Risk Factors Comparison 2024-03-18 to 2023-03-31 Form: 10-K

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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you might lose all or part of your investment. RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL We might not be able to continue as a going concern, which would likely cause our stockholders to lose most or all of their investment. Our audited financial statements for the year ended December 31, ~~2022~~ **2023** were prepared under the assumption that we would continue as a going concern. However, we have concluded that there is substantial doubt about our ability to continue as a going concern, therefore our independent registered public accounting firm included a " going concern " explanatory paragraph in its report on our financial statements for the year ended December 31, ~~2022~~ **2023** , indicating that, without additional sources of funding, our cash at December 31, ~~2022~~ **2023** is not sufficient for us to operate as a going concern for a period of at least one year from the date that the financial statements included in this Annual Report on Form 10- K are issued. Management' s plans concerning these matters, including our need to raise additional capital, are described in Note 2 – Summary of Significant Accounting Policies – Liquidity and Going Concern of our financial statements included within this Annual Report on Form 10- K ~~,~~ **.** ~~however~~ **However** , management cannot assure you that ~~its~~ **our** plans **to raise additional capital** will be successful. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us. ~~Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each placed into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008- 2010 financial crisis. We do not currently have funds deposited with SVB in excess of the FDIC insurance limit. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: ● Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ● Loss of access to revolving existing credit facilities or other working capital sources and / or~~

~~the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; 44 ● Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or ● Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business.~~ We will need to raise additional capital in order to continue developing our product candidates and to manufacture and commercialize them **as well as Mydcombi and clobetasol propionate, currently our only FDA- approved commercial products** . Such funding might not be available on acceptable terms, or at all. Failure to obtain this necessary capital may force us to delay, limit or terminate certain of our product development and commercialization efforts or to continue operations. We require substantial additional funding to continue our research and development activities. We also need substantial funding to advance ~~potential~~ manufacturing and commercialization, and fund our operating expenses and other activities into next year. If additional capital is not available when needed, including because of general market conditions, we may need to significantly scale back or reprioritize our research and development activities, manufacturing and commercialization plans, and potentially even cease our operations. We will require substantial funds to discover, develop, protect and conduct research and development for our product candidates, including preclinical testing for future product candidates and clinical trials of any of our product candidates, and to ~~potentially~~ manufacture and market any ~~such product~~ **products** that **are or** may be approved for commercial sale. Even if we are successful in raising additional capital, such funds may prove to be insufficient for these activities. Our financing needs may change substantially because of research and development, manufacturing and commercialization- related costs, competition, clinical trials and costs arising from additional regulatory approvals. We might not succeed in raising needed additional funds. The timing of our need for additional funds will depend on a number of factors, which factors are difficult to predict or may be outside of our control, including: ● the resources, time and costs required to initiate and complete research and development, to initiate and complete preclinical studies and clinical trials and to obtain regulatory approvals for our product candidates; ● progress in our research and development programs; ● the timing, receipt and amount of milestone, royalty and other payments from any current or future collaborators, if any; and ● costs necessary to protect our intellectual property. If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our operating plan. Additional funds might not be available to us on acceptable terms, or at all, when needed. ~~45Raising~~ -- **Raising** additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies. Until such time as we can generate substantial product revenues, as to which we can make no assurance, we intend to finance our cash needs through equity offerings, debt financings, government and / or other third- party grants or other third- party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our investors' ownership interest will be diluted. Debt 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 are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more clinical research or development programs or delay manufacturing and commercialization plans, which would adversely impact potential revenues, results of operations and our financial condition. If we raise additional capital through future collaborations, strategic alliances or third- party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs **, Mydcombi, clobetasol propionate** or product candidates, or grant licenses on terms that might not be favorable to us. ~~The 44~~**The** terms of ~~the~~ **our** Loan and Security Agreement with Avenue Capital Management II, L. P. and the lenders listed therein require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. On November 22, 2022, we entered into a Loan and Security Agreement with Avenue Capital Management II, L. P. and related entities (together, " Avenue ") **(the " Loan and Security Agreement ")** that is secured by a lien on all of our assets. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any part of our business or intellectual property, incurring additional indebtedness, engaging in mergers or acquisitions, repurchasing shares, paying dividends or making other distributions, making investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things,

limitations on the incurrence of additional debt and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, Avenue may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we were to be liquidated, Avenue' s right to repayment would be senior to the rights of the holders of our common stock. Avenue could declare an event of default upon the occurrence of any event that could reasonably be expected to result in what they interpret as a material adverse effect as defined under the Loan and Security Agreement. Any declaration by Avenue of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability. We have incurred net losses of approximately $ ~~118~~ **145** . ~~2~~ **5** million since inception, have not generated any **significant** product sales revenue and have not achieved profitable operations. Our net losses were approximately $ **27. 3 million and $** 28. 0 ~~million and $ 12. 8~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. We expect to continue to incur substantial losses in future periods while we continue to test and prepare our product candidates for the market. It could be a year or more, if ever, before we **achieve profitability** ~~have a commercialized product~~ . The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we: ● continue the ongoing development of our product candidates; ● seek marketing approvals for our current and future product candidates that successfully complete clinical trials; ● continue to develop a sales, marketing and distribution infrastructure to commercialize **Mydcombi, clobetasol propionate and** any **other** product candidate for which we may obtain marketing approval; ● develop, maintain, expand and protect our intellectual property portfolio; ~~46~~ ● implement additional operational, financial and management systems; ● attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; and ● initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future. Even if we are able to generate **substantial** revenues from the sale of our potential products, we might not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we might not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. In addition, because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. ~~Our~~ **45Our** relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. We ~~are a clinical stage company, which~~ commenced active operations in 2014 ~~. Our~~ **, and our** operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital and developing our product candidates. We have entered into licensing agreements with ~~Bausch Health, for the development and commercialization of MicroPine in the United States and Canada,~~ Arctic Vision, for the development and commercialization of MicroPine, MicroLine and MydcombiTM in Greater China and South Korea, and Senju, for the development and commercialization of MicroPine, MicroLine and Mydcombi in Asia (other than Greater China and South Korea). **Other than FDA approval of** ~~We also submitted an NDA for~~ Mydcombi ~~for pharmacologic mydriasis~~ and **clobetasol propionate** ~~initiated our Phase III VISION studies for presbyopia. However~~ , we have not yet demonstrated our ability to obtain marketing approval, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We will need to transition from a company with a product development focus to a company capable of supporting commercial and manufacturing activities in the near future. We might not be successful in such a transition. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors during such transition. Consequently, any predictions about our future success or viability might not be as accurate as they could be if we had a longer operating history. If we are unable to use carryforward tax losses or benefit from favorable tax legislation to reduce our taxes, our business, results of operations and financial condition may be adversely affected. We have incurred significant net operating losses since our inception in July 2014. As of December 31, ~~2022~~ **2023** , we had federal net operating loss carry- forwards of approximately $ ~~85~~ **104** . ~~9~~ **3** million, of which approximately $ 10. 8 million will expire at various dates from 2034 to 2037 for federal purposes. If we are unable to use carryforward tax losses to reduce our future taxable basis for corporate tax purposes, our business, results of operations and financial condition may be adversely affected. Net operating loss and tax credit carry- forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three- year period in excess of 50 %, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The federal and state income tax returns are generally subject to tax examinations. To the extent we have tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. Any unfavorable tax adjustment could have a significant impact on our results of operations and future cash flows. Furthermore, if the United States government decides to eliminate, or reduce the scope or the rate of any tax benefit, either of which it could decide to do at any time, our results of operations could be adversely affected. ~~47RISKS~~ **46RISKS** RELATED TO DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT **AND PRODUCT** ~~CANDIDATESWe~~ **CANDIDATESOur ability to achieve profitability is highly dependent on the commercial success of Mydcombi and clobetasol propionate, and to the extent Mydcombi and clobetasol propionate are not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common**

