA or other applicable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may, among other measures, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product' s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post- market surveillance. In addition, manufacturers of drug products and their facilities are subject to periodic inspections by the FDA and other regulatory authorities for compliance with cGMP. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Our advertising and promotion of any product candidate that obtains approval for marketing also will be subject to ongoing scrutiny by the FDA and other regulatory authorities in the United States and applicable international jurisdictions. If we or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or untitled letters; • conduct inspections, audits, inquiries, or investigations of us or our facilities or of our collaborators or their facilities; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • impose a consent decree, which can include various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to applications; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and

generate revenue. Advertising and promotion of any product candidate, even after it obtains approval in the United States, will be subject to scrutiny by the FDA. Violations of applicable requirements, including promotion of our product candidates prior to their approval, or promotion of our approved products for unapproved, or off- label, uses, may be subject to enforcement letters, inquiries and investigations, as well as civil and criminal sanctions. Additionally, comparable foreign regulatory authorities may scrutinize advertising and promotion of any product candidate both before and after it obtains approval in their respective jurisdictions. In the United States, engaging in the impermissible promotion of our products for off- label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which imposes civil penalties against individuals and entities for, among other things, knowingly presenting or causing to be presented, false or fraudulent claims for payment of government funds. Actions under the False Claims Act can be brought by the federal government or as a qui tam action by private individuals in the name of the government, who may receive a share of any judgments or settlement amounts. These False Claims Act lawsuits against pharmaceutical and biopharmaceutical companies have increased significantly in number and scope, leading to substantial civil settlements regarding certain sales practices, including promoting off- label uses. This growth in litigation has increased the risk that a pharmaceutical or biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, or agree to comply with burdensome reporting and compliance obligations in exchange for not being excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation, which would have a material adverse effect on our business, financial condition and results of operations. Promotion prior to marketing approval or for off- label uses may also give rise to criminal prosecution in the European Union. The FDA's and other applicable government agencies' policies may change, and additional laws or regulations may be enacted that could prevent, limit or delay regulatory approval, and thus the sale and promotion, of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may face regulatory scrutiny, enforcement action or other consequences, including loss of any marketing approval that we may have obtained, any of which could adversely affect our business, prospects and ability to achieve or sustain profitability. **Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates in those jurisdictions and hurt our prospects.** In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. 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. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, if regulatory approval for any of our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international markets and do not 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 countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline. **Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.** Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement and pricing of our product candidates by third- party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including: • the efficacy and safety profile as demonstrated in clinical trials; • the timing of market introduction of the product candidate as well as competitive products; • the clinical indications for which the product candidate is approved; • acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients; • the potential and perceived advantages of the product candidates, including relative to alternative treatments; • the cost of treatment, including in relation to alternative treatments; • the availability of coverage and adequate reimbursement and pricing by third- party payors, including government payors, and the willingness of patients to pay out- of- pocket in the absence of coverage by third- party payors; • convenience and ease of administration, including relative to alternative treatments; • the frequency and severity of adverse events; • the strength and effectiveness of our sales and marketing efforts; and • any unfavorable publicity relating to the product candidate. Our competitors may develop and market products or services that are less expensive, more effective, safer, otherwise regarded as preferable to, or that reach the market sooner, than our product candidates, which may diminish or eliminate the commercial success of any products or services we commercialize. The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current product candidates may face competition from major

pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide that have marketed drugs or are advancing product candidates to treat the same indications that we plan to treat or, in the case of competition or potential competition with our ActivMAB antibody discovery platform, that have marketed antibody discovery platforms or are advancing approaches that are an alternative to our ActivMAB platform. Many of our competitors have significantly greater financial, technical and human resources. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or antibody discovery platforms that are more effective, more convenient, more widely used or less costly or, in the case of drugs, have a better safety profile than our platforms or product candidates. These competitors may also be more successful than us in manufacturing and marketing their products and have significantly greater financial resources and expertise in research and development. Our competitors will also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We believe that our ability to successfully compete will depend on, among other things: • the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties; • the success, or perceived success, of our platform technologies; • the time it takes for our product candidates to complete clinical development and receive marketing approval; • the ability to commercialize any of our product candidates that receive regulatory approval; • the price of our drug products, including in comparison to branded or generic competitors; • the price of our services, including with respect to the terms on which we are willing to collaborate, including in comparison to other antibody discovery approaches or platform technologies; • whether coverage and adequate levels of reimbursement are available from private and governmental payors, including Medicare; • the ability to establish, maintain and protect intellectual property rights related to our product candidates or platform technologies; • the ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval; and • acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers or by patients. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable. **We may not be able to achieve continued observable effects or the benefits or synergistic effects of pepinemab in combination with other immunotherapies that we have observed in preclinical studies of pepinemab in combination with the anti-CTLA-4 antibody ipilimumab.** Based on our preclinical research, we believe that the combination of pepinemab with immunotherapeutic drugs, such as immune checkpoint inhibitors, could prove beneficial because pepinemab promotes infiltration of immune cells into a tumor. As such, we believe pepinemab could enhance the activity of other agents that increases peripheral immune responses. Most of the preclinical studies with respect to the combination of pepinemab with immunotherapies have involved the anti-CTLA-4 antibody ipilimumab. The results of these studies showed that pepinemab in combination with the CTLA-4 checkpoint inhibitor can greatly enhance the immune response to tumors by amplifying the benefits of this checkpoint inhibitor. However, while we have performed research with respect to pepinemab in combination with other immunotherapies, it is not clear that such combinations will have the same benefits or synergies demonstrated in animal models by the preclinical studies of pepinemab in combination with anti-CTLA-4 antibodies. Accordingly, we may not be able to generate adequate data to demonstrate the efficacy and safety in clinical trials of pepinemab in combination with other immunotherapies, which could result in significant setbacks in clinical trials and changes to our development plans. If future clinical trials do not produce favorable results, our ability to achieve regulatory approval for pepinemab may be adversely impacted. **We may need to develop or obtain additional capabilities, or enter into arrangements with third parties, to commercialize any product candidates that obtain regulatory approval, and we may encounter unexpected costs or difficulties in doing so.** We will need to obtain additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to enter into arrangements with third parties or add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. There can be no assurance that we will be able to enter into third-party commercialization or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third-party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively and / or in compliance with applicable legal and regulatory requirements. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses. We plan to conduct process development activities to support late-stage development and commercialization activities and seek approval of our product candidates. Should we not receive timely approval of our production process, our ability to produce the products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products if we are even able to generate revenues at all. **Even if we commercialize a product candidate, it or any other product candidates that we develop may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.** Our ability to commercialize any product candidates

successfully will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available from government health administration authorities, private health insurers and other organizations. The laws that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program. Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U. S. Department of Veterans Affairs, or the VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, U. S. Department of Defense, or DoD, the Public Health Service and U. S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results. **Current and future legislation may increase the difficulty and cost for commercialization of our product candidates and affect the prices we or our partners may obtain.** The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. In the United States, Medicare covers drug purchases by eligible beneficiaries through Medicare Part D and reimburses such purchases based on average sales prices for physician-administered drugs under Medicare Part B. Medicare cost reduction efforts, among other initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. While Medicare's practices apply only to drug benefits for its beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from Medicare may result in a similar reduction in payments from private payors. The Affordable Care Act significantly changed the way healthcare is financed by both governmental and private insurers. The Affordable Care Act and certain of its provisions have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, the Tax Act included a provision that repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, Congress has repealed certain Affordable Care Act-mandated fees, including the tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the Medicare statute, effective January 1, 2019, to increase the required manufacturer discount to 70% off the negotiated price for Medicare Part D beneficiaries in the coverage gap, commonly referred to as the "donut hole." Additional legislative changes to, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. We continue to evaluate the effect that the Affordable Care Act, as currently enacted or as it may be amended in the future, has on our business. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Congressional Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered automatic reduction to several government programs. In concert with subsequent legislation, this includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2029 unless Congress takes additional action. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been U. S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, and transparency measures. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in additional reductions in Medicare and other health care funding, more rigorous coverage

criteria, new payment methodologies and additional downward pressure on coverage, payment and the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. If we are able to successfully commercialize any of our product candidates and if we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to various government agencies. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non- federal average manufacturer price for the VA FSS pricing program. If we successfully commercialize any of our products and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. For example, if we are found to have knowingly submitted false average manufacturer price, average sales price, **the** best price, or non- federal average manufacturer price information to the government, or fail to timely submit such information, we may be liable for significant civil monetary penalties. The foregoing also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program

**. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates**

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for our products; • termination of clinical trial sites or entire trial programs; • injury to our reputation and significant negative media attention; • withdrawal of trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial subjects or patients; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition

**. Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, the violation of which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings**

Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements and interactions with third- party payors, patients and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following: • the federal Anti- Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, or any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal civil False Claims Act imposes liability, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • HIPAA' s fraud provisions impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters; • HIPAA also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payment Sunshine Act, implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, 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 CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as certain ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to items or services reimbursed by non- governmental third- party payors, including

private insurers; state and foreign 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 in those jurisdictions; state and foreign 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; some states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers, and others restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; other states and cities require identification or licensing of sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Further information about these laws is provided above in the "Government Regulation" section under the heading "United States Government Regulation — Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations." Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Although compliance programs can help mitigate the risk of investigations and prosecution for violations of these laws, the risks cannot be eliminated entirely. It is possible that governmental 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 our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Defending against actions or investigations for violations of these laws and regulations, even if ultimately successful, will incur significant legal expenses and divert management's attention from the operation of our business. Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which may result in penalties and liabilities under certain healthcare laws. Despite the implementation of cybersecurity measures that we believe provides adequate safeguards, our information technology and Internet based systems, including those of our current and future CROs and other contractors and consultants, are vulnerable to damage, interruption, or failure from computer viruses, unauthorized access, intrusion, and other cybersecurity incidents. As the majority of our workforce works remotely, we face heightened risks related to remote work, including strain on our information technology systems. Our information technology and Internet based systems have been in the past, and may be in the future, subject to attempts to gain unauthorized access, breach, malfeasance or other system disruptions, none of which have been material to us to date. In some cases, it is difficult to anticipate or to detect immediately such incidents and the damage caused thereby. Such incidents could result in the exposure of sensitive data including the loss of trade secrets, intellectual property, personal identifiable or sensitive information of employees, customers, partners, clinical trial patients, and others, leading to a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar cybersecurity incidents relating to their computer systems could also have a material adverse effect on our business. Certain data security breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U. S. federal and state law, and requirements of non- U. S. jurisdictions, and financial penalties may also apply. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. 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. We have adopted a code of business conduct and ethics, but 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 be in compliance 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 significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. **We depend on key personnel for our continued operations and future success and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.** To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, we are highly dependent on Dr. Maurice Zauderer, our founder and Chief Executive Officer. The loss of Dr. Zauderer, or one or

more of our other executive officers, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources and different risk profiles than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited. **We Risks Related to our Dependence on Third Parties** We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties, now or in the future, do not successfully carry out their contractual duties, comply with budgets and other financial obligations or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner. We rely, and expect to continue to rely, on third- party CROs to conduct preclinical and clinical trials. Because we rely on third parties to conduct clinical trials, we must rely on the efforts of others and cannot always control or accurately predict the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, we may be subject to potential enforcement by the FDA and analogous regulatory authorities in international jurisdictions for their failure to comply with applicable laws and regulations, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Furthermore, we expect to develop additional relationships with third- party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. Some of our CROs may have other rights to terminate their respective agreements with us, including for reasons such as: if it is determined that the safety of subjects participating in our clinical trials warrants such termination; if we make an assignment for the benefit of our creditors; or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third- party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms and / or in a timely manner. We depend on third- party manufacturers for the manufacture of drug substance and drug product for clinical trials as well as on third parties for our supply chain. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates, which could harm our results of operations. We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or finish- fill drug product for use in human clinical trials or for potential commercialization. Catalent Pharma Solutions, or Catalent, manufactures pepinemab for use in clinical trials according to the terms of a manufacturing agreement with us, and we use other third parties for other aspects of the manufacturing process. We have not contracted with alternate suppliers in the event the organizations we currently utilize, including Catalent, are unable to scale production, or if we otherwise experience any problems with them. If we encounter problems with any of them, including if they are unable to scale production or have problems at their facilities, and we are unable to arrange for alternative third- party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may be delayed in the development of our product candidates. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. **We may not succeed in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize product candidates.** In addition to our current research and development collaborations, a part of our strategy is to enter into additional research and development collaborations in the future, including collaborations with pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time- consuming and complex. Moreover, we may not succeed in our efforts to establish collaborations or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Moreover, if we fail to establish and maintain additional collaborations related to our product candidates: • the development of certain of our current or future product candidates may be terminated or delayed; • our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing; • we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;

