Risk Factors Comparison 2025-03-27 to 2024-03-29 Form: 10-K

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

Risks Related to Our Business, Industry and Existing Operating Revenue Stream Future revenue from sales of our dermatology products may be lower than expected or lower than in previous periods. The vast majority of our operating income for the foreseeable future is expected to come from the sale of our dermatology products. Any setback that may occur with respect to such products could significantly impair our operating results and / or reduce our revenue and the value of our securities. Setbacks for such products could include, but are not limited to, issues related to: supply chain, shipping; distribution; demand; manufacturing; product safety; product quality; marketing; government regulation; pricing; reimbursement; licensing and approval; intellectual property rights; competition with existing or new products; product acceptance by physicians, other licensed medical professionals and patients; and higher than expected total rebates, returns or recalls. Also, the majority of our sales derive from products that are without patent protection and / or are or may become subject to third- party generic competition, the introduction of new competitor products, or increased market share of existing competitor products, any of which could have a significant adverse effect on our operating income. We face challenges as our products face generic competition and / or losses of exclusivity. Our products do and may compete with well- established products, both branded and generic, with similar or the same indications. We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to the FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product " at risk, " or when the regulatory or licensed exclusivity for our products expires or is otherwise lost, we may face generic competition as a result. The majority of our sales derive from products that are without patent protection and / or are or may become subject to third- party generic competition, the introduction of new competitor products, or an increase in market share of existing competitor products, any of which could have a significant adverse impact on our operating income. Three of our marketed products, Qbrexza, Amzeeq, and Zilxi as well as ~~DFD- 29~~ **Emrosi which was approved by the FDA on November 1, 2024** , currently have patent protection. ~~Three~~ **Four** of our marketed products, Accutane, Targadox, ~~and~~ Exelderm **and Luxamend** , do not have patent protection or otherwise are not eligible for patent protection. Accutane currently competes in the Isotretinoin market with five other therapeutic equivalent (" AB rated ") products. Targadox faces AB rated generic competition. Exelderm may face AB rated generic competition in the future. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required to be utilized before or in preference to the branded version under third- party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. If we fail to do so, our results of operations, financial condition or cash flows may be materially adversely affected. Any disruptions to the capabilities, composition, size or existence of our field sales force may have a significant adverse impact on our existing revenue stream. Further, our ability to effectively market and sell any future products that we may develop will depend on our ability to establish and maintain sales and marketing capabilities or to enter into agreements with third parties to market, distribute and sell any such products. Our field sales force has been and is expected to continue to be an important contributor to our commercial success. Any disruptions to our relationship with our field sales force could materially adversely affect our product sales. We may rely on professional employer organizations and staffing organizations for the employment of our field sales force in the future. The establishment, development, and / or expansion of a field sales force, either by us or certain of our partners or vendors, or the establishment of a field sales force to market any products for which we may have or receive marketing approval, is expensive and time- consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non- technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish or maintain arrangements with third parties on commercially reasonable terms, or at all, which would have a material adverse effect on our business, prospects, results of operations, financial condition or cash flows . Our current and potential future product....., in order to maintain the approval . Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective. If the FDA or any regulatory authority limits the scope of our indication, or if we are unable to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. Further, we are only permitted to promote our products for those indications specifically approved by the FDA and there are restrictions around making communications regarding uses not approved and described in the product' s labeling. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to advisory or enforcement action by these authorities. In addition, our failure to follow FDA requirements or guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505 (b) (2)

regulatory approval pathway, or if the requirements for such product candidate under Section 505 (b) (2) are not as we expect, the approval pathway for the product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA' s prior conclusions ~~regarding~~ **25regarding** the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization. ~~28In~~ **In** addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, certain brand- name pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its Section 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). In addition, the pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval. Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. If any of our contract manufacturers fails to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of ~~this~~ **our products or development and commercialization of any future** product candidate **, if approved,** or be unable to meet market demand, and may lose potential revenues. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Any termination or disruption of any current or future relationships relating to product development may materially harm our business and financial condition and frustrate any **development and** commercialization efforts for affected current **or future products** or future product candidates. Any current or future contract manufacturers we engage must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its establishment inspection program. Despite the existence of contract manufacturing agreements and shared cGMP responsibilities, our contract manufacturers' may ignore these contractual provisions, or otherwise fail to meet the minimum standards set forth in the cGMP regulations, resulting in manufacturing non- compliance. This may go unnoticed or uncorrected despite our best efforts to regulatory audit or confirm the CMOs regulatory responsibilities. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recalls, re- stocking costs, damage to our reputation and potential for product liability claims. If the CMOs upon which we rely to manufacture any current products, and any potential product candidates we may in- license or acquire, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues. ~~If~~ **26If** serious adverse or unacceptable side effects are identified during the development of any ~~current or~~ future product candidates, we may need to abandon or limit our development of ~~some of the~~ **these** ~~other potential~~ product candidates. If any ~~current or~~ future product candidates are associated with undesirable side effects, toxicities, or other negative characteristics, we may need to abandon such ~~products~~ **product candidates** ' ~~commercialization,~~ development or limit development to more narrow uses or subpopulations. Such side effects may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims. Many compounds that show initial promise in early- stage testing are later found to cause side effects that prevent further development. If our clinical trials reveal severe or prevalent side effects, our trials could be suspended or terminated, we may be unable to recruit patients and enrolled patients may be unable to complete the trials, and the FDA or