stock may decline. Mydcombi and clobetasol propionate are currently our only products that have been approved by FDA for commercial sale in the U. S. For the year ended December 31, 2023, we recorded net sales of Mydcombi of $ 3, 787. Revenues from sales of Mydcombi have not been sufficient to fund our operations fully in prior periods and we cannot provide assurance that revenues from Mydcombi sales will be sufficient to fund our operations fully in the future. We will need to generate substantially more product revenue from Mydcombi and / or clobetasol propionate generate other revenue such as through sales of future approved products to achieve and sustain profitability. We may be unable to sustain or increase revenues generated from Mydcombi product sales for a number of reasons, including: ● pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U. S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators; ● a lack of acceptance by physicians, patients and other members of the healthcare community; ● interruptions in supply of Mydcombi from our contract manufacturing partners; ● the availability, relative price and efficacy of Mydcombi as compared to alternative treatment options or branded, compounded or generic competing products; ● an unknown safety risk; ● the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of Mydcombi outside of the U. S.; and ● changed or increased regulatory restrictions in the U. S., E. U. and / or other foreign territories. We are dependent on ~~the success of~~ our **ability to successfully commercialize our product** Mydcombi ~~, MicroPine,~~ and ~~MicroLine product candidates~~ **clobetasol propionate,** and our ability to develop, obtain marketing approval for and successfully commercialize ~~these~~ **MicroPine, MicroLine, and any future** product candidates. If we are unable to develop, obtain marketing approval for **and /** or successfully commercialize our **products and** product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed. ~~We~~ **Apart from Mydcombi and clobetasol propionate, we** currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of ~~Mydcombi for mydriasis,~~ MicroPine for pediatric progressive myopia ~~,~~ and MicroLine for presbyopia. Our prospects are substantially dependent on our and our licensees abilities to develop, obtain marketing approval for and successfully commercialize **Mydcombi and clobetasol propionate and** these product candidates. The success of our product candidates will depend on, among other things, our ability to successfully complete clinical trials of each product candidate. Although we have completed multiple Phase II and III studies for our product candidates, including the MIST- 1 and MIST- 2 Phase III trials for Mydcombi, and the VISION- 1 and VISION- 2 Phase III trials for MicroLine, the clinical trial process is uncertain, and failure of one or more clinical trials can occur at any stage of testing. In addition to the successful completion of clinical trials, the success of our product candidates will also depend on several other factors, including the following: ● receipt of marketing approvals from the FDA or other applicable regulatory authorities; ● establishment of supply arrangements with third- party raw materials suppliers and manufacturers; **47** ● establishment of arrangements with third- party manufacturers to obtain finished drug products that are appropriately packaged for sale; ● the performance of our future collaborators for one or more of our product candidates, if any; ● the extent of any required post- marketing approval commitments to applicable regulatory authorities; ● obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally; ● protection of our rights in our intellectual property portfolio; ● launch of commercial sales if and when our product candidates are approved; ● a continued acceptable safety profile of our product candidates following any marketing approval; ● commercial acceptance, if and when approved, by patients, the medical community and third- party payors; ● establishing and maintaining pricing sufficient to realize a meaningful return on our investment; and ● competition with other products. If we are unable to develop, obtain marketing approval for or successfully commercialize our ~~Mydcombi,~~ MicroPine ~~,~~ and MicroLine product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed. ~~48Delays~~ -- **Delays** in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future may occur and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable. The tests and clinical trials of product candidates we develop may not commence, progress or be completed as expected, and delays could significantly impact our product development costs and timelines, as well as a product candidate' s market potential, if ultimately approved. The timing of initiation, conduct and completion of clinical trials and other testing of our product candidates may vary dramatically due to factors within and outside of our control and is difficult to predict accurately. We may make statements regarding anticipated timing for commencement, completion of enrollment, and / or availability of results from our clinical studies, but those statements are predictions based on a number of significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons. Commencement of planned clinical studies may be delayed if we do not secure adequate capital. In addition to lack of adequate capital, commencement and / or completion of these studies may be delayed, terminated or suspended as a result of the occurrence of any of a number of other factors, including the need to obtain authorizations from the FDA and the institutional review boards, or IRBs, of prospective clinical study sites, delayed or inadequate supply of our product candidates or other clinical trial material, slower than expected rates of patient recruitment or enrollment, other factors described below, and unforeseen events. The commencement of clinical trials of our product candidates can be delayed for many reasons, including delays in: ● obtaining required funding; ● obtaining guidance or authorizations from the FDA or foreign regulatory authorities; ● finalizing the trial design as a result of discussions with the FDA, other regulatory authorities or prospective clinical trial investigators or sites; ● reaching agreement on acceptable terms with prospective **contract research organizations, or** CROs **,** and clinical trial sites; **48** ● obtaining sufficient quantities of our product candidates and other clinical trial material; or ● obtaining IRB approval to conduct a clinical trial at a prospective site. In addition, once a clinical trial has begun, it may experience unanticipated delays or be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to several factors, all of which could impact our, or our licensees', ability to complete clinical trials in a timely and cost- efficient manner, including: ● lack of

adequate funding; ● failure to conduct the clinical trial in accordance with regulatory or IRB requirements; ● slower than expected rates of subject recruitment and enrollment; ● higher than anticipated participant drop- out rates; ● failure of clinical trial subjects to use the product as directed or to report data as per trial protocols; ● inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; ● failure to achieve certain efficacy and / or safety standards; ● subjects experiencing severe side effects or other adverse events related to the investigational treatment; ~~49~~ ● delayed or insufficient supply of clinical trial material or inadequate quality of such materials; ● failure of our CROs or other third- party contractors to meet their contractual obligations to us in a timely manner, or at all; or ● delays in quality control / quality assurance procedures necessary for study database lock and analysis of unblinded data. Significant clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations. We or our licensees may experience delays or difficulties in the enrollment and / or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals. Successful and timely completion of clinical trials will require that we or our licensees sponsoring trials for our product candidates enroll a sufficient number of subjects. Subject enrollment, which is an important factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates. Trials may be subject to delays as a result of subject enrollment taking longer than anticipated or subject withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. We cannot predict ~~how~~ **49how** successful we or our licensees will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including: ● the severity and difficulty of diagnosing the disease under investigation; ● the eligibility and exclusion criteria for the trial in question; ● the size of the patient population and process for identifying patients; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● the design of the trial protocol; ● the perceived risks and benefits of the product candidate in the trial in relation to other available therapies, including any new products that may be approved for the indications we are investigating; ● the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation; ● the willingness of patients to be enrolled in our clinical trials; ● the risk that subjects enrolled in clinical trials will drop out of our trials before completion; ● our ability to obtain and maintain clinical trial subject informed consents ● the efforts to facilitate timely enrollment in clinical trials; ~~50~~ ● potential disruptions caused by geopolitical events such as the **ongoing war between** ~~Russian~~ **Russia and** ~~invasion of~~ Ukraine **or between Israel and Hamas** ; ● the patient referral practices of physicians; ● the ability to monitor subjects adequately during and after treatment; and ● the proximity and availability of clinical trial sites for prospective subjects. Inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on ~~contract research organizations (~~ CROs ~~)~~ and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we have limited influence over their performance. Interim " top- line " and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top- line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated, and should ~~be~~ **50be** viewed with caution until the final data are available. Differences between preliminary or interim data and final data could be material and could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Furthermore, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or therapeutic product, if any, and us in general. The information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary, interim and topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. The FDA or

comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates. Our clinical trial results may not support regulatory approval of our product candidates. The results of nonclinical studies and clinical trials may not be predictive of the results of later- stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● we may be unable to demonstrate that our product candidates' risk- benefit ratios for their proposed indications are acceptable; ~~51~~ ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials; ● the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an application for marketing authorization to FDA or comparable foreign regulatory authorities; ● the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third- party manufacturer' s facilities with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects. ~~Our~~ **51Our** product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval and limit the commercial profile of an approved label, and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates. Undesirable side effects caused by any of our product candidates could cause us, our licensing partners, if any, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Results of the clinical trials could reveal a high and unacceptable severity and prevalence of side effects or risks associated with a product candidate' s use. In such an event, our trials could be suspended or terminated and the regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if undesirable side effects of our products are identified following marketing approval, a number of potentially significant negative consequences could result, including: ● marketing of such product may be suspended; ● a product recall or product withdrawal; ● regulatory authorities may withdraw or limit their approvals of such product or may require additional warnings on the label; ● the requirement to develop a REMS for each product or, if a strategy is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority; ● the requirement to conduct additional post- market studies; and ● being sued and held liable for harm caused to subjects or patients. Consequently, our reputation and business operations may suffer. ~~52In~~ **In** addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval. Any of these events could prevent the achievement or maintaining of market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects. We might not be able to develop **any additional** marketable products utilizing our technology and we might not be able to identify and successfully implement an alternative product development strategy. The approach we have adopted to discover and develop product candidates is new and may never lead to marketable products **other than Mydcombi and clobetasol propionate** . We have concentrated our efforts on developing therapeutic product candidates utilizing new advanced technology for drug delivery. To our knowledge, no person or company has developed any therapeutic product utilizing the same technology and no such ophthalmic micro- therapeutic product **other than Mydcombi and clobetasol propionate** has been approved for marketing to date. We are leading a new field of ophthalmic micro- therapeutic research and development and the scientific discoveries that form the basis for our efforts to develop products are relatively new. The scientific evidence to support the feasibility of developing such products and treatments based on these discoveries is limited. Our focus solely on developing products utilizing our proprietary technology, as opposed to more traditional technology, increases the risks associated with investing in our stock. If we are unsuccessful in developing product candidates utilizing our technology or finding additional applications for our technology, we may be required to change the scope and direction of our product development activities. If we are not able to identify and successfully implement an alternative product development strategy, our business may fail. ~~If~~ **52If** the market opportunities for **Mydcombi and clobetasol propionate and** our product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer. We are currently focusing efforts on **commercializing** our Mydcombi **and clobetasol propionate** ~~product~~ **products** ~~candidate~~ , and we have licensed commercialization rights to Mydcombi as well as MicroPine and MicroLine in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea to Arctic Vision (with Senju retaining such licensed rights in the rest of Asia) ~~and to MicroPine in the United States and Canada to Bausch Health~~ . Our understanding of both the number of people who have needs for our products, as well as the subset of people who have the potential to benefit from our product **and product** candidates in varying countries, are based on estimates in published literature. While we believe these estimates are reasonable, they may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of mydriasis, progressive myopia and presbyopia. The number of patients in the United States and elsewhere may turn out to be lower than

expected or these patients might not be otherwise amenable to our product **or product** candidates or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. The commercial success of **Mydcombi and clobetasol propionate and** our product candidates will depend in large part on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community. **There can be no assurance that Mydcombi and clobetasol propionate will achieve commercial success or market acceptance and,** ~~Even~~ **even** if we receive regulatory approval to market our product candidates, our product candidates might not gain market acceptance upon their commercial introduction, **both of** which could prevent us from becoming profitable. We may have difficulties convincing the medical community, third- party payors and consumers to accept and use **Mydcombi, clobetasol propionate and** any of our product candidates that may be approved for commercialization in the future. Other factors that we believe will affect market acceptance of **Mydcombi, clobetasol propionate and** our product candidates **, if approved,** include: ● the timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained; ● safety, efficacy and ease of administration of **Mydcombi, clobetasol propionate or** our product candidates; ● the success of physician education programs; ● the availability of any government and third- party payor reimbursement; ● the pricing of **Mydcombi, clobetasol propionate or** our product candidates, particularly as compared to alternative treatment methods and medications; ~~53~~ ● the extent to which alternative treatment methods and medications are more readily available as compared to the availability of **Mydcombi, clobetasol propionate or** any product candidates that we may develop in the future; and ● the prevalence and severity of any adverse effects. Our licensing partners may fail to use commercially reasonable efforts to commercialize certain of our products. Our licensing partners are contractually obligated to use commercially reasonable efforts in the commercialization of the products for which they have negotiated a license. Uncovering that one or more of our partners is not using commercially reasonable efforts could take time to discover and time to remedy, during which the sales of our products candidates could be lower than we expect. ~~We~~ **53We** face competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, may adversely affect our financial condition and our, or our licensees', ability to successfully market or commercialize our product candidates. The specialty pharma market is highly competitive. If we or our licensees are unable to compete effectively with any existing products, new treatment methods and new technologies, we may be unable to commercialize our current or any future therapeutic products. The specialty pharma market is subject to rapid technological change and is significantly affected by existing rival products and medical procedures, new product introductions and the market activities of other participants. Pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations may pursue the research and development of technologies, drugs or other therapeutic products for the treatment of some or all of the diseases or conditions we are targeting. We may also face competition from products which have already been approved and accepted by the medical community for the treatment of these same indications. As a result of any of the foregoing factors, our competitors may develop or commercialize products with significant advantages over any therapeutic products that we may develop. If our competitors are more successful in commercializing their products than we are, their success could adversely affect our competitive position and harm our business prospects. If we fail to establish and maintain effective manufacturing and distribution processes our business may be adversely affected. We have limited resources for the manufacturing, sales, marketing and distribution of drug products. To achieve commercial success for **Mydcombi, clobetasol propionate and** the product candidates for which we **may in the future** obtain marketing approval, we will need to establish and maintain an adequate sales force, and additional manufacturing, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties **. We received FDA approval for our primary Mydcombi manufacturing facility in February 2024, which we believe will allow us to expand and continue to build our manufacturing operations. However, we may encounter delays in the manufacturing process for Mydcombi that could delay the process of commercialization of the product, which could have a material negative effect on our revenues** . In addition, failure to secure contracts with manufacturers, wholesalers, retailers, or specialty pharmacies could negatively impact the production and distribution of our potential products, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the manufacturing and distribution process, the commercial launch and sales of our potential products may be delayed or severely compromised and our results of operations may be harmed. We are exposed to the risk of claims seeking monetary damages by individuals and the risk of investigations by regulatory authorities, which could cause us to incur substantial liabilities and to limit commercialization of any products that we develop. We are exposed to the risk of claims seeking monetary damages being filed against us for loss or harm suffered by participants of our clinical trials or for loss or harm suffered by users of **Mydcombi, clobetasol propionate or** any **of our** drug **products** that may receive approval for commercialization in the future. In either event, the FDA or the regulatory authorities of other countries or regions may commence investigations of the safety and effectiveness of any such clinical trial or commercialized drug, the manufacturing processes and facilities or marketing programs utilized in respect of any such clinical trial or drug. Such investigations may result in mandatory or voluntary recalls of any commercialized drug or other significant enforcement action such as limiting the indications for which any such drug may be used, or suspension or withdrawal of approval for any such drug. Investigations by the FDA or any other regulatory authority in other countries or regions also could delay or prevent the completion of any of our other clinical development programs. 54Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop. We face an inherent risk of product liability exposure related to the use of **Mydcombi, clobetasol propionate and** our product candidates that we develop in human clinical trials ~~. We face an even greater risk if we commercially sell any products that we develop~~ . If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual

outcome, liability claims may result in: ● decreased demand for **Mydcombi, clobetasol propionate or** any product candidates or products that we develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend the related litigation; ● substantial monetary awards to clinical trial participants or patients; ● loss of revenue; ● reduced time and attention of our management to pursue our business strategy; and ● the inability to commercialize any **future** products that we develop. Our insurance policies might not fully cover the risk of loss associated with our operations. We may need to increase our insurance coverage as we **commercialize Mydcombi and clobetasol propionate and** expand or undertake new our clinical trials for existing and future product candidates ~~. We will need to further increase our insurance coverage if we commence commercialization of any of the product candidates for which we obtain marketing approval~~ . Insurance coverage is increasingly expensive. We might not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In the event that we are required to pay damages for any such claim, we may be forced to seek bankruptcy or to liquidate because our asset and revenue base may be insufficient to satisfy the payment of damages and any insurance that we have obtained or may obtain for product or clinical trial liability might not provide sufficient coverage against potential liabilities. We may not be able to successfully commercialize **Mydcombi, clobetasol propionate and** our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell **Mydcombi, clobetasol propionate or** our product candidates profitably. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time- consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third- party payors for coverage and reimbursement. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third- party payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. 55Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: ● a covered benefit under its health plan; ● safe, effective and medically necessary; ● appropriate for the specific patient; ● cost- effective; and ● neither experimental nor investigational. We cannot be sure that reimbursement will be available for **Mydcombi, clobetasol propionate or** any product that we **may** commercialize **in the future** and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Even if we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a new product' s acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. For products administered by or under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services ~~(~~**, or** CMS ~~)~~, the federal agency responsible for administering the Medicare program, revises the reimbursement amounts paid to health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we, or any third parties we may engage are slow or unable

to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. If the regulatory authorities in such jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected. 56RISKS RELATED TO REGULATORY APPROVAL OF OUR PRODUCT CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERSThe regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for any of our current or future product candidates, our business may be materially and adversely affected. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug or drug- led combination product candidate in the United States until FDA approval of an NDA is obtained, and we cannot market such a product candidate in any other country until we obtain regulatory authorization as required under the laws of such country. Prior to obtaining approval to commercialize any biologic product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical or preclinical studies and clinical trials may be interpreted differently by different regulatory agencies. Even if we believe the nonclinical or clinical data for ~~Mydcombi,~~ MicroPine ~~,~~ and MicroLine are promising, such data may be insufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our products either prior to or after approval, or it may object to elements of our clinical development programs. This could result in substantial additional costs or delays in the development of our product candidates. Our product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; ● the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities of third- party suppliers with which we contract for clinical and commercial supplies of our product candidates; and ● the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of product candidates developed by pharmaceutical manufacturers, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market ~~Mydcombi,~~ MicroPine, MicroLine, or any of our future product candidates, which would significantly harm our business, financial condition, results of operations and prospects. 57We have invested a significant portion of our time and financial resources in the development of our product candidates. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize such product candidates in a timely manner. Even if we receive approval of an NDA or foreign marketing application for ~~Mydcombi,~~ MicroPine, MicroLine or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request or may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. In addition, the FDA and 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 product candidates 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. **MicroPine** ~~We submitted an~~ **and** ~~NDA to~~ **MicroLine may be considered drug / device combinations and** the ~~FDA~~ **process** for ~~marketing~~ **obtaining regulatory** approval ~~of Mydcombi for mydriasis to facilitate the over 100 million estimated office- based comprehensive and diabetic eye exams and four million ophthalmic surgical dilations performed every year~~ in the United States **will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary for approval of combination products. We anticipate that our product candidates in development, MicroPine and MicroLine, will be considered drug / device combination products because, like Mydcombi, they are also pre- filled or co- packaged ophthalmic drug dispenser products intended for use only with the Optejet dispenser** . In October 2021, we received a CRL from the FDA, which in part informed us that pre- filled or co- packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug- device combination products. **If MicroPine** ~~As a result, we~~

~~resubmitted the NDA for~~ **or MicroLine are** ~~Mydcombi providing additional non- clinical device information, and the FDA accepted the resubmitted NDA for filing and review in December 2022, with a PDUFA date of May 8, 2023. However, even if we addressed all of the issues identified in the CRL, the FDA may ultimately decide that the application does~~ not **also designated** ~~satisfy the applicable regulatory criteria and may decline to approve Mydcombi for commercialization, which would materially adversely impact our business. Mydcombi is a drug / device combination and the process for obtaining regulatory approval in the United States will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary for approval of this combination product. A change in the FDA' s prior determination that CDER would lead the review of a marketing application for Mydcombi would adversely impact its development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Mydcombi. Mydcombi is a drug product for mydriasis that is intended to be administered to a patient via our Optejet dispenser, which uses our microdose array print, or MAP, technology. In October 2021, we received a CRL from the FDA, which in part informed us that pre- filled or co- packaged ophthalmic drug dispenser products like Mydcombi have been reclassified~~ as drug- device combination products ~~. If the designation were to be changed~~ , or if either CDER or CDRH were to institute additional requirements for the approval of ~~Mydcombi~~ **MicroPine or MicroLine** , we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would significantly increase the anticipated cost and timeline to completion of ~~Mydcombi~~ **MicroPine or MicroLine** ' s development and require us to raise additional funds. The FDA may determine that the results of our completed clinical trials are not sufficiently robust or convincing and require additional clinical and / or nonclinical studies prior to approval of **MicroPine** ~~Mydcombi. Because Mydcombi is our~~ **or MicroLine. The** ~~lead product candidate, the~~ impact of either a change in the lead FDA review center or the imposition of additional, currently unanticipated requirements for approval could be significant to us and have a material adverse effect on the prospects for developing ~~Mydcombi~~ **MicroPine or MicroLine** , as well as on our business and our financial condition. **If** ~~Furthermore, we anticipate that our other product candidates in development, MicroPine and MicroLine, will also be considered drug / device combination products because, like Mydcombi, they are also pre- filled or co- packaged ophthalmic drug dispenser products intended for use only with the Optejet dispenser. 58Even if~~ we receive regulatory approval for any of our **current or future** product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post- market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements. If the FDA or a comparable foreign regulatory authority approves any of our **current or future** product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post- approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing studies, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of ~~unanticipated~~ **58unanticipated** severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; ● mandated modification of promotional materials and labeling and the issuance of corrective information; ● imposition of a REMS, which may include distribution or use restrictions; ● requirements to conduct additional post- market clinical trials to assess the safety of the product; ● fines, warning letters or other regulatory enforcement action; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us; ● suspension, limitation, or withdrawal of marketing approvals; ● suspension of any of our ongoing clinical trials; ● product seizure or detention, or refusal to permit the import or export of products; ● consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and ● injunctions or the imposition of civil or criminal penalties; Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and operating results would be adversely affected. ~~59In~~ **In** addition, the FDA' s and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. **If** ~~Even if~~ we obtain FDA approval for any of our **current or future** product candidates **in the United States, and although we have obtained FDA approval for Mydcombi and clobetasol propionate** in the United States, we may never obtain approval for or commercialize **Mydcombi, clobetasol propionate or** any of ~~them~~ **our current or future product candidates** in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a