and • we will bear all of the risk related to the development of any such product candidates. **Collaborations may require us to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.**

If we sign a collaboration agreement, license agreement or similar agreement with a collaborator to develop a product candidate, that collaborator may have certain rights to further the development of the product candidate, which could include the design and conduct of clinical trials, the preparation and filing of documents necessary to obtain regulatory approval, and the manufacturing, sale, marketing and other commercialization of the product if it obtains regulatory approval. Dependence on a corporate collaborator may subject us to a number of risks, including: • we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our product candidates, or to compliance with applicable legal and regulatory requirements; • collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing; • collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs; • collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products; • disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources; • collaborators may experience financial difficulties; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; • business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement; • collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and • collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates. **Risks Related to Intellectual Property**

**If we are unable to obtain, maintain or protect intellectual property rights, both in the U. S. and throughout the world, we may not be able to compete effectively in our market or globally.**

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to our inventions. We have also licensed from third party's rights to patents. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we licensed. The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and certain periodic maintenance and annuity fees following patent issuance. It is also possible that we or our licensors, licensees or collaborators will 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. Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution, and maintenance of patent applications and patents encompassing technology that we license from, or license to, third parties and in these circumstances are reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not at all times be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending, and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then such patent rights can only be enforced to the extent the issued claims cover the infringing technology. Additionally, in some countries, applicants are not able to protect methods of treating human beings or medical treatment processes. Countries such as India and elsewhere have enacted various rules and laws precluding issuance of patent claims covering methods a doctor may practice on a human being or any other animal to treat a disease or condition. Further, many countries have enacted laws and regulatory regimes that do not provide patent protection for methods of use of known compounds. In such countries and jurisdictions, only product claims may be obtained, and only when those products are new or novel. The lack of such patent protection may have a materially adverse effect on our business and financial condition. Furthermore, 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 those candidates receive regulatory approval and are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek patent term extensions where these are available

upon regulatory approval in those countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, but no more than fourteen years beyond the date of product approval, for a product that represents the first permitted commercial use of the active ingredient. However, the applicable authorities, including the USPTO and the FDA in the United States, and equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to reference our clinical and preclinical data and launch their products earlier than might otherwise be possible. Finally, our patent portfolio encompasses both issued patents and pending patent applications around the world in various jurisdictions, and the pending patent applications or issued patents encompassing each of the different technology areas may be assigned different relative and future values, either based on commercial relevance, patent position strength, patent coverage, claim scope, or any other variables associated with intellectual property. That is, some aspects of our patent portfolio, encompassing various aspects of our product candidates and platform technology, may be more valuable than other aspects of our patent portfolio. For example, the patents and patent applications encompassing the pepinmab technology may be of particular value to our company because they encompass specific product candidates and medical indications critical to the future of our business. Inability to obtain patents encompassing these critical technologies could more adversely impact our business than inability to obtain patents encompassing other aspects of our business. Thus, adverse events experienced within these specific patent portfolios could critically hamper our ability to commercialize and conduct business in these key technology areas. Globally, filing, prosecuting, enforcing and defending patents on product candidates and laboratory methods or platform technology in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, as noted above, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors or collaborators may not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' 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 or collaborators have patent protection, but where enforcement laws are not as protective as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals or laboratory platform technology, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or stop the marketing of products competing with our and our licensors' or collaborators' commercial efforts generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions requires significant financial resources and can divert our and our licensors' or collaborators' efforts and attention away from other critical aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly, and could place our and our licensors' or collaborators' patents at risk of not issuing. This could in turn provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other post- grant proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch, biosimilar versions of our products in many countries without conducting extensive clinical trials. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. **Changes in patent law and legal precedent concerning patents could diminish the value of patents in general, thereby impairing our ability to protect our product candidates**. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time- consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Patent legislation could increase the

uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in 2011 and many of its implementing regulations became effective in 2013. The Leahy-Smith Act includes a number of significant changes to U. S. patent law, including changing U. S. patent law to award a patent to the first inventor to file, rather than to the first to invent. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The changes in patent law due to the Leahy-Smith Act and its implementing regulations could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition. Additionally, the Leahy-Smith Act provides for various post-grant proceedings providing challengers various legal avenues and opportunities to challenge and invalidate any issued patents we may obtain in the United States. Thus, even when claims issue in patents in the United States, they are not invulnerable to attack, modification, and / or cancellation. New proposals continue to be announced in the U. S. Congress that aim to further change these laws, creating instability in both value and strength of U. S. patents, especially in the biotechnology field. Therefore, the Leahy-Smith Act, and any other follow-on laws that may be enacted in the United States represent a substantial risk in the valuation of our patent portfolio. For instance, legislation has been proposed that attempts to curb patent abuse by non-practicing entities that own patent rights. Such proposed legislation in the United States has included provisions making it substantially more expensive and riskier to litigate patent rights in the United States. Should any of these provisions be enacted in the United States that compromise patentees' abilities to enforce their patent rights, substantial uncertainty will surround our ability to enforce our patents in the United States without incurring substantial financial risk. We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, distracting, unpredictable, and unsuccessful, and therefore could have a materially adverse impact on the success of our business and financial condition. Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. Licensees or licensors may violate contractual agreements governing the practice of patented inventions. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. These legal proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators. Accordingly, despite our or our licensors' or collaborators' best efforts, we or our licensors or collaborators may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States, or in countries where enforcement is less robust due to local customs and underdeveloped enforcement protocols. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in a patent infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, in part or in whole, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patent claims do not encompass the putatively infringing technology in question. An adverse result in any litigation proceeding could place one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly. Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, post-grant review, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings in the United States or other jurisdictions instigated by third parties or brought by us or our licensors or collaborators may be necessary. For applications and granted patents not subject to the first to file provisions of the Leahy-Smith Act, interference proceedings may be initiated by the USPTO to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to obtain a license to the disputed technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or if the prevailing party offers no license at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates or platform technology. Even if we successfully defend such litigation or proceedings, they typically require substantial financial assets, and it may distract our management and other employees during such proceedings. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a materially adverse effect on the price of shares of our common stock. Third parties may initiate legal proceedings against us alleging that we or our employees infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain, and an adverse determination could have a materially adverse effect on the success of our business and financial condition. Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our

licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, post-grant reviews, inter partes reviews, or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license to the disputed technology on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. 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 product candidates or force us to cease some of our business operations, which could materially harm our business and financial condition. In addition, many of our employees, including our senior management, were previously employed at universities or in industry at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed assignment, proprietary right, non-disclosure, or non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of any third parties in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims, which could be costly and cause significant delays and could materially harm our business and financial condition. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, lose the services of key personnel, or sustain significant monetary damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management. **The terms of our patents may not be sufficient to effectively protect our drug candidates and business.** In most countries in which we file patent applications, including the U. S., the term of an issued patent is twenty years from the earliest claimed filing date of a non-provisional patent application in the applicable country. With respect to any issued patents in the U. S., we may be entitled to obtain a patent term extension or extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. Although such extensions may be available, the life of a patent and the protection it affords is by definition limited. Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging approximately from 2032 to 2044, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our technologies, platforms and product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that a related patent may expire before any particular product candidate can be commercialized or that such patent will remain in force for only a short period following commercialization, thereby reducing any significant advantage of the patent. If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U. S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of fourteen years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension due to, for example, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs. As a result, our ability to generate revenues could be materially adversely affected. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business. We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Certain of these license agreements provide us with the exclusive right

