Risk Factors Comparison 2025-03-17 to 2024-03-21 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this report, including the consolidated financial statements, the notes thereto and the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " included elsewhere in this report before deciding whether to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our common stock and / or Warrants could decline, and you could lose part or all of your investment. Summary of Risks Associated with Our Business Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled " Risk Factors " immediately following this summary. Some of these risks include: · We are a pre- revenue company with a limited operating history; · We may not be able to successfully develop or commercialize our product candidates or do so on a timely or cost- effective basis; · Our business may be negatively affected by the impacts of public health emergencies, epidemics and pandemics ~~, such as COVID- 19~~ ; · We depend on a limited number of product candidates and our business could be materially adversely affected if one or more of our key product candidates do not perform as well as expected and do not receive regulatory approval; · The market for our product candidates, including ~~DMT 310~~ **XYNGARI ™** and DMT 410, may not be as large as we expect; · Our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business; · We may experience failures of or delays in clinical trials which could jeopardize or delay our ability to obtain regulatory approval and commence product sales; · We face intense competition from both brand and generic companies which could limit our growth and adversely affect our financial results; · We are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations; · We may not be able to develop or maintain sales capabilities or effectively market or sell any products that we may successfully commercialize; · Manufacturing or quality control problems may damage our reputation, require costly remedial activities, or otherwise negatively impact our business; · Our profitability will depend on coverage and reimbursement by third- party payors, and healthcare reform and other future legislation may lead to reductions in coverage or reimbursement levels; · We currently, and may in the future need to, license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms; · We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop, manufacture and market our products and product candidates; · The raw material for our product candidates, ~~DMT310~~ **XYNGARI ™** and DMT410, is derived from naturally occurring ~~ingredients~~ **ingredient** that grow only in limited areas that need to be harvested annually. Due to unforeseen environmental conditions or circumstances, our supplier may not be able to harvest as much raw material as we require, or any at all, which may negatively impact our ability to conduct preclinical studies, clinical trials, and ultimately commercialize our product candidates; ~~42~~ · We currently rely on a third party for the raw materials needed for ~~DMT310~~ **XYNGARI ™** and DMT410, and if we encounter any difficulties in accessing or procuring alternative sources on acceptable terms, or at all, our business may suffer; · Our current licensed patents covering ~~DMT310~~ **XYNGARI ™** expired between 2022 and 2023, which was prior to our anticipated date for any market launch. While we have been issued patents covering **XYNGARI ™ and** DMT410 in certain jurisdictions, other of our current pending patents covering ~~DMT310~~ **XYNGARI ™** and DMT410 have not been issued yet and there is no guarantee they will get issued. We may not be able to obtain additional patent coverage, which could limit our market opportunity due to competition from other products; · If we fail to comply with our obligations under any of our third- party agreements, we could lose license rights that are necessary to develop our product candidates; · Our directors, executive officers and certain stockholders (one of which is an affiliate of our Chief Executive Officer) own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant control over matters subject to stockholder approval; and · We will need to add personnel, which will increase the size and complexity of our organization and we may experience difficulties executing growth and corporate strategies. ~~Risks~~ **41Risks** Related to Our Financial Position and Need for Capital We are a clinical stage pharmaceutical company with a limited operating history. We are a clinical- stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We must complete clinical studies and receive regulatory approval before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early- stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital- intensive business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early stage clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things: · successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound; · successfully

complete the clinical trials, non- clinical testing and other requirements necessary to obtain regulatory approval for the marketing of our drug candidates, including ~~DMT310~~ **XYNGARI ™** and DMT410; · successfully manufacture our clinical products and establish commercial drug supply; · secure, maintain and, as necessary, defend our intellectual property rights; · secure market exclusivity and / or adequate intellectual property protection for our drug candidates; · attract and retain an experienced management and advisory team; · secure acceptance of our drug candidates in the medical community and with third- party payors and consumers; · launch commercial sales of our drug candidates, whether alone or in collaboration with others; ~~43~~ · comply with post- marketing regulatory requirements; · raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and · utilize the funds that we have and may raise in the future to efficiently execute our business strategy. ~~If~~ **42If** we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected. We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. We have never generated revenue from operations, are unlikely to generate revenues for several years, and are currently operating at a loss and expect our operating costs will increase significantly as we incur costs related to preclinical development, the clinical trials for our drug candidates and to operating as a public company. We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. We have incurred losses in each year since we commenced operations in December 2014. We incurred net losses of approximately $ ~~7~~ **12** . ~~8~~ **3** million and approximately $ ~~9~~ **7** . ~~6~~ **8** million for the years ended December 31, **2024, and** 2023 ~~, and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of approximately $ ~~53~~ **65** . ~~4~~ **7** million. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. Revenue from our current and potential future collaborations is uncertain because milestones or other contingent payments under our agreements may not be achieved or received. As of December 31, ~~2023~~ **2024** , we had capital resources consisting of cash and cash equivalents of $ ~~7~~ **3** . ~~4~~ **2** million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical studies for our product candidates will require substantial funds to complete. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our securities and our ability to raise capital. We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates. We believe that our existing cash, together with interest thereon, will be sufficient to fund our operations into the third quarter of ~~2024~~ **2025** . We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Our currently anticipated expenditures for the development of our product candidates, ~~DMT310~~ **XYNGARI ™** and DMT410, exceed our existing cash. We will need to raise additional capital to fund our operations and continue to support our planned development and commercialization activities. ~~44The~~ -- **The** amount and timing of our future funding requirements will depend on many factors, including: · the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in- license or acquire; · the results of the clinical trials for our product candidates in the United States and any foreign countries; · the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all; · the number and characteristics of any additional future product candidates we develop or acquire; · our ability to establish and maintain strategic collaborations, licensing, co- promotion or other arrangements and the terms and timing of such arrangements; · the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs; · the degree and rate of market acceptance of any approved products; · costs under our third- party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize; · costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish; **43** · costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates; · costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation; · costs associated with any product recall that could occur; · costs of operating as a public company; · the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments; · costs associated with any acquisition or in- license of products and product candidates, technologies or businesses; and · personnel, facilities and equipment requirements. We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material

adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited. ~~45Raising~~ **We will need to raise** additional capital **which** may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates **, and additional capital may not be available on favorable terms or at all which may force us to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. To develop and bring our product candidates to market, we must commit substantial resources to costly and time- consuming research, preclinical studies and clinical trials and marketing activities** . Until such time, if ever, as we can generate substantial **product** revenue, we **expect to seek additional funding to meet our operational needs and capital requirements. While we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2025, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect, including if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. Our requirements for additional capital will depend on** ~~may~~ **many factors including: 44 · changes in direction of our research and development programs ; · the time and expense for preclinical studies and clinical trials for our product candidates ; · the time and costs involved in obtaining regulatory approval for our product candidates ; · the cost increases and other potential impacts of macroeconomic factors, including heightened inflation and rising interest rates, liquidity concerns at and failures of banks and other financial institutions, exchange rate fluctuations, tariffs, trade wars, supply chain disruptions and increases in commodity, energy and fuel prices, costs associated with protecting our intellectual property rights ; · successful commercialization of our product candidates ; · competitive and technical advances ; · patent development or regulatory changes ; · development of marketing and sales capabilities ; · payments received under current and future collaboration agreements, if any ; and · market acceptance of our products. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If additional sources of financing are not available on favorable terms, or at all, including as a result of actions taken by central banks to counter inflation, volatility in the capital markets, liquidity concerns at and failures of banks and other financial institutions and related market uncertainty, or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, management may need to curtail our development efforts and planned operations to conserve cash. 45We expect to** finance our **operations** ~~cash needs~~ through a combination of equity offerings, debt financings, ~~marketing and distribution arrangements and other~~ **government or private party grants,** collaborations, strategic alliances and licensing arrangements **. We currently have on file with the SEC a shelf registration statement on Form S- 3 which allows us to offer and sell** ~~or~~ **our registered common stock, preferred stock, debt securities and or warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. On June 7, 2024, we entered into an At The Market Agreement (the " ATM Agreement ") with H. C. Wainwright & Co., LLC (" Wainwright "), pursuant to which, from time to time, we may offer and sell shares of the common stock registered under the shelf registration statement pursuant to one or more " at the market " offerings. As of December 31, 2024, we have sold $ 1. 7 million in gross proceeds of our Common Stock pursuant to this ATM Agreement, which does not include $ 0. 3 million of compensation to Wainwright, auditors, lawyers, and** other ~~sources~~ **administration fees. While we had no remaining capacity to sell shares of common stock under the ATM Agreement as of December 31, 2024, to the extent we have any capacity in the future, any future sales of our common stock under the ATM Agreement with Wainwright could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations. To the extent additional capital is raised through the sale and issuance of shares or other securities convertible into shares, the ownership interest of our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock** . We do not currently have any **other** committed external ~~source~~ **sources** of funds. ~~In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.~~ To the extent ~~that~~ we raise additional capital through the sale of equity or convertible debt securities, ~~your~~ **our stockholders'** ownership interest will **or could** be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect ~~your~~ **our stockholders'** rights as a common stockholder **. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities** . Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions ~~,~~ such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, ~~intellectual property,~~ future revenue streams or product candidates ~~or~~ **,** grant licenses on terms that may not be favorable to us ~~. If we are unable to raise additional funds through equity~~ or **commit**

~~debt financings when needed, we may be required~~ to ~~delay, limit, reduce or terminate product candidate development or~~ future ~~commercialization efforts~~ **payment streams** . The reports of our independent registered public accounting ~~firms~~ **firm** for the fiscal years ended December 31, **2024 and** 2023 ~~and 2022 each~~ contain an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Due to the uncertainty of our ability to meet our current operating and capital expenses, in their reports on our audited annual financial statements as of and for the years ended December 31, ~~2023~~ **2024** , and December 31, ~~2022~~ **2023** , our independent audit ~~firms~~ **firm** included **an** explanatory ~~paragraphs~~ **paragraph** regarding concerns about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and ~~Warrants~~ **warrants** and we may have a more difficult time obtaining financing. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations. Changes in tax laws may materially adversely affect our business financial condition, results of operations and cash flows. We are subject to tax laws, regulations and policies of the jurisdictions in which we do business, which may include U. S. federal, state, and local governments and taxing authorities in foreign jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and otherwise adversely affect our tax positions and / or our tax liabilities. The income tax rules in the jurisdictions in which we operate are constantly under review by taxing authorities and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We are unable to predict what tax proposals may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall effective tax rates in the future in jurisdictions where we have operations, and increase the complexity, burden and cost of tax compliance. ~~We~~ **46We** are exposed to risks related to foreign currency exchange rates. Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our supply of our raw material for our ~~DMT310~~ **XYNGARI ™** and DMT410 product candidates. When the United States dollar weakens against the Euro, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the Euro, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations . 46Risks Related to Development, Regulatory..... and commercialize our programs and product candidates . Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations. Disruptions to the global economy may impede global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations. ~~47Furthermore~~ **Furthermore** , inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected. Adverse global conditions, including economic uncertainty, may negatively impact our financial results. Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States as a result of tax reform or changes to existing trade agreements or tax conventions, may adversely impact our business. In addition, the global macroeconomic environment could be negatively affected by, among other things, public health emergencies, pandemics or epidemics, instability in global economic markets, increased U. S. trade tariffs and trade disputes with other countries **and any resulting trade wars** , instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, ~~Hamas' attack on Israel and~~ the ~~resulting~~ **ongoing** ~~conflict~~ **conflicts in the Middle East** , and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets. **Risks Related to Development, Regulatory Approval and Commercialization** Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular ~~DMT310~~ **XYNGARI ™** and DMT410. Our portfolio of product candidates includes one late- stage product candidate, ~~DMT310~~ **XYNGARI ™** , a once weekly topical, naturally derived product candidate for the treatment of acne and psoriasis, and an early- stage candidate, DMT410, a combination treatment regimen to aid in the topical delivery of botulinum toxin for the treatment of hyperhidrosis and aesthetic skin conditions. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization or partnering of our product candidates. In the future, we may also become dependent on just one of our product candidates or any future product candidates that we may in- license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following: **47** · the ability to raise additional capital on acceptable terms, or at all; · timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party contractors; · whether we are required by the U. S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates; · acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

· our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates; · our ability to develop a suitable drug product release assay; · our ability to identify an active compound within the drug product that can be detected in a pharmacokinetics study; · the prevalence, duration and severity of potential side effects experienced in connection with our product candidates or future approved products, if any; ~~48~~ · the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities; · achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any; · the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP, or good agricultural and collection practices, or GACP; · a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates; · our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others; · acceptance by physicians, patients and payors of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments; · our ability to comply with numerous post- approval regulatory requirements; · our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; · our and our partners' ability to avoid third- party patent interference or intellectual property infringement claims; and · our ability to in- license or acquire additional product candidates or commercial- stage products that we believe we can successfully develop and commercialize. ~~If~~ **48If** we are unable to achieve one or more of the above factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays and increased costs or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue operations. Clinical drug development for our product candidates is very expensive, time- consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization. Clinical drug development for our product candidates is very expensive, time- consuming, difficult to design and implement and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication, which is impossible to predict. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. Our product candidates are in various stages of development and a failure of one more clinical trials can occur at any stage of testing or at any time during the trial process. We expect that clinical trials for these product candidates will continue for several years, but may take significantly longer than expected to complete. ~~49We~~ **We** have not completed all clinical trials for the approval of any of our product candidates. In previous communications with the FDA they had asked us to show that hydrogen peroxide was not an active ingredient in our ~~DMT310~~ **XYNGARI ™** product. While FDA did not require us to test hydrogen peroxide as a third arm in our current ~~DMT310~~ **XYNGARI ™** Phase 3 clinical program, they may ask for additional evidence to support our belief that hydrogen peroxide is not an active ingredient in our ~~DMT310~~ **XYNGARI ™** product. If we fail to convince the FDA that hydrogen peroxide is not an active ingredient and merely a fluidizing agent, then we may have to alter our clinical plans or reformulate our product based on FDA feedback. If we chose to reformulate our lead product candidate, ~~DMT310~~ **XYNGARI ™**, then we may decide to redo our Phase 2 and Phase 3 studies, which would be time consuming and expensive and there is no certainty of success. We may experience delays in ongoing and future clinical trials for our product candidates and do not know if future clinical trials, if any, will begin on time, need to be redesigned, enroll adequate number of patients on time or be completed on schedule, if at all. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including: · discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, experienced by study participants or other safety issues; · lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints; · slower than expected rates of subject recruitment and enrollment rates or inability to enroll a sufficient number of patients in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment; · delays or difficulties in our clinical trials due to quarantines or other restrictions resulting from public health emergencies, epidemics, and / or pandemics ~~, such as the COVID- 19 pandemic~~ ; · difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason; · difficulty in obtaining IRB approval for studies to be conducted at each clinical trial site; · delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials; · difficulty or inability to find a partner that will allow us to test their product for our DMT410 program; · inadequacy of or changes in our manufacturing process or the product formulation or method of delivery; ~~50~~ **49** · changes in applicable laws, regulations and regulatory policies; · delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third- party contractors; · inability to add a sufficient number of clinical trial sites; · uncertainty regarding proper formulation and dosing; · failure by us, our employees, our CROs or their employees or other third- party contractors to comply with contractual and applicable regulatory requirements or to perform