comparable foreign regulatory authorities could order issue a clinical hold, or order us to cease further development or deny approval of the product candidate. The FDA may also request additional data, which it has done with increased prevalence in recent years, which has resulted in substantial delays in new drug approvals. Undesirable side effects caused by any ~~current or~~ future product candidates could also result in the inclusion of unfavorable information in our product labeling, **if approved,** denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of such product candidate. ~~29If~~ **If** one or more of our current products or any future product candidate receives marketing approval and we or others later identify undesirable adverse events or side effects caused by this product, or we fail to comply with post- market regulatory requirements, a number of potentially significant negative consequences could result, including: ● regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication; ● regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market; ● we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of any current or future product candidate or could substantially increase our development and commercialization costs and expenses, which could delay or prevent us from generating significant revenues. All of our current and future products will remain subject to substantial regulatory scrutiny even after receiving regulatory approval. Any products ~~or current~~ or future product candidates we may license or acquire will be subject to ongoing regulatory and compliance requirements and oversight by the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and other licensed medical professionals and recordkeeping of the drug. The Food and Drug Administration Amendments Act of 2007 granted significant expanded authority to the FDA, much of which was aimed at improving the safety of drug products before and after approval. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off- label marketing. While physicians and other healthcare providers may choose to prescribe drugs for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These " off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U. S. generally do not regulate the practice of medicine, including the clinical behavior of physicians and other healthcare providers in their choice of treatments. Regulatory authorities do; however, restrict communications by pharmaceutical companies on the subject of off- label use. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. ~~In~~ **27In** addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on such products or their manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a product; ● restrictions on product distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters, untitled letters, or Form 483s; ~~30~~ ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits; ● suspension or withdrawal of marketing or regulatory approvals; ● suspension of any ongoing clinical trials; ● denial of permits to import or export our products; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. The FDA' s policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our ~~current or~~ future product candidates **. There is added uncertainty with the new presidential administration that began in 2025** . 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. Our current and future relationships with customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of our current products **and any** ~~or current or~~ future product candidates for which we obtain marketing approval. Our current and future arrangements with third- party payors for the sales of our products and sales to customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute (" AKS ") and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any current products or ~~current or~~ future product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U. S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include: ● AKS, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which

payment may be made under federal and state ~~healthcare~~ **28healthcare** programs, such as Medicare and Medicaid. The OIG continues to make modifications to existing AKS safe harbors which may increase liability and risk as well as adversely impact sales relationships. The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ~~31~~ ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (" CMS "), information related to " payments or other transfers of value " made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists, chiropractors, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse- midwives and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; ● **U. S. Foreign Corrupt Practices Act, or FCPA, which prohibit us and third parties working on our behalf from making payments to foreign government officials to assist in obtaining or retaining business. Specifically, the anti- bribery provisions of the FCPA prohibit the willful use of the mails or any means of instrumentality of interstate commerce corruptly in furtherance of any offer, payment, promise to pay, or authorization of the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business to, any person; enforcement actions may be brought by the Department of Justice or the SEC; legislation has expanded the SEC' s power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent- based claims, such as those under the FCPA, from five years to ten years;** ● Increased OIG scrutiny on the sale of our products through specialty pharmacies by means of direct investigation or by issuance of unfavorable Opinion Letters which may curtail or hinder the sales of our products based on risk of enforcement upon our- selves or our buyers; ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; ● state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and ● state and foreign laws governing the privacy and security of health information in certain circum- stances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. ~~Efforts~~ **29Efforts** to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business. We have established and implemented a corporate compliance program designed to prevent, detect and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of our products. Nonetheless, enforcement agencies or private plaintiffs may take the position that we are not in compliance with such requirements and, if such noncompliance is proven, the Company and, in some cases, individual employees, may be subject to significant liability, including the aforementioned administrative, civil and criminal sanctions. ~~32We are~~ **Our products and future product candidates may become** subject to **unfavorable pricing** ~~new legislation, regulatory~~ **regulations** ~~proposals~~ **, third- party coverage** and ~~managed care~~ **reimbursement practices or healthcare reform** initiatives ~~that may increase~~ **, which could harm** our **business. Our** ~~costs of compliance and adversely affect our~~ ability to ~~market~~ **successfully commercialize** our products, ~~obtain collaborators~~ **or any future product candidate for which we receive marketing authorization, will depend in part on the extent to which coverage** and ~~raise capital~~ **reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations** . ~~In~~

Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and ~~certain~~ **elsewhere is cost containment. It is currently unknown what impact, if any, proposed changes by the federal and state governments in the U. S. and similar changes in foreign countries may have on pricing and reimbursement, particularly with respect to government programs such as Medicare and Medicaid. The United States and many** foreign jurisdictions ~~, there~~ have **enacted or proposed** ~~been, and we expect there will continue to be, a number of~~ legislative and regulatory changes ~~to~~ **affecting** the healthcare system ~~that could impact our ability~~ **, including implementing cost- containment programs** to ~~sell our licensed~~ **limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic** products ~~profitably~~ **for branded prescription drugs** . In ~~March 2010,~~ the ~~Patient Protection and~~ **United States, the** Affordable Care Act ~~, as amended by the Health Care and Education Reconciliation Act of 2010 (the " PPACA " or collectively, the " ACA "),~~ was ~~signed into law~~ **intended to broaden access to health insurance** , ~~which substantially changed~~ **reduce or constrain** the ~~way~~ **growth of** healthcare **spending** ~~is financed by both governmental and private insurers in the United States. By way of example~~ , **enhance remedies against fraud** ~~the ACA: increased the minimum level of Medicaid rebates payable by manufacturers of brand~~ -- **and abuse, add transparency requirements** ~~name drugs from 15. 1 % to 23. 1 %; required collection of rebates~~ for **the healthcare and health insurance industries,** ~~drugs paid by Medicaid managed care organizations; imposed~~ - **impose new taxes and** ~~a non- deductible annual fee~~ **fees** on ~~pharmaceutical manufacturers or importers who sell certain " branded prescription drugs " to specified federal government programs; implemented a new methodology under which rebates owed by manufacturers under~~ the **health industry** ~~Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded the eligibility criteria for Medicaid programs; created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in,~~ and **impose additional health policy reforms** ~~conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation (" CMMI ") at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending~~ . ~~Since its enactment, there~~ **There** have been **significant ongoing judicial, administrative,** executive ~~, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On January 20, 2017, President Trump signed an~~ **and legislative efforts** ~~executive order stating that his administration intended~~ to **modify or eliminate** ~~seek prompt repeal of~~ the Affordable Care Act ~~, and, pending repeal, directed the U~~ . **Changes** ~~S. Department of Health and Human Services and other executive departments and agencies~~ to **and under** ~~take all steps necessary to limit any fiscal or regulatory burdens of~~ the Affordable Care Act **remain possible but it is unknown what form** ~~. On January 28, 2021, President Biden signed an~~ **any** ~~Executive Order on Strengthening Medicaid and~~ **such changes or any law proposed to replace or revise** the Affordable Care Act **would take** ~~and stated his administration' s intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order~~ , ~~the Department of Health~~ and **how or whether it may affect our business in** ~~Human Services, United States Treasury, and the Department of Labor are directed to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they~~ - **the future. We expect that changes to the Affordable** ~~are~~ **Care** ~~consistent~~ **Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially** with **regard to** ~~ensuring both coverage under the ACA and making high- quality~~ healthcare ~~affordable and accessible~~ ---- **access** ~~to Americans. On March 11~~ , **financing or** ~~2021, President Biden signed into law the~~ **other legislation in individual states, could have a material adverse effect** ~~American Rescue Plan Act of 2021 to further strengthen Medicaid and the ACA and~~ on ~~April 5, 2022, President Biden signed the Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage in which he~~ **the** ~~celebrated the significant progress his administration believes has been made across the U. S. in making healthcare more affordable and accessible. In this Executive Order, President Biden directed agencies " with responsibilities related to Americans' access to health coverage " to " review agency actions to identify ways to continue to expand the availability of affordable health coverage. " The continued expansion of the government' s role in the U. S.~~ healthcare industry ~~may further lower rates of reimbursement for pharmaceutical products~~ . ~~While we~~ **We also expect that the Affordable** ~~are~~ **Care Act, as well as** ~~unable to predict the likelihood of changes to the ACA or~~ other healthcare ~~laws which~~ **reform measures that have and** may ~~negatively impact our profitability, we continue to closely monitor all changes. President Biden intends, as his predecessor did, to take action against drug prices which are considered " high. " Drug pricing continues to~~ be **adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our products and any future product candidates, if approved. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in** a **similar reduction in payments from private payers** ~~subject of debate at the executive and legislative levels of U. S. government~~ . The ~~American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the~~ Inflation Reduction Act of 2022 **(the " IRA ")** contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. **Orphan drugs that treat only one rare disease are exempt from the IRA' s drug negotiation program.** Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the **IRA** ~~Inflation Reduction Act of 2022~~ . The ~~Inflation Reduction Act of 2022 could have the effect~~ **effects** of