country- by- country basis regarding safety and efficacy. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. For example, approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. ~~Drug~~ **59Drug** product approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. ~~We~~ **Other than Mydcombi and clobetasol propionate in the United States, we** do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or " off- label " uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business. We must comply with requirements concerning advertising and promotion for **Mydcombi, clobetasol propionate and** any product candidates for which we obtain marketing approval **in the future** . Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory and governmental authorities, Department of Justice, Office of Inspector General for the U. S. Department of Health and Human Services, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities grant regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our current product candidates and any future product candidates, we may not market or promote them for those indications and uses, referred to as off- label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, which may require additional nonclinical studies or clinical trials, and must abide by the FDA or a comparable foreign regulatory or governmental authority' s strict requirements regarding the content of promotion and advertising. While physicians may choose to prescribe products for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by pharmaceutical companies concerning off- label use. ~~60If~~ **If** we are found to have impermissibly promoted **Mydcombi, clobetasol propionate or** any of our current product candidates and any future product candidates, we may become subject to significant liability and government sanctions or enforcement actions. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. In the United States, engaging in the impermissible promotion of **Mydcombi** ~~our~~ **or clobetasol propionate or, for our** ~~products~~ **product candidates** , following approval, for off- label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting products for off- ~~label~~ **60label** uses. In addition, False Claims Act lawsuits may expose manufacturers to follow- on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products ~~, if any,~~ we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. In the United States, the promotion of pharmaceutical products are subject to additional FDA requirements and

restrictions on promotional statements. If ~~after one or more of our current or future product candidates obtains marketing approval~~ the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed. Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off- label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation. Our relationships with customers, health care providers, physicians, prescribers, purchasers, third- party payors, charitable organizations and patients **are** ~~will be~~ subject to applicable anti- kickback, fraud and abuse and other health care laws and regulations, which ~~could~~ expose us to **potential** criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. **As a result of our commercialization of Mydcombi** ~~Although we do not currently have any products on the market~~ , **we are (and** upon commercialization of ~~Mydcombi, MicroPine, MicroLine, or~~ **our** ~~any of our future~~ product candidates, ~~if approved, we~~ will **continue to** be **)** subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Health care providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third- party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the federal Anti- Kickback Statute, or the AKS, and the FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, ~~61structuring~~ **structuring** and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The health care laws that may affect us include: the federal fraud and abuse laws, including the AKS; false claims and civil monetary penalties laws, including the False Claims Act and Civil Monetary Penalties Law; federal data privacy and security laws, including HIPAA, as amended by HITECH; and the federal Physician Payments Sunshine Act which requires us to report to CMS annually any transfers of value made to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, chiropractors, and other advanced practice health care professionals), certain non- physician health care practitioners and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction. ~~The~~ **61The** scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable health care laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from other aspects of its business. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded health care programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, if any of the physicians or other health care providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Healthcare legislative reform measures may have a material adverse effect on our financial condition or results of operations. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or the ACA,

was passed. The ACA was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. As another example, the 2021 Consolidated Appropriations Act, which was signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product' s average sales price to the Department of Health and Human Services ~~(~~**, or** HHS ~~),~~ as of January 1, 2022, as well as several changes to the statutes governing FDA' s drug and biologic programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or have been effectively repealed through Executive Orders and / or executive agency actions. However, following several years of litigation in the federal courts, in June 2021, the U. S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA' s constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. ~~62Further~~ -- **Further** , over the past several years there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The probability of success of these newly announced policies, many of which have been subjected to legal challenge in the federal court system, and their potential impact on the U. S. prescription drug marketplace is unknown. There are likely to be continued political and legal challenges associated with implementing these reforms as they are currently envisioned. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries, and called on HHS to release a comprehensive plan to combat high prescription drug prices. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time- consuming administrative actions. Accordingly, there remains a large amount of uncertainty regarding the federal government' s approach to making pharmaceutical treatment costs more affordable for patients. **62In** ~~Most recently, in~~ August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. The effect of the Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. There remains a large amount of uncertainty regarding the federal government' s approach to making pharmaceutical treatment costs more affordable for patients. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost, or WAC, of their product if the increase exceeds 16 %, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such an increase. Similarly, Vermont requires pharmaceutical manufacturers to disclose price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U. S. Supreme Court also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. We cannot predict the likelihood, nature or extent of government regulation that may arise

from future legislation or administrative or executive action. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. ~~63We~~ **We** are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the United States Foreign Corrupt Practices Act, or FCPA, and the United Kingdom Bribery Act 2010, or Bribery Act, which apply wherever we do business around the world. We may also become subject to local anti- corruption laws in countries where we may do business in the future, such as Canada' s Corruption of Foreign Public Officials Act, the Criminal Law and Anti- unfair Competition Law of the People' s Republic of China, the Hong Kong Prevention of Bribery Ordinance, and the Act on Preventing Bribery of Foreign Public Officials in International Business Transactions, or OECD Anti- Bribery Convention, enacted by the Organisation for Economic Co- operation and Development, and adopted by South Korea along with more than 40 other countries, and which is designed to criminalize bribery of public officials in connection with international ~~business~~ **63business** transactions. The Bribery Act, FCPA, the OECD Anti- Bribery Convention, and similar international treaties and various countries' local anti- corruption laws, referred to as Anti- Corruption Laws, generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, for example, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. We may in the future operate in jurisdictions that pose a high risk of potential violations of Anti- Corruption Laws, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under Anti- Corruption Laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. As we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are also subject to other laws and regulations governing our potential international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. We might not be completely effective in ensuring our compliance with all applicable Anti- Corruption Laws or other legal requirements, including Trade Control laws. If we are not in compliance with Anti- Corruption Laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of Anti- Corruption Laws or Trade Control laws by U. K., U. S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. ~~64Inadequate~~ **Inadequate** funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. The coronavirus pandemic has also adversely affected the operations of necessary government agencies. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which

could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. In addition, competing demands from other companies or issues can affect the timeliness for which the FDA can review and process our regulatory submissions. ~~RISKS~~ **64RISKS** RELATED TO OUR BUSINESS OPERATIONS AND MANAGING GROWTHWe are highly dependent on the services of our senior management team, including our Chief Executive Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, scientific and sales personnel, our business will be harmed. We are highly dependent on our senior management team, including our Chief Executive Officer. The employment agreements we have with our executive officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical, scientific, and sales personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business and commercialization of our product candidates, we might not be able to sustain our operations or grow. We might not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other medical technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates and consultants than what we have to offer. If we are unable to continue to attract, retain and motivate high- quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop drug candidates and our business will be limited and we may experience constraints on our development objectives. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. We have limited corporate infrastructure and may experience difficulties in managing growth. As of March ~~30~~ **15** , ~~2023~~ **2024** , we had only ~~41~~ **57** full time employees and we rely on third-party contractors for the provision of professional and other services. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day- to- day operations and devote a substantial amount of time to managing these growth activities. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, ~~65operational~~ -- **operational** inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we might not be able to implement our business strategy. Our future financial performance, our ability to **successfully** commercialize **Mydcombi, clobetasol propionate and our** drug candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth. We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively. ~~Our~~ **In the ordinary course of our** business **, we collect and store sensitive data and intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business- critical information including research and development information, operational information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks. The secure processing, storage, maintenance, and transmission of this critical information is vital to our** operations ~~could suffer in the event of system failure~~ **and business strategy, and we devote significant resources to protecting such information** . **Although we take** ~~Despite the implementation of security~~ measures ~~, our internal computer systems and those of our contract research organizations, and other contractors and consultants are vulnerable~~ to ~~damage~~ **protect sensitive information** from ~~computer viruses,~~ unauthorized access **or disclosure** , **our information technology** ~~natural disasters, terrorism, war and telecommunication and electrical failures. If such an~~ **and** ~~event were~~ **infrastructure may be vulnerable** to ~~occur and cause~~ **attacks by hackers or viruses, breaches,** interruptions **due to employee error, malfeasance, faulty password management, lapses** in **compliance with privacy and 65security mandates,** ~~our~~ **or other disruptions. The risk of a security breach or disruption, particularly through cyber-attack or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Our IT networks and related systems are essential to the operation of our business and our ability to perform day- to- day** operations **.** ~~, it could result in a material disruption of our drug development programs~~ . For example, the loss of clinical trial data from completed or ongoing or planned 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 further development of our product candidates could be delayed. **Although we make efforts to maintain the security and integrity of these types of IT networks and related systems, and we have implemented various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.** Our **information technology systems may have vulnerabilities, and we may not have the resources or technical sophistication**