their services in a timely or acceptable manner; · failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products; · scheduling conflicts with participating clinicians and clinical institutions; · failure to design appropriate clinical trial protocols; · insufficient data to support regulatory approval; · inability or unwillingness of medical investigators to follow our clinical protocols; or · difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data. In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient, or API, through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. As a result, safety and efficacy can be difficult to establish. The topical route of administration may involve new formulations and dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the API for ~~DMT310~~ **XYNGARI ™** is a milled sponge powder, and we are not aware of previous FDA approvals of sponges as a prescription drug. We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed ~~of success by eliminating one way in which the government previously prevailed in such cases~~ . ~~As a result~~ **46Risks Related to Development** , ~~significant regulatory~~ **Regulatory Approval** ~~policies could be subject to increased litigation~~ and **Commercialization** ~~judicial scrutiny.We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the pharmaceutical industry,or the regulatory agencies that oversee the pharmaceutical industry,will affect our business.~~ We face risks related to public health emergencies,epidemics and other outbreaks of communicable diseases, **such as the coronavirus (COVID- 19) pandemic,** which could significantly disrupt our operations,including our clinical trials and preclinical studies,and adversely affect our business and results of operations.Public health crises **,such as the COVID- 19 pandemic or similar outbreaks** ,could have an adverse effect our business.Quarantines,travel restrictions and other public health and safety measures implemented in response to a pandemic,including a resurgence of COVID- 19,could adversely impact our operations,and the ultimate impact is highly uncertain and cannot be predicted with confidence.Effects of a pandemic,including a resurgence of COVID- 19,that may delay or otherwise adversely affect our ongoing and planned preclinical activities,our planned clinical trials as well as our business generally,include:· delays related to disruptions at CROs and contract manufacturers,or in the supply chain;· delays in receiving approval from regulatory authorities to initiate our planned clinical trials;· delays or difficulties in clinical site initiation,including difficulties in recruiting clinical site investigators and clinical site staff who,as healthcare providers,may have heightened exposure;· delays or difficulties in enrolling and retaining patients in clinical trials;· delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;· difficulties interpreting data from clinical trials;· diversion of healthcare resources away from the conduct of clinical trials;· interruption of key clinical trial activities,such as clinical trial site monitoring,due to limitations on travel imposed or recommended by federal or state governments,employers and others;· interruption or delays in the operations of the FDA or other regulatory authorities,which may impact review and approval timelines;and interruptions,difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely **,including those hired during the COVID- 19 pandemic** . ~~51Any~~ -- **Any** of these effects,and other effects of a pandemic,including a resurgence of COVID- 19,could have a material adverse effect on our business,financial condition,results of operations and prospects.Further,uncertainty around these and related issues could lead to adverse effects on the economy of the United **States,Canada,and other economies,which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates** . Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials. Approval may be delayed or denied because we cannot satisfy FDA' s Chemistry, Manufacturing and Control Requirements. Formulation and manufacturing of drugs is another important step in development. Our applications must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA' s current Good Manufacturing Practices (" cGMP ") requirements. The manufacturing process must consistently produce quality batches of the product, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our product candidates may be delayed or denied. ~~51We~~ **We** may be unable to obtain regulatory approval for ~~DMT310~~ **XYNGARI ™** , or our other early- stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing,

manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post- market information related to our drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of a new drug application, or NDA, or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we or our partners receive the requisite approval from the applicable regulatory authorities of such countries. ~~To~~ **52To** gain approval to market a new drug such as ~~DMT310~~ **XYNGARI ™** or DMT410, the FDA and / or foreign regulatory authorities must receive, among other things, preclinical and clinical data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the drug product for the intended indication applied for in an NDA, or other applicable regulatory filing. The development and approval of a product derived from a natural source and new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in nonclinical development, clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in clinical trials does not ensure that later clinical trials will be successful, or that nonclinical studies will be successful. The results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct. For example, for ~~DMT310~~ **XYNGARI ™**, the results of our Phase 2a and Phase 2b clinical trials may not accurately predict results of the ongoing Phase 3 clinical trials that have a larger number of patients. Nor will the human safety data collected from our Phase 2a and Phase 2b clinical trial predict the outcome of our pharmacokinetic plan. The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may: · disagree with the design or implementation of one or more clinical trials; · not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate' s safety or other perceived risks to outweigh its clinical or other benefits; · not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval; · disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate; · determine the data collected from clinical trials may not be sufficient to support the submission of an NDA, or other applicable regulatory filing; · require additional preclinical studies or clinical trials; ~~52~~ · identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates; · require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug- sensitive population; · grant approval contingent on the performance of costly additional post- approval clinical trials; · approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability; · not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates; · not approve of the manufacturing processes, controls or facilities of third- party manufacturers or testing labs with which we contract; · consider our products a device instead of a drug requiring a different approval process and manufacturing needs; · consider one of our products a combination product instead of a singular drug requiring additional clinical trials or increased number of patients per study, or · change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval. ~~There~~ **53There** have been only three products approved by the FDA under the botanical guidance. Each of these products' active ingredient was derived from the extract of a plant (s). Further, ~~neither~~ **none** of the products were approved for the indication of acne ~~vulgaris~~. While freshwater sponges, such as Spongilla, are technically animals, FDA has allowed us to reference the botanical guidance for raw material quality control relating to the manufacturing of the drug product. We do not know how any other regulatory authority will treat ~~DMT310~~ **XYNGARI ™** for their approval process. In addition, the FDA or other regulatory authorities may change their policies, issue additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Any delay, limitation or denial in any applicable regulatory approval for any of our product candidates would delay or adversely impact commercialization of our product candidates and would harm our business, financial condition, operating results and prospects. We have ~~initiated~~ **completed enrollment of** our first Phase 3 clinical trials for ~~DMT310 and~~ **XYNGARI ™, but that does not guarantee successful completion. We** may be unable to successfully complete it or any future clinical trials. The conduct of a Phase 3 clinical program is a complicated process. Although members of our management team have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company have not conducted a Phase 3 clinical trial before, and as a result may require more time and incur greater costs than we anticipate. Failure to include the correct treatment regimen, complete, or delays in, our Phase 3 clinical trials, could prevent us from or delay us in commencing future clinical trials for ~~DMT310~~ **XYNGARI ™**, obtaining regulatory approval of and commercializing our product candidates, which would adversely impact our financial performance. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as ~~DMT310~~ **XYNGARI ™**, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. ~~53Patient~~ -- **Patient** enrollment is affected by other factors including: · the severity of the disease under investigation; · the eligibility criteria for the study in question; · the perceived risks and benefits of the product candidate under study; · the efforts to facilitate timely enrollment in clinical trials; · the patient referral practices of physicians; · he ability to monitor patients adequately during and after treatment;