~~reducing~~ the **IRA** ~~prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect~~ on ~~our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and~~ the pharmaceutical industry in general ~~is~~ **are** not yet known. ~~33At~~ **30At** the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any current product or future product candidate. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any ~~current or~~ future product candidates, if any, may be. In addition, increased Congressional scrutiny of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. ~~Public~~ **We also do not know what impact any changes made by the new presidential administration will have on our business. Such actions may impact the development and commercialization of drug products and could materially harm our business and financial conditionPublic** concern regarding the safety of any of our ~~current or~~ **products and any** future ~~drug products~~ **product candidates** could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to incur additional costs. In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and the establishment of risk management programs. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any other potential future product candidate, our ability to obtain of such product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any potential future product candidate, the indications for which such product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize potential future product candidate may be otherwise adversely impacted. ~~.~~Our ~~current and~~ potential future product candidates may not receive regulatory approval,or such approval may be delayed,which would have a material adverse effect on our business and financial condition.Further,even if a product **candidate** receives regulatory approval,such product will remain subject to substantial regulatory scrutiny. ~~Our~~ **Although all of our** current ~~and~~ **products have been approved by the FDA any** potential future product candidates and the activities associated with their development and commercialization,including their
design,testing,manufacture,safety,efficacy,recordkeeping,labeling,storage,approval,advertising,promotion,sale and distribution,are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and abroad.Our failure to obtain marketing approval for any ~~current or~~ future product candidates will prevent us from commercializing the product candidates.Further,any ~~products or~~ future ~~products~~ **product** candidates we license or acquire will be subject to ongoing requirements and review by such regulatory authorities.We have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process.To secure marketing approval,we will be required to establish a product candidate' s safety and efficacy by submitting extensive preclinical and clinical data and supporting information for each therapeutic indication.We will further be required to submit information about the product manufacturing and to undergo regulatory inspection of our third- party manufacturing facilities to ensure ongoing compliance with cGMP requirements.Any of our ~~current or~~ future product candidates may not be effective,may be only moderately effective or may prove to have undesirable or unintended side effects,toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit ~~commercial~~ **31commercial** use.If **any** ~~our current or~~ future product candidates receive (s) marketing approval,the accompanying label may limit the approved use of our drug in this way,which could limit sales of the product. ~~27The~~ -- **The** marketing approval process,both in the United States and abroad,is time consuming and expensive.Approval may take many years,and if it is granted can vary substantially based upon a variety of factors,including the type,complexity and novelty of the product candidates involved.Our product candidates could be delayed in receiving,or fail to receive,regulatory approval for many reasons,including:the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;the FDA or comparable foreign regulatory authorities may disagree with our development strategy;we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or is suitable to identify appropriate patient populations;the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks.Changes to marketing approval policies or the regulatory