to practice technologies worldwide or in specific geographic regions. In addition, under certain of our existing licensing agreements, we are obligated to pay royalties on net product sales of our drug candidates once commercialized, pay a percentage of sublicensing revenues, make other specified payments relating to our drug candidates and / or pay license maintenance and other fees. We also have clinical development obligations under certain of these agreements that we are required to satisfy. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided in these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company- owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platforms and product candidates and the methods used to manufacture those platforms and product candidates. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our technologies, platforms and product candidates. Our inability to protect our confidential information and trade secrets would harm our business and competitive position. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach these agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position and our business.

**Risks Related to Our Securities**  
**Our Common Stock was delisted from trading on Nasdaq and is currently available for quotation on the OTCBK Market, which involves additional risks compared to being listed on a national securities exchange. Our ability to sell equity securities and the liquidity of the Common Stock will be adversely affected if we are unable to transfer our listing to another national securities exchange or, at minimum, a medium that offers greater liquidity than the OTCBK Market. The delisting of the Common Stock from the Nasdaq has materially and adversely impacted us in several ways, including, without limitation, by (i) reducing the liquidity and market price of the Common Stock; (ii) reducing the number of investors willing or able to hold or acquire the Common Stock, which will negatively impact our ability to raise equity financing; (iii) impairing our ability to provide equity incentives to its employees; (iv) impacting the Common Stock as it currently falls within the definition of a " penny stock," which would cause brokers trading the Common Stock to adhere to more stringent rules; (v) causing analysts to limit or stop coverage of the Common Stock; and (vi) limiting availability of market quotations for the Common Stock. Although our Common Stock is available for quotation on the OTCBK Market, the delisting of the Common Stock on Nasdaq limits the liquidity of the public trading market for our Common Stock. The lack of an active, liquid trading market for our Common Stock could have material adverse effects on our business, financial condition and future prospects due to, among other things, impairing the ability of holders of our Common Stock to sell their shares at the time they wish to sell them or at a price that they consider reasonable and reducing the trading liquidity and fair market value of the shares of the Common Stock, as well as our ability raise funds through the sale of equity or equity- linked securities that will be required to operate our existing and future businesses. The relatively low trading volume of our common stock may limit your ability to sell your shares. We have historically experienced a relatively low trading volume of shares a day. If our low trading volume continues in the future, holders of our shares may have difficulty selling shares of our common stock in the manner or at a price that they desire. Our common stock is subject to currently listed for trading on the penny stock rules, which makes Nasdaq Capital Market under the symbol " VCNX ". The continued listing of our common stock less liquid. The SEC has adopted a set of rules called the " penny stock rules " that regulate broker- dealers with respect to trading in securities with a bid price of less than \$ 5. 00. These rules do not apply to securities registered on certain national securities exchanges (including the Nasdaq Stock Market), provided that current price and volume information regarding transactions in such securities is provided by the exchange. Our stock is not listed on such an exchange and we have no expectation that our common stock will be listed on such an exchange in the future. The penny stock rules require a broker- dealer to deliver to the customer a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. Additionally, the broker- dealer must provide the customer with other information. The penny stock rules also require that, prior to a transaction in a penny stock, the broker- dealer must determine in writing that the penny stock is a suitable investment for the purchaser. The broker- dealer must also**