· the proximity and availability of clinical trial sites for prospective patients; and · factors we may not be able to control, such as potential pandemics that may limit subjects, principal investigators or staff or clinical site availability (e. g., ~~the outbreak~~ **a resurgence** of COVID- 19). ~~We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. 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 drug candidates and our business would be substantially harmed. We expect to enter into agreements with third- party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Even~~ **54Even** if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians, patients and payors for approved indications, and may not be commercially successful. The degree and rate of adoption of our current or future product candidates, if approved, will depend on a number of factors, including: · the clinical indications for which the product is approved and patient demand for approved products that treat those indications; · the effectiveness of our product as compared to other available therapies; · the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved; · the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients; · acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment; · physician and patient willingness to adopt a new therapy, including for ~~DMT310~~ **XYNGARI ™**, a sponge product, over other available therapies to treat approved indications; · patients' perception of a product derived from a freshwater sponge as one for which will provide medical treatment; · overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications; ~~54~~ · proper training and administration of our product candidates by physicians and medical staff; · patient satisfaction with the results and administration of our product candidates and overall treatment experience; · the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times; · the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies; · the prevalence and severity of any side effects of our product candidates; · limitations or warnings contained in the FDA- approved labeling for our product candidates; · any FDA requirement to undertake a risk evaluation and mitigation strategy, or REMS; · the effectiveness of our sales, marketing and distribution efforts; · our ability to maintain sufficient quantities of supply to meet demand; · adverse publicity about our product candidates or favorable publicity about competitive products; and · potential product liability claims. ~~If~~ **55If** any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business. We intend to seek NCE exclusivity for ~~DMT310~~ **XYNGARI ™** and future product candidates, and we may be unsuccessful in obtaining such exclusivity. As part of our business strategy, we intend to seek new chemical entity, or NCE, exclusivity for ~~DMT310~~ **XYNGARI ™** or future

product candidates. In the United States, a pharmaceutical manufacturer may obtain five years of non- patent exclusivity upon NDA approval of an NCE which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An " active moiety " is defined as the molecule or ion responsible for the drug substance' s physiological or pharmacologic action. During the five- year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505 (b) (2) NDA for the same active moiety and that relies on the FDA' s findings regarding that drug, except that FDA may accept an application for filing after four years if the follow- on applicant makes a paragraph IV certification. This exclusivity period may be extended by an additional six months if certain requirements are met to qualify the product for pediatric exclusivity, including the receipt of a written request from the FDA that we conduct certain pediatric studies, the submission of study reports from such studies to the FDA after receipt of the written request and satisfaction of the conditions specified in the written request. We believe that ~~DMT310~~ **XYNGARI ™** constitutes an NCE and should be eligible for NCE exclusivity. However, we may be unable to successfully obtain such exclusivity, and if any of our competitors obtains FDA approval of an NDA for a similar drug product before we do, they, and not us, may be eligible for NCE exclusivity. If we do not obtain NCE exclusivity for ~~DMT310~~ **XYNGARI ™**, or if a competitor obtains NCE exclusivity for a similar product before we submit and receive approval of an NDA for ~~DMT310~~ **XYNGARI ™**, our ability to commence sales and generate revenue would be adversely affected. ~~55Our~~ -- **Our** product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous pharmaceutical companies, generic drug companies, biotechnology companies, cosmetic companies and academic and research institutions are engaged in the development, patenting, manufacturing and marketing of health care products competitive with those that we are developing, including but not limited to **LEO Pharma, Journey Medical,** VYNE Therapeutics ~~, Cassiopea~~, Galderma, Sun Pharmaceuticals Ltd., Sol- Gel, Arcutis Biotherapeutics, Arena Pharmaceuticals, Amgen, AbbVie, Bristol Meyers Squib ~~, Lilly, Nestle~~, Pfizer, and others. Many of our competitors have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long- term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over- the- counter treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved, off- label, and over the counter treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects. For more information about the competition we face, see " Business — Competition. " Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States. We expect to face generic or similar type of product competition for our product candidates, which could adversely affect our business, financial condition, operating results and prospects. Upon the expiration or loss of any patent protection for any of our product candidates that are approved, or upon the " at- risk " launch, despite pending patent infringement litigation against the generic product or its equivalent, by a generic competitor of a generic version of any of our product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects. ~~It~~ **56It** is unknown how the FDA or any regulatory authority will view an attempted generic version of ~~DMT310~~ **XYNGARI ™** because it is derived from a natural material that refers to principles of the botanical guidance. There are no currently approved generic versions of a natural product on the market and no FDA guidelines on the approval process for a generic version of a natural product. Therefore, it is unknown how difficult it will be for a generic version of a natural product to be approved for commercial sale in the United States. It is unclear whether the FDA will view Spongilla lacustris or a similar sponge species that is harvested from a different location than ~~DMT310~~ **XYNGARI ™** raw material is harvested as identical to ~~DMT310~~ **XYNGARI ™** raw material and therefore could follow the generic pathway to approval. ~~56Any~~ -- **Any** product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review. Even after we or our partners achieve U. S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate' s approval may contain requirements for potentially costly post- approval studies and surveillance, including Phase 4 clinical trials or a REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include

submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP requirements, with the FDA' s good clinical practice, or GCP, or good agricultural and collections practices, or GACP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post- approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries. If we, our partners, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: · impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses; · mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; · require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; · issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available; · commence criminal investigations and prosecutions; · impose injunctions, suspensions or revocations of necessary approvals or other licenses; · impose other civil or criminal penalties; · suspend any ongoing clinical trials; · delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners; · refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States; · suspend or impose restrictions on operations, including costly new manufacturing requirements; or · seize or detain products or require us or our partners to initiate a product recall. ~~The~~ **57The** regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post- approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability. ~~57We~~ **We** may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials. We **are currently and** may in the future choose to conduct one or more of our clinical trials outside the United States, including in Canada, Europe and South America. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U. S. population and U. S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan. Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post- approval regulatory action. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects. Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U. S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including: · regulatory authorities may withdraw their approval of the product; · regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product; · regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies; · we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS; · we may have limitations on how we promote the product; · we may be required to change the way the product is administered or modify the product in some other way; the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post- marketing testing and surveillance to monitor the safety or efficacy of the product; · the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post- marketing testing and surveillance to monitor the safety or efficacy of the product · sales of the product may decrease significantly; · we could be sued and held liable for harm caused to patients; and · our brand and reputation may suffer. 58Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates. We may

face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: · withdrawal of clinical trial participants; · termination of clinical trial sites or entire trial programs; · inability to gain regulatory approval of our product candidates; · the inability to commercialize our product candidates; · decreased demand for our product candidates; · impairment of our business reputation; · product recall or withdrawal from the market or labeling, marketing or promotional restrictions; · substantial costs of any related litigation or similar disputes; · distraction of management' s attention and other resources from our primary business; · substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or · loss of revenue. 59We currently maintain product liability insurance coverage, which may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects. If any of our product candidates are approved for marketing and we are found to have improperly promoted off- label uses, or if physicians misuse our products or use our products off- label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed. The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off- label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off- label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management' s attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off- label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off- label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician' s independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients. We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates. At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. ~~60For~~ -- **For** example, on December 5, 2022, we announced topline results from our Phase 2 trial of once- weekly topical application of ~~DMT310~~ **XYNGARI ™** for the treatment of moderate- to- severe rosacea. While the data was supportive of ~~DMT310~~ **XYNGARI ™** as a treatment for inflammatory skin diseases, the rosacea study did not meet its primary endpoints. Based on the foregoing, we decided not to devote any further financial resources to development of this indication for ~~DMT310~~ **XYNGARI ™**, and we determined not to pursue further development efforts regarding this indication for ~~DMT310~~ **XYNGARI ™**. We or