landscape during the development period may cause rejection of or delays in the approval of an application.Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or decide that our data is insufficient for approval and require costly additional preclinical studies or clinical trials.In addition,varying interpretations of the data obtained from preclinical and clinical testing could delay,limit or prevent marketing approval of a product candidate.Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable.If we experience delays in obtaining or fail to obtain or maintain any necessary approvals of any ~~current or~~ future product candidates,receive approval for fewer or more limited indications than we request or without including the labeling claims we desire,our future commercial prospects may be harmed and our ability to generate revenue may be materially impaired.Even if we do receive approval,it may be contingent on the performance of costly post- marketing clinical trials to verify whether or not the drug provides the anticipated clinical benefit,in order to maintain the **approval.** If we experience delays or difficulties in the enrollment of patients in any future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate any future clinical trials for any ~~current or~~ future 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 similar regulatory authorities outside the United States. Some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as our ~~current or potential~~ future product candidates, and patients who would otherwise be eligible for any future clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors, including: ● the severity of the disease under investigation; ● the eligibility criteria for a study; ● the perceived risks and benefits of the product candidate under study; ● the efforts to facilitate timely enrollment in clinical trials; ● the patient referral practices of physicians; ● the ability to monitor patients adequately during and after treatment; ~~and34~~ -- **and** ● the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for any future clinical trials would result in significant delays and could require us to abandon any future clinical trials altogether. Enrollment delays in any future clinical trials may result in increased development costs for any ~~current or~~ future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. ~~We~~ **32We** expect intense competition for our products and **any** ~~current or~~ future product candidates, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications. We face, and will continue to face, competition in the development and marketing of products from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including specialty and other large pharmaceutical companies, and OTC companies and generic manufacturers. The dermatology competitive landscape is highly fragmented, with many mid- size and smaller companies competing in the prescription sector. Our competitors are pursuing the development and / or acquisition of pharmaceuticals, medical devices and OTC products targeting the same diseases, conditions, and indications as our products. There can be no assurance that our competitors' developments, including the development of other drug technologies and methods of preventing the incidence of disease, will not render our current products ~~or current~~ or future product candidates obsolete or noncompetitive. If patents covering any of our currently marketed products expire or are successfully challenged, or when the regulatory or licensed exclusivity for our products expires or is otherwise lost, we will face increased competition from generic versions of our products. Generic versions are generally significantly less expensive than branded versions and third- party reimbursement programs may require or prefer that a generic version is used before the branded version. Accordingly, when a branded product loses market exclusivity, the product faces intense price competition from generic versions. To successfully compete for business with managed care and pharmacy benefits management organizations, we must demonstrate that our products offer medical and cost advantages when compared with other forms. Competitive factors vary by product line and geographic area in which the products are sold. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts. The commercial opportunity for our products and / or **future** product ~~future~~ candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in- licensed intellectual property. Many of our potential competitors have substantially greater capital resources, development resources, including personnel and technology, clinical trial and regulatory experience, expertise in the prosecution of intellectual property rights, and manufacturing, distribution, and sales and marketing than we do. As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize any ~~current or~~ future product candidates. Our competitors may also develop drugs or products that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their drugs or products. If we are unable to compete effectively ~~, our business~~ , our business, prospects, results of operations, financial condition or cash flows may be materially adversely affected. If our products do not achieve broad market acceptance, including by government and third- party payors, the revenues that we generate from sales will be limited. The commercial success of our products or any ~~current or~~ future product candidates will depend upon their acceptance by the medical community and coverage and reimbursement for our products by third- party payors, including government payors. The degree of market acceptance of our products or any other potential product candidate we may develop, license or acquire will depend on a number of factors, including: ● the success of any potential clinical studies during the drug development process; ● limitations of use, contraindications, or warnings contained in the product' s FDA- approved labeling; ● changes in the standard of care for the targeted indications for any ~~current or~~ future product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; ~~35~~ ● ability to be listed on formularies (lists of recommended or approved medicines and other products) and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications; and ● potential advantages over, and availability of, alternative treatments. ~~Our~~ **33Our** ability to effectively promote and sell our **current** products and any ~~other current or~~ future product candidates **for which we receive marketing authorization,** we may develop, license or acquire in the marketplace will

also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto formularies, as well as our ability to obtain sufficient third- party coverage or reimbursement. Since many insurance plans are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the marketplace will also depend on our ability to effectively promote any ~~current or~~ future product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with any ~~current or~~ future product candidates. If any ~~current or~~ future product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third- party payors on the benefits of any ~~current or~~ future product candidates may require significant resources and may never be successful. Further, in both domestic and foreign markets, any future product sales will depend in part upon the availability of coverage and reimbursement from third- party payors. Such third- party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We may need to conduct post- marketing studies in order to demonstrate the cost- effectiveness of any future products to the satisfaction of target customers and their third- party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our current or future products might not ultimately be considered cost- effective. Adequate third- party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. Risks Related to Our Reliance on Third PartiesIf we are unable to maintain sales, marketing, and distribution capabilities, or to enter into agreements with third parties to market and sell **our** current **products** or **any** future product candidates **for which we receive marketing authorization** , we may not be successful in generating revenues from selling and commercializing any such product candidates. In order to commercialize any **of our** current **products** or **any** future **products or** product candidates that have not yet received marketing approval or for which we have not yet acquired rights, we may need to build additional marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services tailored to those products, and we may not be successful in doing so. In the event of successful development and regulatory approval of any potential new product candidate, or a new product acquisition, we expect to build a targeted specialist field sales force to market or co- promote that specific product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a field sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a future product candidate or acquired product for which we recruit a field sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to maintain our current products' marketing and sales organizations and / or commercialize any future products on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians and other healthcare providers or persuade adequate numbers of physicians and other healthcare providers to prescribe any future products; ● the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. ~~36We~~ **34We** are dependent on third parties to supply raw materials used in our products, to manufacture our products, and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors, and collaboration partners to meet their contractual obligations to us or obligations pursuant to applicable laws and regulations may materially adversely affect our business, financial condition, results of operations and cash flows. We rely on third parties to supply raw materials, to manufacture, warehouse, and distribute our products, as well as to provide customer service support, medical affairs services, clinical studies, sales, and other technical and financial services. All third- party suppliers and contractors are subject to FDA requirements, as well as those of comparable regulatory authorities. Our business and financial viability are dependent on the continued supply of goods and services by these third parties, the regulatory compliance of these third parties and on the strength, validity and terms of our various contracts with these third parties. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us on schedule or in accordance with our expectations, misappropriation of our proprietary information, including trade secrets and know- how, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the future development, future approval, manufacture or commercialization of our products, result in non- compliance with applicable laws and regulations, cause us to incur failure- to- supply penalties with our wholesale customers, disrupt our operations or cause reputational harm to our company, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. We may also be unsuccessful in resolving any underlying issues with such suppliers, distributors and partners or replacing them within a reasonable time and on commercially reasonable terms. We do not expect to have the resources or capacity to commercially manufacture any future approved product candidates ourselves. We will likely continue to be heavily dependent upon third- party manufacturers, over whose manufacturing practices and processes we will have oversight, but not direct control, which may adversely affect our ability to develop and commercialize products in a timely or cost- effective manner, if at all. If any of our third- party manufacturers should become unavailable to us for any reason, including as a result of capacity constraints, differing priorities, financial difficulties or insolvency, we would likely incur added costs and delays in identifying or qualifying replacements. We may be unable to establish agreements with such replacement manufacturers or to do so on terms acceptable to us, and our