to anticipate or prevent rapidly evolving types of cyberattacks, such as ransomware attacks. A significant cyber incident, including system failure, security breach, disruption by malware or other damage, could interrupt or delay our operations, result in a violation of applicable cybersecurity and privacy and other laws, damage our reputation, cause a loss of customers or expose sensitive customer data, or give rise to monetary fines and other penalties, which could be significant. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We engage third- party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third- party service providers' systems. We and our third-party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third- party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third- party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management' s attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing- attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant additional expenses. Any such security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U. S. states, the U. S. federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful. In addition, our insurance may be insufficient to cover our losses resulting from cyber- attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation. 66Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and other comparable foreign regulatory authorities, provide accurate information to the FDA and other comparable foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and in other jurisdictions, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIESWe rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on

third parties to conduct our current and future preclinical studies and clinical trials. CROs that manage our preclinical studies and clinical trials as well as clinical investigators, including in investigator- initiated clinical trials, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities ~~66for~~ -- **for** all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites, including clinical trial sites in investigator- initiated clinical trials, fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, clinicaltrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or comply with applicable regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials or investigator- initiated clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts ~~of~~ **67of** interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Further, under certain circumstances, these third parties may terminate their agreements with us upon prior written notice. Entering into arrangements with alternative CROs, clinical trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed. Furthermore, any CROs we contract with or clinical investigators that conduct investigator-initiated studies involving our product candidates may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or the corresponding protocols, as applicable, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. We **may encounter delays in** ~~are contracting with third parties for~~ the ~~manufacture~~ **manufacturing** of ~~components of our product candidates~~ **the second generation Optejet device** , **including** ~~particularly for commercialization, just~~ as **a result** ~~we do to provide materials required for the production~~ of ~~the Optejet and for some of~~ our ~~current research and development activities. This~~ reliance on third parties **for manufacturing activities, and this may cause delays in the commercialization of our products and our product candidatess. Any such delays would** ~~increases~~ **increase** the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development and commercialization efforts. We do not currently operate and might not be able to timely implement adequate internal manufacturing facilities for all of the components necessary for ~~clinical or~~ commercial production of **Mydcombi** ~~our product candidates. In addition, we rely on, and expect to continue to rely on, a number of third parties for the supply of parts, formulations, active pharmaceutical ingredients, and other materials required for our research and development activities~~ . If we are unable to establish adequate manufacturing processes internally or to reach and maintain agreements with third parties to help us **with** ~~, our research and development,~~ manufacturing, ~~and~~ **our** commercialization activities would be delayed ~~. 67We rely on third parties to provide the materials required for our research and development activities~~ . Reliance on third- party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the third- party suppliers we contract with and are dependent on those third parties for the production of components of our product candidates in accordance with relevant

applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If either we or our third- party suppliers fail to comply with these requirements, we may be subject to regulatory enforcement action, including the seizure of products and shutting down of production. We do not currently have any agreements with third- party suppliers for the long- term commercial supply of components for **Mydcombi. We may be unable to conclude agreements for commercial supply with a sufficient number of suppliers or may be unable to do so on acceptable terms. If we are unable to reach acceptable agreements with a sufficient number of suppliers of materials, our commercialization activities will be delayed and our ability to implement our business plan will be compromised. Our manufacturing process is complicated and expensive and it requires months of advance planning. We rely on a limited number of manufacturers for our current supply of Mydcombi for commercialization. If we were unable to acquire the necessary amount of deliverables to meet market demand, our ability to commercialize could be delayed substantially. Additionally, we do not currently operate and might not be able to timely implement adequate internal manufacturing facilities for all of the components necessary for clinical or commercial production of our product candidates. In addition, we rely on, and expect to continue to rely on, a number of third parties for the supply of parts, formulations, active pharmaceutical ingredients, and other materials required for our research and development activities. If we are unable to establish adequate manufacturing processes internally 68or to reach and maintain agreements with third parties to help us, our research and development, manufacturing, and commercialization activities would be delayed. We rely on third parties to provide the materials required for our research and development activities. Reliance on third- party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the third- party suppliers we contract with and are dependent on those third parties for the production of components of our product candidates in accordance with relevant applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If either we or our third- party suppliers fail to comply with these requirements, we may be subject to regulatory enforcement action, including the seizure of products and shutting down of production. We do not currently have any agreements with third- party suppliers for the long- term commercial supply of components for** our product candidates. We may be unable to conclude agreements for commercial supply with a sufficient number of suppliers or may be unable to do so on acceptable terms. If we are unable to reach acceptable agreements with a sufficient number of suppliers of materials, our research and development activities will be delayed and our ability to implement our business plan will be compromised. Our manufacturing process is complicated and expensive and it requires months of advance planning. We rely on a limited number of manufacturers for our current supply of product candidates and may need to rely on them extensively for adequate supply of our products during commercialization. If we were unable to acquire the necessary amount of deliverables to complete our clinical trials and ultimately commercialize our products, our progress could be delayed substantially. Even if we are able to establish and maintain agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: ● reliance on the third party for regulatory, compliance and quality assurance; ● the possible breach of the manufacturing agreement by the third party; ● the possible misappropriation of our proprietary information, including our trade secrets and know- how; and ● the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. We or our third- party suppliers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce **Mydcombi** ~~our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved,~~ in sufficient quantities for commercialization or to meet an increase in demand, **or, for our unapproved clinical products, our clinical trials,** as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure by us or our third- party suppliers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of **Mydcombi and** our product candidates ~~,~~ may have a material adverse effect on our business. Our third- party suppliers may be subject to inspection and approval by regulatory authorities ~~before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time~~ . Our third- party suppliers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third- party suppliers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of **Mydcombi and** product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. If any of our third- party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize **Mydcombi and** our product candidates could suffer significant interruptions. ~~Any~~ **69Any** disruption, such as a fire, natural hazards or vandalism at our third- party suppliers could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster- recovery facilities available. In case of a disruption, we will have to establish alternative component supply sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we