our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business. We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results. ~~If~~ **60If** we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered. For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third- party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third- party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co- payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, the market for our product candidates will depend significantly on access to third- party payors' drug formularies, or lists of medications for which third- party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third- party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Further, third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third- party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third- party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third- party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects. ~~61Healthcare~~ -- **Healthcare** legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, may have a negative impact on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or the ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U. S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. On September 9, 2021, the Biden Administration published a wide- ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The United States Department of Health and Human Services (" HHS ") plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (the " IRA ") in August 2022, which ~~will~~ , among other things, ~~allow~~ **allows** the HHS to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services (" CMS ") reimburses under Medicare Part B and Part D, although only high- expenditure single- source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers

that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions **took** ~~will take~~ effect progressively starting in 2023, **and so far have withstood** although they may be subject to legal challenges. ~~Other~~ **61Other** examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. 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 drugs. ~~62In~~ **In** addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for ~~DMT310~~ **XYNGARI ™** or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require: · additional clinical trials to be conducted prior to obtaining approval; · changes to manufacturing methods; · recalls, replacements, or discontinuance of one or more of our products; and · additional recordkeeping. Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of ~~DMT310~~ **XYNGARI ™** or other product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations. We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include: · the federal Anti- Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs; · federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; · the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; ~~63~~ **62** · HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; · the ~~federal physician~~ **Physician Payments** ~~sunshine~~ **Sunshine Act** requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and · state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and certain criminal healthcare

fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Our ~~business involves the use of hazardous materials and we and our third- party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business. The manufacturing activities of our third- party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage. 64Our~~ employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results. ~~Our~~ **63Our** future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize ~~DMT310~~ **XYNGARI ™** or our other product candidates in foreign markets, we would be subject to additional risks and uncertainties, including: · our customers' ability to obtain market access and appropriate reimbursement for our product candidates in foreign markets; · our inability to directly control commercial activities because we are relying on third parties; · the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; · different medical practices and customs in foreign countries affecting acceptance in the marketplace · import or export licensing requirements; · longer accounts receivable collection times; · longer lead times for shipping; · language barriers for technical training; · reduced protection of intellectual property rights in some foreign countries; · foreign currency exchange rate fluctuations; and · the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. ~~65Foreign~~ -- **Foreign** sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations. Development of test methodology for ~~DMT310~~ **XYNGARI ™** presents unique challenges due to the complex mixture of constituents in the product. Determination of appropriate assay (s) for release and quality control evaluations could require significant development time and cost to successfully complete and uncertain. ~~DMT310~~ **XYNGARI ™** is comprised of both inorganic and organic constituents, and unlike most pharmaceutical products, there is no single active component to characterize for purposes of assay development. In order to release the drug product and test for stability we plan to develop a cell- based bioassay to assess inhibitory effects of ~~DMT310~~ **XYNGARI ™** on

pro- inflammatory cytokines known to play a role in the pathogenesis of various skin diseases. While this approach may show activity, it may not be suitable as a quality control release potency assay for ~~DMT310~~ **XYNGARI ™** . Furthermore, this technique may not have sufficient sensitivity to be considered stability- indicating and detect small changes or degradation to the product. If we are not able to develop a suitable potency assay utilizing this approach, we may have to identify and develop an alternative bioassay platform or secondary approaches that may require additional orthogonal methodologies to meet our testing requirements. This could be expensive, time consuming and its success uncertain, leading to delays in filing of the NDA. ~~Risks~~ **64Risks** Related to Our Dependence on Third Parties We are dependent on one supplier for the raw material used to produce ~~DMT310~~ **XYNGARI ™** and DMT410. The termination of this contract would result in a disruption to product development and our business will be harmed. We currently only have one qualified source of supply for the raw material used in ~~DMT310~~ **XYNGARI ™** and DMT410. While we have an exclusive supply agreement with our supplier, our supplier may not comply with the terms of our agreement and may supply to third parties. ~~DMT310~~ **XYNGARI ™** and DMT410 contain a wild growing freshwater sponge that grows in an area of the Volga River delta in Russia that is partially protected by a Russian government entity. The Russian government entity allocates a quantity of freshwater sponge that may be harvested each harvest season and may determine in any year that no sponge or a smaller quantity of sponge than harvested in previous years may be harvested in a particular year, which could impact our ability to obtain raw material to manufacture and supply ~~DMT310~~ **XYNGARI ™** and DMT410. If we have not adequately stockpiled raw materials, or even if we do stockpile raw material, we could not have enough raw material to meet the quantity demands to conduct our non- clinical and clinical studies or to supply product for the market if approved. The freshwater sponge contained in ~~DMT310~~ **XYNGARI ™** and DMT410 can only be harvested once per year based on the presence of certain environmental conditions. If these environmental conditions are not present during the harvest season, then our supplier may not be able to harvest the raw material required, which could impact our ability to manufacture and supply ~~DMT310~~ **XYNGARI ™** and DMT410. The ability of our supplier to harvest the sponge may also be impacted by severe weather and limit the length of time they can harvest, which could limit the amount of raw material that can be harvested, which may impact our ability to manufacture and supply ~~DMT310~~ **XYNGARI ™** and DMT410. The portion of the Volga River delta where the sponge grows could also become contaminated from pollutants, which could contaminate the sponge to be harvested by our supplier, making it unusable in humans, impacting our ability to manufacture and supply ~~DMT310~~ **XYNGARI ™** and DMT410. ~~66Even~~ -- **Even** if we are able to obtain supply, we and our supplier are exposed to a number of environmental and geopolitical risks, including: · risk of contamination being introduced in the Volga River, thereby polluting the ~~spongilla~~ **Spongilla** lacustris population through environmental factors that we cannot control, which could result in new impurities or reduced supply of raw materials; · loss of Spongilla lacustris habitat and other similar environmental risks to the sponge population whether due to climate change, over- development, or otherwise; · risk of disease in the Spongilla lacustris geographic area where harvested; · risk of trade issues between the U. S. and Russia; · restrictions on trade of certain items between the U. S. and Russia; · restriction on means of payment with Russian entities; and · other unforeseen geopolitical factors that limit our ability access our supply of raw material. Restrictions could be imposed on the harvesting of the raw material. Such events could have a significant impact on our cost and ability to produce ~~DMT310~~ **XYNGARI ™** and DMT410 and anticipated line extensions. The country from which we obtain the raw material could change its laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. In addition, any business, global or economic challenges our existing supplier faces, whether in the ordinary course of business or not, could impair its ability to supply our needs for raw materials. Accordingly, there is a risk that supplies of our raw materials may be significantly delayed by or may become unavailable as a result of any issues affecting our supply and production of naturally sourced products. In addition, if we need a new or additional suppliers, it may take a substantial amount of time and financial resources to identify any additional supplier (s) who can supply our required raw materials in the quality and quantity required for our pre- clinical and we may not be able to negotiate new agreements with an alternate or new supplier on terms that we deem commercially reasonable or at all, and the failure by us to enter into such agreements could harm our financial condition, business, clinical trials and prospects. ~~Our~~ **65Our** business may be affected by new sanctions **, import restrictions,** and export controls targeting Russia and other responses to Russia' s invasion of Ukraine. As a result of Russia' s invasion of Ukraine, the United States, the United Kingdom and the European Union governments, among others, have developed coordinated sanctions **, import restrictions,** and export- control measure packages against Russian individuals and entities. We are currently a party to an exclusive supply agreement for the supply of the Spongilla raw material used in ~~DMT310~~ **XYNGARI ™** and DMT410. The counterparty to this supply agreement is a Russian entity. To date, none of these sanctions **, import restrictions,** or export- controls have impacted our ability to perform under our supply agreement. However, the imposition of enhanced **import restrictions,** export controls ~~and~~ **, or** economic sanctions on transactions with Russia ~~and~~ **or** Russian entities by the United States, the United Kingdom, and / or the European Union **could make it challenging to process financial transactions in accordance with legal requirements and** could prevent us from performing under this existing contract or any future contract we may enter or remitting payment for raw material purchased from our supplier. **If there is any limitation or restriction on our ability to make timely and compliant payments to our supplier, our supplier may refuse or delay the delivery of Spongilla raw material which could result in production interruptions, delays in the progress of clinical trials, increased costs to source alternative suppliers, and a material adverse impact on our operations, financial condition, and results of operations.** We' ve received multiple shipments of Spongilla raw material from our supplier during fiscal years ~~2022 and~~ 2023 **and 2024** containing additional quantities of Spongilla raw material which we believe will provide us with sufficient quantities of Spongilla to ~~initiate and~~ complete the ~~DMT310~~ **XYNGARI ™** Phase 3 clinical program in moderate- to- severe acne and support filing an NDA for ~~DMT310~~ **XYNGARI ™** in acne in the event of the successful completion of the ~~DMT310~~ **XYNGARI ™** Phase 3 clinical program. Depending on the extent and breadth of new sanctions **, import restrictions,** or export controls that may be imposed against Russia, otherwise or as a result of the impact of the war in the Ukraine, it is possible that