reputation, business, financial condition and results of operations could be negatively impacted. The pharmaceutical manufacturing process requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Further, the CMOs with which we contract must comply with strictly enforced federal, state, and foreign regulations, including the cGMP requirements enforced by the FDA. We will rely on our CMOs to comply with all such regulatory requirements, including cGMP requirements, and failure to do so may result in fines and civil penalties, suspension of production, suspension, delay, or withdrawal of product approval, product seizure or recall, and may limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in costly recall procedures, re- stocking costs, damage to our reputation and potential for product liability claims. The FDA would likely hold us ultimately responsible for any product our CMO manufactures and regulatory enforcement for failure to meet FDA requirements would impact both the CMO and ourselves. The FDA considers the owners of drug products to be ultimately responsible for their products, even where a CMO or other third- party manufacturer fails to meet FDA requirements specific to manufacturing activities. Despite the fact that we have limited oversight, and no direct control over these manufacturing activities, any failure by a CMO to meet the requirements of the regulations would have an adverse impact on both the CMO and ourselves. We also may rely on third-party manufacturers to purchase from third- party suppliers the materials necessary to produce **any** ~~our current or~~ future product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have any control over the process or timing of the acquisition of these raw materials by our third- party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of raw material components related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval. We rely, and expect to continue to rely, on third parties to conduct any future preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials or to comply with applicable regulatory requirements. We expect to rely on third- party contract and clinical research organizations, clinical data management organizations, and medical institutions and clinical investigators to conduct future preclinical studies and clinical trials. Any future agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay any future product development activities. ~~37Our~~ **35Our** reliance on any third parties for research and development activities will reduce our own control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of any future preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that any future preclinical studies are conducted in accordance with good laboratory practice (“ GLP ”) as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (“ GCPs ”) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our future clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that any such regulatory authority, upon inspection of any future clinical trial, will determine that such clinical trial complies with cGMP regulations. In addition, any future clinical trials must be conducted with product produced under cGMP regulations and subject to an IND. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory 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. The third parties with whom we may contract to help perform future preclinical studies or clinical trials 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 our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any ~~current or~~ future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates. If any of our future relationships with these third- party contract research organizations or clinical research organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we will carefully manage any future relationships with contract research organizations or clinical research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future. We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable. As part of our strategy to mitigate development risk, we intend on developing product candidates with validated mechanisms of action and assess potential clinical efficacy early in the development process or otherwise acquire the rights to products for which marketing approval has already been obtained. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. If the third- party data and results we rely upon prove to be inaccurate, unreliable or not applicable to future product candidates or acquired products, we could make inaccurate assumptions and conclusions about **any** ~~current or~~ future product candidates and our research and development efforts could be compromised. If successful product liability claims are brought against us, we may incur substantial liability, and may have to limit the commercialization of certain current or future products or product

candidates. The use of our products and any ~~current or~~ future product candidate we may license, acquire or develop in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product or product candidate we develop or sell allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Product liability claims might be brought against us by consumers, health care providers or others who use, administer, or sell our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● termination of clinical trial sites or entire trial programs or withdrawal of clinical trial participants; ● regulatory investigations by governmental authorities related to regulatory issues or alleged non- compliances; ● litigation costs and potential monetary awards to patients or other claimants; ~~38~~ **36** ● harm to our reputation and / or decreased demand for our products and corresponding revenue loss; ● reduced resources of our management to pursue our business strategy; and ● the inability to commercialize our current products or any ~~current or~~ future product candidates **for which we receive marketing authorization** . We ~~have obtained or~~ will obtain limited product liability insurance coverage for any and all ~~current or~~ future clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Our current insurance coverage includes the sale of commercial products, but we may be unable to maintain or obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and materially adversely affect our business, results of operations, financial condition or cash flows. We began marketing and promoting Accutane ®, an isotretinoin product in the second quarter of 2021. Isotretinoin has a black box warning for use in pregnant women. Isotretinoin also has warnings for side effects related to psychiatric disorders and inflammatory bowel disease, among others. Historically, isotretinoin has been the subject of significant product liability claims, mainly related to irritable bowel disease. Currently, there is no significant isotretinoin product liability litigation. In 2014, the federal multi- district litigation (“ MDL ”) court ruled that the warning label for isotretinoin was adequate and dismissed all remaining federal isotretinoin cases. The MDL dissolved in 2015, effectively ending federal isotretinoin lawsuits. Isotretinoin cases continued in New Jersey state court until 2017, when the trial court judge dismissed the remaining isotretinoin product liability cases. Accordingly, we have substantial defenses should a product liability claim arise related to isotretinoin. However, we cannot predict the ultimate outcome of any litigation and the Company may be required to pay significant amounts as a result of settlement or judgments should any new product liability claim be brought. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. If we 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. Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations **, including climate- related initiatives** . These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. **37The use of artificial intelligence in the healthcare industry and challenges with properly managing its use could adversely affect our business. We may incorporate artificial intelligence (“ AI ”) solutions into our business, and applications of AI may become important in our operations over time. Our competitors or other third parties may incorporate AI into their businesses more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. There are also significant risks involved in developing and deploying AI, and there can be no assurance that the usage of AI will enhance our products or the development of any future product candidates or be beneficial to our business, including our efficiency or profitability. For example, any AI- related efforts, particularly those related to generative AI, could subject us to risks related to harmful content, inaccuracies, bias, discrimination, intellectual property infringement or misappropriation, defamation, data privacy, cybersecurity, and sanctions and export controls, among others. It is also uncertain how various laws will apply to content generated by AI. We are subject to the risks of new or enhanced governmental or regulatory scrutiny, litigation, or other legal liability, ethical concerns, negative consumer perceptions as to automation and AI, or other complications that could adversely affect our business, reputation, or financial results. AI’ s rapid development is the subject of evolving review by various U. S. governmental and regulatory agencies, and other foreign jurisdictions are applying, or are considering applying, their intellectual property, cybersecurity, data protection and other laws to AI, and / or are considering general legal frameworks on AI. We may not be able to timely comply with these frameworks and, if such regulatory actions are contrary to our use of AI, would require us to expend our limited resources to adjust our use accordingly.** ~~39Risks~~ --