receive the purchaser's written agreement to the transaction. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for a stock such as ours that is subject to our compliance with a number of listing standards, including Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of \$ 2.5 million in stockholders' equity (the **penny stock rules. The Series A Preferred Stock ranks senior** "Equity Standard") or the alternative requirements of having a market value of listed securities of \$ 35 million or net income from continuing operations of \$ 500,000 in the most recently completed fiscal year or two of the last three most recently completed fiscal years (the "Alternative Standards"). In October 2023, Nasdaq informed us that if we fail to evidence compliance with the Equity Standard or the Alternative Standards upon the filing of this Annual Report on Form 10-K, we may be subject to delisting. If Nasdaq staff notifies us that we are subject to delisting, we will be permitted to appeal Nasdaq staff's determination to a hearings panel. Our stockholders' deficit as of December 31, 2023 was \$ 2.3 million and as such, we expect that Nasdaq will find we are not in compliance with the Equity Standard under Listing Rule 5550(b)(1). We do not meet the requirements of the Alternative Standards. As such we anticipate the Listing Qualifications Staff of Nasdaq will notify us that we no longer meet the requirements of Nasdaq Listing Rule 5550(b)(1). Upon notice from Nasdaq of noncompliance with Listing Rule 5550(b)(1), we may be granted 45 calendar days from the date of any notification letter to submit a plan to regain compliance with the Equity Standard (the "Compliance Plan"), and while there is no certainty we will be granted additional time, we may receive a compliance period, typically of no more than 180 days, to regain compliance with the Equity Standard. If the Company fails to regain compliance with the Nasdaq continued listing standards, after any compliance period, if granted, Nasdaq will provide notice that the Company's common stock **with respect to rights on the distribution of assets upon liquidation, dissolution and winding up. The Series A Preferred Stock has a liquidation preference before our common stockholders equal to the greater of (i) \$ 175,000 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock (the "Original Share Price"), plus any accrued but unpaid dividends thereon, whether or not declared, together with any other dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. As of December 31, 2024, the holder of the shares of Series A preferred stock were entitled to a liquidation preference of \$ 1.75 million, in the event of any liquidation, dissolution or winding up of the Company. Further, upon the occurrence of Deemed Liquidation Event (generally defined to include certain fundamental transactions involving the Company including a merger or sale of substantially all of the Company's assets) or other liquidation of the Company, the holders of the Series A Preferred Stock will receive a distribution of the Company's assets per their liquidation preference before any holders of common stock receive a distribution. As a result, in the event of a liquidation of the Company the proceeds received by the common stockholder may be reduced. Shares of common stock issuable upon conversion of our Series A Preferred Stock will be subject dilutive to our delisting- existing stockholders upon conversion and adversely**. A delisting or even notification of failure to comply with such requirements would likely have a negative effect affect on the market price of our common stock. **As of December 31, 2024, we had outstanding 10 shares of Series A Preferred Stock with and- an** would impair your ability to sell or purchase our **aggregate liquidation preference of \$ 1.75 million. The Series A Preferred Stock are presently convertible into shares of** common stock when you wish to do so. In addition, the delisting of our common stock could lead to a number of other-- **the** negative implications **conversion of** such **would** as a loss of media and analyst coverage, a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and likely result in **immediate dilution** a reduced level of trading activity in the secondary trading market for our securities, and materially adversely impact our ability to raise capital on acceptable terms or at all. Delisting-- **existing holders** from Nasdaq could also have other negative results, including the potential loss of confidence by our current or prospective third-party providers and collaboration partners, the loss of institutional investor interest, and fewer licensing and partnering opportunities. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. If our common stock were no longer listed on Nasdaq, investors might only be able to trade on one of the over-the-counter markets, if at all. There is no assurance that prices for our common stock would be quoted on one of these other trading systems or that an active trading market for our common stock would exist, which would materially and adversely impact the market value of our common stock and your ability to sell our common stock. Certain of our management, including our chief executive officer, chairman of our board, and their affiliates, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. **As Certain of March 22, 2024, our management, including our chief executive officers- officer and directors, chairman of our board, and their respective affiliates beneficially, owned-- own a significant percentage** approximately 51.5% of our outstanding common stock **and will be able to exert significant control over matters subject to stockholder approval**, including Albert D. Friedberg, our Chairman, who beneficially owned 39.9% of our outstanding common stock, including 38.5% of our outstanding common stock beneficially owned by FCMI Parent. As a result, these stockholders have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the

prevailing market price for our common stock. These large affiliate holdings may also contribute to a lack of liquidity in our stock. Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. We may also seek additional funding through government or other third-party funding and other collaborations, strategic alliances and licensing arrangements. These financing activities may have an adverse impact on our stockholders' rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it may result in dilution to our existing stockholders and / or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects. We are subject to the periodic reporting requirements of the Exchange Act. We designed 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. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. 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.