our business, results of operations, and financial condition could be materially and adversely affected. ~~67We~~ **We** have in the past relied and expect to continue to rely on third- party CROs and other third parties to conduct and oversee our clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all. We have in the past relied and expect to continue to rely on third- party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA' s regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third- party contractors are required to comply with GCP, GLP, and GACP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP, GLP and GACP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP, GLP and GACP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow- up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA ~~We~~ **66We** rely completely on third- party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole- source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the raw materials and APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates. ~~68We~~ **We** rely and will continue to rely on **a** certain third ~~parties~~ **party** as the sole source of the materials ~~they supply~~ **it supplies** or the finished products ~~they~~ **it** ~~manufacture~~ **manufactures** . Any of our existing **and future** suppliers or manufacturers may: · fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise; · fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost- effective manner, or at all, to sufficiently meet our **clinical or** commercial needs; · be unable to meet our production demands due to issues related to their reliance on sole- source suppliers and manufacturers; · supply us with product that fails to meet regulatory requirements; · become unavailable through business interruption or financial insolvency; · lose regulatory status as an approved source; · be unable or unwilling to renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or · discontinue production or manufacturing of necessary drug substances or products. In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of

time, may not be successful and, in most cases, require review and approval by the FDA. Any need to find and qualify new suppliers or manufacturers could significantly delay production of our product candidates, adversely impact our ability to market our product candidates and adversely affect our business. Replacements may not be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials. Any interruption in the supply of a drug substance or other material or in the manufacture of our product candidates could have a material adverse effect on our business, financial condition, operating results and prospects. We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs and GACP, we are dependent on our contract suppliers and manufacturers for day- to- day compliance with cGMPs or GACP for production of raw materials, APIs, and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP and GACP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all. ~~69In~~ **67In** addition, these contract manufacturers ~~are~~ **may** ~~engaged~~ **engage** with other companies to supply and manufacture materials or products for such companies, which ~~also~~ **may** ~~exposes~~ **expose** our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier' s or manufacturer' s facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers, including our supplier of Spongilla lacustris, are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging. If we are not able to establish and maintain collaborations, we may have to alter our development and commercialization plans. The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner' s resources and experience, the terms and conditions of the proposed collaboration and the proposed partner' s evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners. Future collaborations we may enter into may involve the following risks: · collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations; · collaborators may not perform their obligations as expected; · changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities; · collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate; ~~70~~ · collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours; · product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates; · disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; · collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or

proprietary information or expose us to potential litigation; · collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and · collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. ~~Collaborations~~ **68Collaborations** typically impose detailed obligations on each party. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to our partners' product candidates, in which we have invested substantial time and money, would be lost. We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Risks Related to Managing Our Growth, Our Employees and Our Operations We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth. Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and near- term future growth. We will need to further expand our chemistry and manufacturing team, clinical team, managerial, operational, financial, and other resources to support our planned research, development and commercialization activities. To manage our operations, growth and various projects effectively requires that we: · continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures; · attract and retain sufficient numbers of talented employees; · develop a marketing, sales and distribution capability; ~~71~~ · manage our commercialization activities for our product candidates effectively and in a cost-effective manner; · establish and maintain relationships with development and commercialization partners; · manage our preclinical and clinical trials effectively; · manage our third- party supply and manufacturing operations effectively and in a cost- effective manner, while increasing production capabilities for our current product candidates to commercial levels; and · manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties. In addition, historically, we have utilized and continue to utilize the services of part- time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals. ~~If~~ **69If** we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including: **Gerald T. Proehl,** our Chief Executive Officer, President and Chairman of our board of directors (the " Board ") ~~, Gerald T. Proehl~~ ; **Kyri K. Van Hoose, C. P. A, M. B. A.,** our Senior Vice President, Chief Financial Officer ~~, Kyri K. Van Hoose, C. P. A, M. B. A.~~ ; ~~our Senior Vice President, Development,~~ Christopher J. Nardo, M. P. H., Ph. D. **our Chief Development Officer** ; and ~~our Senior Vice President, Regulatory Affairs and Quality Assurance,~~ Maria Bedoya Toro Munera, Ph. D. ~~,~~ M. B. A. **, our Senior Vice President, Regulatory Affairs and Quality Assurance** . The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in- licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives. ~~72In~~ **In** addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours ~~. Our ability to attract and retain qualified members of our Board may be impacted due to new state~~