Risks Related to our GrowthA significant part of our future growth may depend on our ability to identify and acquire or in-license products, and if we do not successfully identify and acquire or in- license related product candidates or integrate them into our operations, we may have limited growth opportunities. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in- licensing products, product candidates, businesses or technologies that we believe are a strategic fit with our focus on the dermatological marketplace. Future in- licenses or acquisitions may entail numerous operational and financial risks, including: ● exposure to unknown liabilities; ● disruption of our business and diversion of our management' s time and attention to develop acquired products or technologies; ● difficulty or inability to secure financing to fund development activities for such acquired or in- licensed technologies in the current economic environment; ● incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions; ● higher than expected acquisition and integration costs; ● increased amortization expenses; ● difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; ● impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and ● inability to retain key employees of any acquired businesses. ~~We~~ **38We** have limited resources to identify and execute the acquisition or in- licensing of third- party products, current or future product candidates, businesses, and technologies and to integrate them into our current infrastructure. As a result, we focus on research programs and product candidates that we identify for specific indications, which may cause us to forego or delay pursuit of opportunities with other product candidates or for other indications that may have greater commercial potential. Further, we may devote resources to potential acquisitions or in- licensing opportunities that are ultimately not completed or of which we do not realize the anticipated benefits. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Additionally, we may compete with larger pharmaceutical companies and other competitors for new collaborations and in- licensing opportunities. These competitors likely will have greater financial resources than we do and may have greater expertise in identifying and evaluating new opportunities. The realization of any of the foregoing risks related to our acquisition and in-license strategy could materially adversely affect our business, results of operations, financial condition or cash flows. ~~40Our~~ -- **Our** growth is subject to economic and political conditions. Our business is affected by global and local economic and political conditions as well as the state of the financial markets, inflation, recession, financial liquidity, currency volatility, growth, and policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location. ~~Our operating history may make it difficult to evaluate~~ **Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect** our business **, particularly if these measures occur in regions** ~~and prospects as it relates to clinical trials or regulatory approvals. We were~~ **where** ~~incorporated~~ **drug products are manufactured or raw materials are sourced. With the new presidential administration** in ~~October 2014~~ **the U. S., additional** and ~~have only been conducting~~ **higher tariffs and sanctions may be imposed on goods imported from China and other countries which could increase the cost of goods needed to** ~~commercial~~ **commercialize our products and development of any future product candidates. Further, such actions by the U. S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business,** operations **,** ~~with respect to our products since 2015. We have not yet demonstrated an~~ **and financial condition** ~~ability to successfully complete clinical trials or obtain regulatory approvals. Consequently, any predictions about our future performance may not be as accurate as they~~ could be **materially harmed** ~~if we had a history of successfully developing and commercializing future pharmaceutical products. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to expand our capabilities to support any future commercial activities. We may not be successful in adding such capabilities. We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance~~ . We may not be able to manage our business effectively if we are unable to attract and retain key personnel. We may not be able to attract or retain qualified management and commercial, sales, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede sales growth of our branded and generic products, the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We may decide to sell assets, which could adversely affect our prospects and opportunities for growth. We may from time to time consider selling certain assets if we determine that such assets are not critical to our strategy or we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, we may be forced to sell assets in response to liquidation or other claims described herein, and any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. As a result, any such sale could have a material adverse effect on our business, financial condition, results of

operations and cash flows. ~~There~~ **39There** is substantial doubt regarding our ability to continue as a going concern. We may need to raise additional funding (which may not be available on acceptable terms to the Company, or at all) and / or to delay, limit or terminate certain of our product development and commercialization efforts or other operations. Our current assumptions, projected commercial sales of our products, clinical development plans and regulatory submission timelines are uncertain and may not emerge as expected. Additionally, as a result of recurring losses from operations, we have concluded that there is substantial doubt regarding our ability to continue as a going concern for a period of at least 12 months from the date of the issuance of the financial statements included in this Annual Report on Form 10- K for the year ended December 31, ~~2023~~ **2024** . In addition to reductions in sales force and marketing expenses, we may also seek to raise capital through additional debt or equity financing, which may include sales of securities under our existing shelf registration statement on Form S- 3, including under the Sales Agreement with B. Riley, or under a new registration statement. ~~41Our~~ -- **Our** efforts to raise additional funding may divert our management from its day- to- day activities, which may adversely affect our ability to develop and commercialize our products. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. Potential indebtedness in addition to our current **amended and restated credit** facility with SWK **Funding LLC (" SWK ")** , if incurred, would result in increased fixed payment obligations, and we may be required to agree to further certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may be required to relinquish rights to some of our technologies or products or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If funding for our operations is not available or not available on terms acceptable to us, our strategic plans may be limited. In addition, in order to address our current funding constraints, we may be required to further revise our business plan and strategy, which may result in us (i) significantly curtailing, delaying or discontinuing ~~our DFD- 29 research or development programs or~~ the commercialization of ~~any other~~ **certain of our** products, (ii) selling certain of our assets and / or (iii) being unable to expand our operations or otherwise capitalize on our business opportunities. Such measures may become necessary whether or not we are able to raise additional capital. As a result, our business, financial condition, and results of operations could be materially affected. Risks Related to Development and Regulatory Approval of Our **Future** Product CandidatesOur business is dependent on the successful development and regulatory approval of our current and any future product candidates. As of December 31, ~~2023~~ **2024** , our major marketed products that have been approved by the FDA for sale in the United States include Qbrexza ®, Accutane ®, Amzeeq ®, Zilxi ®, Exelderm ®, Targadox ® and Luxamend ®. **In addition, Emrosi was approved by the FDA on November 1, 2024.** However, our business remains dependent on the successful development and regulatory approval of additional product candidates. ~~On June 29, 2021, we entered into a license, collaboration, and assignment agreement with DRL to initiate a Phase III clinical development program for a collaborative product candidate, DFD- 29, that is being evaluated for the treatment of inflammatory lesions of rosacea.~~ The success of our business, including our ability to finance our company and generate additional revenue in the future, may depend on the successful development and **marketing** ~~regulatory approval~~ of **Emrosi** ~~the DFD- 29 product candidate~~ and any future product candidates that we may develop, in- license or acquire. The clinical success of ~~our current and~~ any future product candidates will depend on a number of factors, including the following: ● our ability to raise additional capital on acceptable terms, or at all; ● timely completion of ~~our~~ **any** clinical trials **we undertake in the future in respect of any future product candidates** , which may be significantly slower or cost more than we ~~currently~~ **then** anticipate and will depend substantially upon the performance of third- party contractors as well as our ability to timely recruit and enroll patients in our clinical trials, which may be delayed due to numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same or similar indications; ● whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our current **products or any future product candidates; 40 ● acceptance of** ~~or~~ **our proposed indications and primary endpoint assessments relating to the proposed indications of any future product candidates by the FDA and similar foreign regulatory authorities; ● our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of** any future product candidates; ● ~~acceptance of our proposed indications and primary endpoint assessments relating to~~ the ~~proposed indications~~ **prevalence, duration and severity** of **potential side effects experienced with** our current **products** or any future product candidates ~~by~~ **; ● the timely receipt of necessary marketing approvals from** the FDA and similar foreign regulatory authorities; ● **achieving** ~~our ability to demonstrate to the satisfaction of the FDA~~ and ~~similar foreign~~ **maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all** regulatory **requirements applicable** ~~authorities the safety, efficacy and acceptable risk~~ to ~~benefit profile of our current or~~ any future product candidates; ● ~~the prevalence, duration and severity of potential side effects experienced with our current or any future product candidates; ● the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities; 42 ● achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current or any future product candidates; ●~~ our ability to successfully obtain the substances and materials used in ~~our current or~~ any future product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing; ● the ability of third parties with whom we contract to manufacture clinical trial supplies of ~~our current or~~ any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with