would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this ~~68occurs~~ -- **occurs** , we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to third- party suppliers occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our product candidates and any products that may obtain approval in the future. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities or under new processes in clinical trials or, for any products reaching approval, in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption **, such as loss of potential sales of Mydcombi** . For these reasons, a significant disruptive event of any third- party suppliers could have drastic consequences, including placing our financial stability at risk. ~~Our~~ **Mydcombi, clobetasol propionate and our** product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and other applicable regulatory requirements and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future suppliers could delay clinical development or marketing approval. If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for **Mydcombi, clobetasol propionate or** any of our product candidates, we could experience delays in our planned clinical studies or commercialization. For example, the COVID- 19 pandemic may impact our ability to procure sufficient supplies for the development of our current and future product candidates, and the extent of such impacts will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID- 19 or treat its effects. We could be unable to find alternative suppliers of acceptable quality and experience that can produce and supply appropriate volumes at an acceptable cost or on favorable terms. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay **commercialization of Mydcombi** ~~our clinical trials and~~ , ~~for~~ **clobetasol propionate and** any **other** product candidates that reach approval, **and** ~~the commercialization of~~ our ~~products~~ **clinical trials** , which would materially adversely affect our business, financial condition and results of operation. If we, our service providers or our third- party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. If we, our service providers, or any third- party manufacturers fail to comply with laws regulating the protection of the environment and health and human safety, we could be subject to enforcement actions and our business prospects could be adversely affected. Our **commercialization and** research and development activities, and the research and development activities of our service providers and third- party manufacturers, may involve the use of hazardous materials and chemicals or the maintenance of various flammable and toxic chemicals. Failure to adequately handle and dispose of these materials could lead to liabilities for resulting damages, which could be substantial. We also may be subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood- home pathogens and the handling of bio- hazardous materials. ~~If~~ **70If** we, our service providers, or any third- party manufacturers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our product candidates. These enforcement actions may include: ● restrictions on, or prohibitions against, marketing **our products or** our product candidates; ● restrictions on importation of **our products or** our product candidates; ● suspension of review or refusal to approve new or pending applications; ● suspension or withdrawal of product approvals; ● product seizures; ● injunctions; and ● civil and criminal penalties and fines. ~~69RISKS~~ -- **RISKS** RELATED TO OUR INTELLECTUAL PROPERTY AND POTENTIAL LITIGATIONOur success depends on our ability to protect our intellectual property and proprietary technology. Our success depends in large part on our ability to obtain and maintain patent, trade secret and other intellectual property protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive and time- consuming and we might not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. If the scope of the patent protection we obtain is not sufficiently broad, we might not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and might not adequately protect our rights or permit us to gain or keep any competitive advantage. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, contractors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. Our pending and future patent applications might not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the coverage claimed in a patent application can

be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they might not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries might not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. ~~Some~~ **71Some** of our future patents and patent applications may be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we would need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation might not be provided to us. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our patents covering our proprietary technology may be subject to challenge, narrowing, circumvention and invalidation by third parties. Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. ~~70Moreover --~~ **Moreover** , we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to our product candidates but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still might not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We cannot be sure that we were the first to make the technologies claimed in our patents or patent applications or that we were the first to file for patent protection. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we may license or purchase patent rights were the first to make relevant claimed inventions or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs. ~~The~~ **72The** patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: ● the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such

an event, competitors might be able to enter the market earlier than would otherwise have been the case; ● the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance; ● patent applications might not result in any patents being issued; ~~71~~ ● patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise might not provide any competitive advantage; ● our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates; ● there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and ● countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects. It is difficult and costly to protect our intellectual property and our proprietary technologies, and we might not be able to ensure their protection. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the composition, use and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third- party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third- party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third- party patents. We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and ~~future~~ **73future** patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and / or materially harm our business. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and might not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● we might not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs; ● it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent (s) will be insufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages; ● if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under United States or foreign laws; or ● if issued, the patents under which we hold rights might not be valid or enforceable. ~~72In~~ **In** addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost- effective to extend our portfolio by pursuing additional development of a product or product candidate for follow- on indications. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Obtaining and maintaining patent protection of our technologies depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance 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. Under the terms of some of our licenses or future licenses, we may not have the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to comply with these requirements. Failure by us or our licensors to maintain protection of our patent portfolio could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, 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, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our present or future partners, collaborators, licensees, or licensors, 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. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations, and prospects. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time and if we do not obtain protection under the Hatch- Waxman Amendments and similar non- U. S. legislation for extending the term of patents covering each of our product candidates, our business may be materially

harmed. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire ~~before~~ **74before** or shortly after such candidates are commercialized. As a result, our patent portfolio might not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we might 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. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business, financial condition, results of operations, and prospects. ~~73Changes~~ -- **Changes** to the patent law in the United States or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. The Leahy- Smith America Invents Act, or the America Invents Act, reformed U. S. patent law in part by changing the U. S. patent system from a " first to invent " system to a " first inventor to file " system, expanding the definition of prior art, and developing a post- grant review system. This legislation changed U. S. patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013. Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post- grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post- grant review can be filed by a third party in a nine- month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine- month period for filing a post- grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post- grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts, and use a lower burden of proof than used in litigation in U. S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U. S. patent invalidated in a USPTO post- grant review or inter partes review proceeding than invalidated in a litigation in a U. S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we, our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us. In addition, court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the United States or other jurisdictions that impairs our ability to protect our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects. ~~We~~ **75We** might not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some foreign countries can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we might not be able to prevent third parties from practicing our inventions in certain foreign countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our

patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights might not be effective or sufficient to prevent them from competing. ~~74Agreements~~ **Agreements** through which we license patent rights might not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings 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 might not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, might not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may have U. S. and non- U. S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and / or methods of use for the treatment of the disease indications for which we are developing our product candidates that may cover our product candidates or approach to complement inhibition. If any third- party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, or our approach to complement inhibition, we might not be free to manufacture or market our product candidates as planned without obtaining a license, which might not be available on commercially reasonable terms, or at all. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post- grant proceedings before the USPTO. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now ~~or~~ **76or** arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it might not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we might not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we might not have sufficient resources to bring these actions to a successful conclusion. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. If we are found to infringe, misappropriate, or otherwise violate a third party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. However, we might not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby ~~75giving~~ **giving** our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property and proprietary technology. Many of our current and former employees and our licensors' current and former employees, including our senior management,

were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. ~~We~~ **77We** may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe, misappropriate, or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which might not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other ~~76interim~~ -- **interim** proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business. We may be reliant upon licenses to certain patent rights and proprietary technology form third parties that are important or necessary to the development of our product candidates. These and other licenses might not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we might not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Our licensors may have relied on third party consultants or collaborators or funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in- license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. In addition, the agreements under which we license patent rights might not give us control over patent prosecution or maintenance, so that we might not be able to control which claims or arguments are presented and might not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We cannot be certain that patent prosecution and maintenance activities by our licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in any licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, it could have a material adverse effect on our business, financial condition, results of operations, and prospects. Further, the agreements under which we currently license intellectual property or

technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract ~~interpretation~~ **78interpretation** disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights under current and any future collaborative development relationships; ● our diligence obligations under any license agreement and what activities satisfy such obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our license counterparties and us and our partners; and ● the priority of invention of patented technology. In spite of our efforts, our license counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, which may remove our ability to develop and commercialize the product candidates and technology covered by these license agreements. If any in- licenses are terminated, competitors would have the freedom to seek ~~77regulatory~~ -- **regulatory** approval of, and to market, products identical to ours. It is possible that we may be unable to obtain any additional licenses that we require at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates, technology, or the methods for manufacturing them or to develop or license replacement technology, all of which might not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed. In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. However, trade secrets are difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our trademarks and trade names are not adequately protected, then we might not be able to build name recognition in our marks of interest and our business may be adversely affected. Our trademarks or trade names, including Optejet ®, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We might not ~~be~~ **79be** able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks might not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we might not be able to compete effectively and our business may be adversely affected. RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCKA significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March ~~28~~ **15** , ~~2023~~ **2024** , we had ~~37~~ **47** , ~~991~~ **386** , ~~746~~ **349** shares of common stock outstanding, ~~1~~ **10** , ~~125~~ **926** , ~~831~~ **554** shares of common stock issuable upon exercise of warrants ~~issued in the private placement completed in March 2020~~ , **6** ~~which may be resold without restriction~~ , **154** ~~and 4~~ , **595** ~~870, 130~~ shares of our common stock issuable upon exercise of ~~warrants and pre- funded warrants issued in~~ **options, 2, 327, 747 of shares issuable upon** the ~~registered direct offering completed~~ **conversion of convertible debt, 241, 764 shares of common stock issuable upon the vesting and / or delivery of restricted stock units and $ 3. 0 million** in ~~March 2022~~ **shares of common stock issuable to Bausch Health Companies Inc. upon achievement of certain regulatory milestones** . The price of our common stock has been, and may continue to be, volatile and may fluctuate substantially, which could result in substantial losses for purchasers of our common stock. The stock market historically has experienced extreme price and volume fluctuations, such as those seen in ~~2022~~ **2023** . As a result of this volatility, you might not be able to sell your

common stock at or above the price at which you purchase it. From our IPO in ~~78~~January -- **January** 2018 through March ~~30~~ **15** , ~~2023~~ **2024** , the per share trading price of our common stock has been as high as $ 10. 74 and as low as $ 1. ~~50~~ **05** . ~~It~~ **The per share trading price of our common stock** might continue to fluctuate significantly in response to various factors, some of which are beyond our control. These factors include: ● general economic, industry and market conditions, including as a result of the ~~evolving~~ coronavirus pandemic and geopolitical events such as the **ongoing war between** ~~Russian~~ - **Russia and** ~~invasion of~~ Ukraine **or between Israel and Hamas; ● our ability to successfully manufacture and commercialize Mydcombi and clobetasol propionate** ; ● our ability to successfully conduct clinical trials, submit NDAs and gain marketing approval for our product candidates; ● results of clinical trials of our product candidates or those of our competitors; ● the success of competitive products or technologies; ● commencing, maintaining, or terminating of licensing agreements and other collaborations; ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of expenses related to any of our product candidates or clinical development programs; ● the results of our efforts to discover, develop, acquire or in- license additional product candidates; **80** ● actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ● our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● significant lawsuits, including patent or stockholder litigation; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems; ● market conditions in the pharmaceutical and biotechnology sectors; **and** ● the other factors described in this " Risk Factors " section. We have broad discretion in the use of our cash, including the net proceeds from our financings, and might not use them effectively. Our management will have broad discretion in the application of our cash, including the net proceeds from our financing transactions, and could spend our cash in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from our financings, in a manner that does not produce income or that loses value. ~~79Our~~ -- **Our** business is subject to changing regulations regarding corporate governance, disclosure controls, internal control over financial reporting, and other compliance areas that will increase both our costs and the risk of noncompliance. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, the Dodd- Frank Act, and the rules and regulations of our stock exchange. The requirements of these rules and regulations will increase our legal, accounting, and financial compliance costs, will make some activities more difficult, time- consuming, and costly, and may also place undue strain on our personnel, systems, and resources. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we performed system and process evaluation and testing of our internal control over financial reporting so that management could report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. Our compliance with Section 404 of the Sarbanes- Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. Prior to our IPO, we had never been required to test our internal controls within a specified period. We are required to disclose changes made to our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act until we are no longer a " smaller reporting company " as defined in the rules of the SEC. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources. We may be adversely affected by the effects of inflation. Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates ~~and~~ **81and** capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. Recently, inflation has increased throughout the U. S. economy. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, 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. Failure to develop and maintain adequate financial controls could cause us to have material weaknesses, which could adversely affect our operations and financial position. An internal control system, no matter how well- designed, cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we might not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that we are required to include in our periodic reports filed with the

SEC under Section 404 of the Sarbanes- Oxley Act. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers, and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not be effective, however, in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes- Oxley Act in a timely manner, that our internal controls are perceived as inadequate, or that we are unable ~~80to~~ **to** produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline. We are an " ~~emerging growth~~ **smaller reporting** company " and the reduced disclosure requirements applicable to ~~emerging growth~~ **smaller reporting** companies may make our common stock less attractive to investors. We are **considered a " smaller reporting company " under Rule 12b- 2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as** an ~~emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this~~ exemption from **providing selected financial data** ~~new or revised accounting standards. For as long as we continue to be an~~ **and** ~~emerging growth company, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding~~ executive compensation **information. These** ~~in our periodic reports and proxy statements,~~ exemptions ~~from the requirements of holding a nonbinding advisory vote on executive compensation~~ and ~~stockholder approval of any golden parachute payments~~ **reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are** not **required to review** ~~previously approved, and exemptions from the requirements of auditor attestation reports on the effectiveness of~~ our internal control over financial reporting **and may make it harder for investors to analyze our results of operations and financial prospects** . We cannot predict if investors will find our common stock less attractive because we ~~will~~ **may** rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our **common** stock ~~price~~ **prices** may be more volatile. We will remain ~~an emerging growth~~ **a smaller reporting** company until ~~the earliest~~ **our public float exceeds $ 250 million as** of ~~(i)~~ the ~~end~~ **last business day** of ~~the~~ **our most recently completed second quarter if our annual revenues are $ 100 million or more as of our most recently completed** fiscal year **,** ~~in which the market value of our~~ **or until our public float** ~~common stock that is held by non- affiliates~~ exceeds $ 700 million as of ~~June 30~~ **the last business day** of **our most recently completed second quarter if our annual revenues are less** ~~that~~ **than $ 100 million as of our most recently completed** fiscal year ~~, (ii) the end of the fiscal year in which we have total annual gross revenue of $ 1. 07 billion or more during such fiscal year, (iii) the date on which we issue more than $ 1 billion in non- convertible debt in a three- year period, or (iv) December 31, 2023~~ . Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation, and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove ~~our~~ **82our** current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions: ● allow the authorized number of our directors to be changed only by resolution adopted by a majority of our Board; ● limit the manner in which stockholders can remove directors from the Board, as may be permitted by law; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board; ● limit who may call stockholder meetings; ● authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so- called " poison pill, " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and ● require all stockholder action to take place at duly called stockholder meetings and disallow the ability of our stockholders to act by majority written consent. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining ~~81~~ **with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is, to the fullest extent permitted by law, the sole and exclusive forum for substantially all disputes between us and our stockholders. These choice of forum provisions could limit the ability of stockholders to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Unless we consent to the selection of an alternative forum, our certificate of incorporation provides that the Court of Chancery of the State of Delaware, or the Court of Chancery, will be, to the fullest extent permitted by law, the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or agent to the Company or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or DGCL, or our certificate of incorporation or bylaws; any action to enforce or determine the validity of our certificate of incorporation or bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Since**

the choice of forum provisions are only applicable to " the fullest extent permitted by law, " as provided in our certificate of incorporation, the provisions do not designate the Court of Chancery as the exclusive forum for any derivative action or other claim for which the applicable statute creates exclusive jurisdiction in another forum. As such, the choice of forum provisions do not apply to any actions arising under the Securities Act of 1933, as amended, or the Exchange Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our 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 materially adversely affect our business, financial condition and operating results. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. 83