~~laws, including recently enacted gender and diversity quotas. In September 2018, the state of California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors. In September 2020, the state of California enacted AB 979 requiring public companies headquartered in California to maintain minimum representation on their boards of directors from members of underrepresented communities as follow: by the end of 2021, at least one director from an underrepresented community, by end of 2022, public company boards with more than four but fewer than nine members will be required to have at least two directors from underrepresented communities, and public company board with nine or more members will be required to have at least three directors from underrepresented communities. Failure to achieve designated minimum levels in a timely manner exposes such companies to financial penalties and reputational harm. We cannot assure that we can recruit, attract and / or retain qualified members of the board and meet the above quotas as a result of the California laws, which may expose us to penalties and / or reputational harm~~ . We currently have limited marketing capabilities and no outside sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue. We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our management team has experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are unable to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, our business, financial condition, operating results and prospects would suffer. ~~Our~~ **70Our** failure to successfully in- license, acquire, develop, and market additional product candidates or approved products would impair our ability to grow our business. We intend to in- license, acquire, develop, and market additional products and product candidates and we may in- license or acquire commercial- stage products or engage in other strategic transactions. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists, and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements. ~~73The~~ -- **The** process of proposing, negotiating, and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales, and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in- licensing of third- party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all. Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near- and long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including: · exposure to unknown liabilities; · disruption of our business and diversion of our management' s time and attention in order to develop acquired products, product candidates or technologies; · incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions; · substantial acquisition and integration costs; · write- downs of assets or impairment charges; · increased amortization expenses; · difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; · impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and · inability to retain our key employees or those of any acquired businesses. ~~Accordingly~~ **71Accordingly** , there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results, and prospects. ~~74Manufacturing~~ -- **Manufacturing** and supply of the APIs and other substances and materials used in our product candidates is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality

assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed. Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price, and successful delivery of our product candidates and can impede, delay, limit or prevent the successful development and commercialization of our product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include: · failure of our manufacturers to follow cGMP or GACP requirements or mishandling of product while in production or in preparation for transit; · inability of our contract suppliers and manufacturers to efficiently and cost- effectively increase and maintain high yields and batch quality, consistency and stability; · our inability to develop an FDA approved bioassay for release of any future product; · difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes; · transportation and import / export risk, particularly given the global nature of our supply chain; · delays in analytical results or failure of analytical techniques that we depend on for quality control and release of any future product; · natural disasters, pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and · latent defects that may become apparent after the product has been released and which may result in recall and destruction of product. Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, which could harm our business, financial condition, operating results and prospects. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations. Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: **72** · delays in the commencement, enrollment and the timing of clinical testing for our product candidates; · the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; ~~75~~ · any delays in regulatory review and approval of product candidates in clinical development; · the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; · the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production; · our ability to obtain additional funding to develop our product candidates; · expenditures that we will or may incur to acquire or develop additional product candidates and technologies; · the level of demand for our product candidates, should they receive approval, which may vary significantly; · potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market; · the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved; · our dependency on third- party manufacturers to supply or manufacture our product candidates; · our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner; · market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates; · our ability to receive approval and commercialize our product candidates outside of the United States; · our ability to establish and maintain collaborations, licensing or other arrangements; · our ability and third parties' abilities to protect intellectual property rights; · costs related to and outcomes of potential litigation or other disputes; · our ability to adequately support future growth; · our ability to attract and retain key personnel to manage our business effectively; · potential liabilities associated with hazardous materials; · our ability to maintain adequate insurance policies; and · future accounting pronouncements or changes in our accounting policies. ~~76Our~~ **73Our** operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn. Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products may be tied to the discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk. Our business and operations would suffer in the event of failures in our internal computer systems. Despite the implementation of security measures, our internal computer systems, and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or 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. 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 commercialization and development of our products and product candidates could be delayed. We are increasingly dependent on information

technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we **may** collect, store, and transmit ~~large amounts of~~ confidential information **and data** , and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third- party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow. ~~77Risks~~ **74Risks** Related to Our Intellectual Property We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us. Our success with respect to our product candidates and technologies will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents or enforce confidentiality contracts. Our patents include licensed patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our products. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use, or sell products identical to, or substantially similar to, our product candidates. The patent application process, also known as patent prosecution, is expensive and time- consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, 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. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, 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 and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents, and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates. ~~78The~~ **75The** laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we

encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: · we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents; · others may independently develop similar or alternative technologies or duplicate any of our technologies; · the patents of others may have an adverse effect on our business; · any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties; · any patents we obtain on our in- licensed issued patents may not be valid or enforceable; and · we may not develop additional proprietary technologies that are patentable. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from its earliest non-provisional priority application filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early- stage product candidates. The licensed U. S. patents relating to ~~DMT310~~ **XYNGARI ™** expired in 2022 and 2023 or we have abandoned and will not be eligible for patent term extension if approval occurs after patent expiration. ~~Proprietary~~ **76Proprietary** trade secrets and unpatented know- how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know- how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information, or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know- how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know- how is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. ~~79For~~ -- **For** example, on September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy- Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy- Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy- Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given

to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. ~~We~~ **77We** may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our 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 pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. ~~80Obtaining~~ -- **Obtaining** and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business. **78The complexity and uncertainty of European laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes.** If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. For more information about these license arrangements, see " Business — **Material** ~~Collaborations and License~~ Agreements. " If we are sued for infringing intellectual property rights of third parties, it will be costly and time- consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. In addition,

there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in- licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in- licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to those owned or in- licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch- Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party' s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party' s patents. ~~81As~~ **79As** a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re- examination or other post- grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or of our other products. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third- party claims that we infringe its intellectual property rights, we may face a number of issues, including: · infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management' s attention from our core business; · substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party' s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; · a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do; · if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross- licenses to intellectual property rights for our products or technologies; and · redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results, and prospects. Because we rely on certain third- party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party' s intellectual property rights, our business, financial condition, operating results, and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third- party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost- sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology. The occurrence of any of the foregoing could adversely affect our business, financial condition, or operating results. ~~We~~ **80We** may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time- consuming. Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. This can be expensive and time- consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products. ~~82Interference~~ -- **Interference** , derivation, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or

may be invoked against us by third parties. Even if we are successful, domestic, or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock or Warrants could be significantly harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. We consider proprietary trade secrets or confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets or confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, collaborators, contractors, and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, collaborators, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know- how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our employees, consultants, collaborators, contractors and advisors to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. ~~We~~ **81We** may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers. As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome. If our patent term expires before or soon after our products are approved, or if manufacturers of generic or biosimilar drugs successfully challenge our patents, our business may be materially harmed. Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including generic or biosimilar medications. ~~83Depending~~ -- **Depending** upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Act, and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor' s product or product use. As a result, our revenue from applicable products could be reduced, possibly materially. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire

before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. ~~If~~ **82If** our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Our proprietary information may be lost, or we may suffer security breaches. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. ~~84Risks~~ **Risks** Related to the Securities Markets and Ownership of Our Common Stock and Warrants The market price of our common stock and Warrants have been volatile and can fluctuate substantially, which could result in substantial losses for holders of our securities. The market price of our common stock ~~is~~ **and Warrants have been** highly volatile. The market price for our common stock and Warrants may be volatile and subject to wide fluctuations in response to factors including the following: · actual or anticipated fluctuations in our quarterly or annual operating results; · actual or anticipated changes in the pace of our corporate achievements or our growth rate relative to our competitors; · failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; · issuance of new or updated research or reports by securities analysts; · share price and volume fluctuations attributable to inconsistent trading volume levels of our common stock or Warrants; · additions or departures of key management or other personnel; **83** · disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; · announcement or expectation of additional debt or equity financing efforts; · sales of our common stock or Warrants by us, our insiders or our other stockholders; and · general economic, market or political conditions in the United States or elsewhere. In particular, the market prices of clinical- stage companies like ours have been highly volatile due to factors, including, but not limited to: · any delay or failure in a clinical trial for our product candidates or receive approval from the FDA and other regulatory agents; · developments or disputes concerning our product candidate' s intellectual property rights; · our or our competitors' technological innovations; ~~85~~ · fluctuations in the valuation of companies perceived by investors to be comparable to us; · announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents; · failure to complete significant transactions or collaborate with vendors in manufacturing our product; and · proposals for legislation that would place restrictions on the price of medical therapies. These and other market and industry factors may cause the market price and demand for our common stock and Warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock or Warrants and may otherwise negatively affect the liquidity of our common stock and Warrants. In addition, the stock market in general, and Nasdaq Capital Markets and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have instituted securities class action litigation against the company that issued the security. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management. Our Warrants may not have any value. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of our outstanding Warrants. In the event that our common stock price does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value. A Warrant does not entitle the holder to any rights as common stockholders until the holder exercises the Warrant for a share of our common stock. Until you acquire shares of our common stock upon exercise of your Warrants, your Warrants will