cGMP; and ● a continued acceptable safety profile during clinical development of ~~our current or~~ any future product candidates. If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully complete and obtain regulatory approvals of ~~our current or~~ any future product candidates, which could materially adversely affect our business, results of operations, financial condition or cash flows. Clinical drug development is very expensive, time- consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of ~~our current or~~ any future product candidates, which could prevent or delay regulatory approval and commercialization. Clinical drug development is very expensive, time- consuming and difficult to design and implement, and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. The clinical trials for these product candidates may take significantly longer than expected to complete. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an institutional review board (" IRB ") or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including: ● discovery of serious or unexpected adverse events, toxicities, or side effects experienced by study participants or other safety issues; ● lack of effectiveness of any product candidate during clinical trials or the failure of a product candidate to meet specified endpoints; ● slower than expected rates of subject recruitment and patient enrollment in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as atopic dermatitis; ● difficulty in retaining subjects who have initiated participation in a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason; ● difficulty in obtaining IRB approval for studies to be conducted at each site; **41** ● delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials; ● inadequacy of or changes in our manufacturing process or the product formulation or method of delivery; ● changes in applicable laws, regulations and regulatory policies; ● delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third- party contractors; ~~43~~ ● inability to add a sufficient number of clinical trial sites; ● uncertainty regarding proper dosing; ● failure of our contract research organizations (" CROs ") or other third- party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner; ● failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the **conduct** ~~con- duct~~ of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products; ● scheduling conflicts with participating clinicians and clinical institutions; ● failure to design appropriate clinical trial protocols; ● inability or unwillingness of medical investigators to follow our clinical protocols; ● difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or ● insufficient data to support regulatory approval. We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to ~~our current or~~ any future product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed. We expect to rely on third- party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process for ~~our~~ **any future** product candidates. If these third parties do not meet our requirements, conduct the trials as required or otherwise provide services as anticipated, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or successfully commercialize, ~~our current or~~ any future product candidates when expected or at all. We expect to rely on third- party CROs and other third parties to conduct and oversee our clinical trials, other aspects of our product development and our regulatory submission process. We will also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA' s regulations and GCPs, which are meant to protect the rights, integrity, and confidentiality of study subjects and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of our clinical trials, the subsequent collection and analysis of data from the clinical trials, the preparation for and submission of our filings with the FDA and comparable foreign regulatory authorities and the successful commercialization of our product. ~~We~~ **42We** rely heavily on third parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities ~~. For example, our agreement with DRL for the regulatory submission and approval for DFD- 29 is heavily reliant on DRL' s ability to conduct clinical manufacturing for clinical supply of product, attending FDA meetings, advising on the Phase III study design, assisting in identifying third- party CROs, and drafting and advising on the NDA and other regulatory submissions~~ . We and our CROs and other third- party contractors are required to comply with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may not accept ~~or~~ data, or may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot provide assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with products manufactured and produced under cGMP