not provide you any rights as a common stockholder. Upon exercise of your Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date. ~~We~~ **84We** are an " emerging growth company, " and will be able take advantage of reduced disclosure requirements applicable to " emerging growth companies, " which could make our common stock and Warrants less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act and, for as long as we continue to be an " emerging growth company, " we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to " emerging growth companies, " including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an " emerging growth company " for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $ 1. 235 billion, (ii) the date that we become a " large accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, which would occur if the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $ 1 billion in non- convertible debt during the preceding three year period. We intend to take advantage of these reporting exemptions described above until we are no longer an " emerging growth company. " Under the JOBS Act, " emerging growth companies " can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not " emerging growth companies. " We cannot predict if investors will find our common stock or Warrants less attractive if we choose to rely on these exemptions. If some investors find our common stock or Warrants less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and Warrants and the price of our common stock and Warrants may be more volatile. ~~86There~~ -- **There** may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company. If we fail to remediate a material weakness, or if we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock and Warrants. Prior to the completion of our initial public offering in August 2021, we had been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. As a public company, we have designed a control environment as required of public companies under the rules and regulations of the SEC. Proper systems of internal controls over financial accounting and disclosure controls and procedures are critical to the operation of a public company. We may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives. Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us. ~~If~~ **85If** securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock and Warrants depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our securities would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our stock price and Warrant price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause the price of our securities and trading volume to decline. Future sales of our common stock, Warrants or securities convertible into our common stock may depress our stock price. Sales of a substantial number of shares of our common stock, Warrants or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and Warrants. If a large number of shares of our common stock, Warrants or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and Warrants and impede our ability to raise future capital. Our failure to maintain compliance with Nasdaq' s continued listing requirements could result in the ~~desilting~~ -- **delisting** of our common stock **Our** ~~and / or our Warrants On November 15, 2023, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC (" Nasdaq ") indicating that, based upon the closing bid price of our~~ common stock **is currently listed** ~~for the last 30 consecutive business days, we are not in compliance with the requirement to maintain a minimum bid price of $ 1. 00 per share for continued listing~~ on the Nasdaq Capital Market ~~, as set forth in~~ **. Continued listing of a security on** Nasdaq **Capital Market is conditioned upon** ~~Listing Rule 5550 (a) (2) (the " Notice "). We were provided a compliance period of 180 calendar days from the date of the Notice, or until May 13, 2024, to regain~~ compliance with **various continued listing standards. In** the **past** ~~minimum closing bid requirement~~ , ~~pursuant to~~ **we have**

received notices from Nasdaq **' s** Listing ~~Rule 5810 (c) (3) (A). 87We will~~ **Qualifications Department indicating that we had not complied with certain of the Nasdaq Capital Market' s** ~~continue~~ **continued listing standards. While we have** ~~to monitor the closing bid price of our common stock and seek to regain~~ **regained** compliance ~~with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or~~ **for each instance** ~~implementation of such a reverse stock split could negatively affect the price of our common stock and / or Warrants. If we do not regain compliance within the allotted compliance periods~~ , ~~including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock and Warrants will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There~~ **there** can be no assurance that we will **continue to** ~~regain compliance with the minimum bid price requirement during the 180- day compliance period or~~ maintain compliance with the ~~other~~ Nasdaq listing requirements. A delisting could substantially decrease trading in our common stock ~~and Warrants~~ , adversely affect the market liquidity of our common stock ~~and Warrants~~ as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, ~~customers~~ and employees and **lead to** fewer business development opportunities. Additionally, the market price of our common stock ~~and / or our Warrants~~ may decline further **,** and stockholders may lose some or all of their investment **. In the event of a delisting, we anticipate that we would take actions to restore our compliance with the Nasdaq Capital Market or another national exchange' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed on the Nasdaq Capital Market, stabilize our market price, improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq Capital Market' s minimum bid price requirement, or prevent future non- compliance with the Nasdaq Capital Market or another national exchange' s listing requirements** . Anti- takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt. Our amended and restated certificate of incorporation, bylaws and Delaware corporate law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board. Our corporate governance documents include provisions: · classifying our Board into three classes; · authorizing " blank check " preferred stock, which could be issued by our Board without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock; **86** · limiting the liability of, and providing indemnification to, our directors and officers; · limiting the ability of our stockholders to call and bring business before special meetings; · requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board; · controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and · providing our Board with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15 % of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our amended and restated certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock or Warrants, and could also affect the price that some investors are willing to pay for our common stock and Warrants. ~~88Our~~ -- **Our** ability to use our net operating loss carryforwards may be limited. As of December 31, ~~2023~~ **2024** , we had net operating loss carryforwards, or NOLs, of approximately $ ~~14~~ **20** . ~~2~~ **3** million for federal income tax purposes and approximately $ 5. 0 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership by 5 % stockholders over a three- year period, the corporation' s ability to use its pre- change NOLs and other pre- change tax attributes to offset its post- change income may be limited. We may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. Ownership changes that materially limit our use of our historical NOLs could harm our future operating results by effectively increasing our future U. S. federal income tax and U. S. state income tax obligations **. We have not yet completed a Section 382 analysis, and therefore, there can be no assurances that any previously experienced ownership changes have not materially limited our utilization of affected NOLs** . In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, however, the deductibility of our federal NOLs generated in such years will be limited to 80 % of taxable income if utilized in taxable years beginning after December 31, 2020. Federal net operating losses incurred in years beginning before January 1, 2018, are subject to a twenty- year carryforward but are not limited to 80 % of taxable income. We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock and Warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investment. ~~Our~~ **87Our** amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be

initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our amended and restated certificate of incorporation requires that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following: · any derivative action or proceeding brought on our behalf; · any action asserting a claim for breach of any fiduciary duty owed by any director, officer or other employee of ours to the Company or our stockholders; · any action asserting a claim against us or any director or officer of ours arising pursuant to, or a claim against us or any of our directors or officers, with respect to the interpretation or application of any provision of, the DGCL, our certificate of incorporation or bylaws; or · any action asserting a claim governed by the internal affairs doctrine; provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any of the foregoing actions for lack of subject matter jurisdiction, any such action or actions may be brought in another state court sitting in the State of Delaware. The exclusive forum provision is limited to the extent permitted by law, and it will not apply to claims arising under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or for any other federal securities laws which provide for exclusive federal jurisdiction. ~~89Furthermore~~ -- **Furthermore**, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may limit or discourage a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees, and may result in increased costs for investors to bring a claim. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. **88**