~~44regulations~~ -- **regulations** . Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process. If any of our CROs or clinical trial sites terminate their involvement in our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites in a timely manner, or do so on commercially reasonable terms or at all. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow- up information on patients enrolled in our ongoing clinical trial unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA and comparable foreign regulatory authorities. Additionally, the regulatory submission process for a product candidate is complex. We expect to rely on a third- party service provider for the preparation and submission of filings with the FDA and comparable foreign regulatory authorities for approval of ~~our current and~~ any future product candidates. Our reliance on third- party CROs may adversely affect our development timelines if the third- party CROs do not meet the requirements or satisfy the obligations required to obtain regulatory approval. Any significant delays caused by our collaboration partner or third- party CROs may have an adverse effect on our development timelines or otherwise may delay approval and commercialization of ~~DFD- 29~~ **any future product candidates** . If our relationship with such service provider is terminated prior to completion of our regulatory submission process, we may not be able to enter into an arrangement with an alternative service provider in a timely manner, or do so on commercially reasonable terms, and our submission may be substantially delayed. We are currently dependent on DRL for the manufacture and clinical supply of **Emrosi** ~~DFD- 29~~ drug product. Any interruption in our supply may cause serious delays in the timing of our clinical trials, increase our costs and adversely impact our financial results. Pursuant to the terms of our agreement with DRL for the exclusive, worldwide rights to develop and commercialize **Emrosi** ~~DFD- 29~~ for the evaluation of treatment, among other potential indications, inflammatory lesions of rosacea (the " **Emrosi** ~~DFD- 29~~ Agreement "), DRL is responsible for the manufacture and supply to us of **Emrosi** ~~DFD- 29~~ drug product and we are completely reliant upon DRL to provide us with adequate supply for our use. We may experience an interruption in supply if, among other reasons, we incorrectly forecast our supply requirements, DRL allocates supply to its own development programs, DRL incorrectly plans its manufacturing production or DRL is unable to manufacture **Emrosi** ~~DFD- 29~~ drug product in a timely manner to match our ~~development or~~ commercial needs. Transferring technology to a new manufacturer will require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and require review and approval by the FDA and applicable foreign regulatory bodies. Such manufacturer must comply with cGMP requirements enforced by the FDA and applicable foreign regulatory bodies through facilities inspection programs and review of submitted technical information. We may be unable to obtain regulatory approval for ~~our current or~~ any of our future product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact our business and our operating results. We may never obtain regulatory approval to commercialize ~~our current or~~ any future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post- market information related to ~~our current and~~ any future product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any ~~of our current or any~~ future product candidates in the United States until we receive approval of an NDA, BLA or other applicable regulatory filing from the FDA. We are also not permitted to market **any of** our ~~product~~ **products** ~~or our current~~ or any future product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries. ~~To~~ **43To** gain approval to market a new drug, the FDA and foreign regulatory authorities must receive preclinical, clinical and chemistry, manufacturing and controls data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA, BLA or other applicable regulatory filing. The development and approval of new drug products and biologic products involves a long, expensive and uncertain process. A delay or failure can occur at any stage in the process. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These ~~45setbacks~~ -- **setbacks** have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct. The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, including: ● the FDA or the applicable foreign regulatory body may disagree with the design, implementation, choice of dose, analysis plans or interpretation of the outcome of one or more clinical trials; ● the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate' s safety or other perceived risks to out- weigh its clinical or other benefits; ● the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval; ● the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from pre- clinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate; ● the data collected from clinical trials may not be sufficient to support the submission and approval of an NDA, BLA or other applicable regulatory

filing; ● the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials; ● the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of ~~our current or~~ any future product candidates; ● the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug- sensitive population; ● the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post- approval clinical trials; ● the FDA or the applicable foreign regulatory agency may grant approval but impose substantial and costly post- approval requirements; ● the FDA or the applicable foreign regulatory agency may approve ~~our current or~~ any future product candidates for a more limited indication or a narrower patient population than we originally requested; ● the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of ~~our current or~~ any future product candidates; ● the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third- party manufacturers or testing labs with which we contract; or ● the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval **, including changes in policies and regulation in the United States as a result of the new presidential administration** . ~~Of~~ **44Of** the large number of drugs and biologics in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. **Any** ~~Our current and any~~ future product candidates may not be approved by the FDA or applicable foreign regulatory agencies even though they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time- consuming clinical trials in order to obtain marketing approval or ~~46approval~~ -- **approval** to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of ~~our current and~~ any future product candidates and would harm our business, financial condition, operating results and prospects. We may conduct clinical trials for ~~our current and~~ any future product candidates, in whole or in part, outside of the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials, which would likely result in additional costs to us and delay our business plan. We may in the future choose to conduct, one or more of our clinical trials outside the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U. S. population and U. S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time- consuming and delay aspects of our business plan. Risks Related to Intellectual Property, Generic Competition and Paragraph IV LitigationIf we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our products or any ~~current or~~ future product candidates that we may license or acquire and our manufacturing methods, as well as successfully defending these patents and trade secrets against third- party challenges, which is expensive and time- consuming. A patent is the grant of a property right which allows its holder to exclude others from, among other things, selling the subject invention in, or importing such invention into, the jurisdiction that granted the patent. We have obtained, acquired or in- licensed a number of patents and patent applications covering key aspects of certain of our principal products. In the aggregate, our patents are of material importance to our business taken as a whole. We seek to protect our proprietary position by filing or obtaining licenses under patent applications in the United States and abroad related to our products and any ~~other current or~~ future product candidates. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents cover them. Our success is predicated, in part, by our ability to maintain the integrity of our trade secrets. It is possible that we or our licensors will fail to timely identify patentable aspects of our research and development output before it is too late to obtain patent protection, which may result in third parties using our proprietary information, impairing our abilities to compete in the market, to generate revenues, and to achieve profitability. Moreover, should we enter into other collaborations, we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of our patents. Therefore, such patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. ~~The~~ **45The** patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U. S. The patent situation outside the U. S. is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of

methods of treatment of the human body more than United States law does. 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 eighteen (18) months after a first filing, if at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, ~~47or~~ **or** that we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U. S. patent application relating to any ~~current or~~ future product candidates or a similar invention, we may have to participate in derivation proceedings declared by the USPTO to determine proper inventorship of a claimed invention. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U. S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. 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. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act "), was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office ~~recently~~ developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first- inventor- to- file provisions, which became effective on March 16, 2013. Courts continue to consider the constitutionality of certain provisions of the Leahy- Smith Act, including the Supreme Court in a recent decision affecting inter partes review procedures. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or other administrative 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, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us. We may also be unable to manufacture or commercialize products without infringing third- party patent rights, under which a license might not be available. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize **any** ~~our current or~~ future product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. ~~Generic~~ **46Generic** drug approvals and successful challenges against the validity of our patents may cause us to lose exclusivity of some of our products. In the U. S., the Hatch- Waxman Act provides non- patent regulatory exclusivity for five years from the date of the first FDA approval of a new drug compound in an NDA. The FDA, with one exception, is prohibited during those five years from accepting for filing a generic, or ANDA that references the NDA. In reference to the foregoing exception, if a patent is indexed in the FDA Orange Book for the new drug compound, a generic may file an ANDA four years from the NDA approval date if it also files a Paragraph IV Certification with the FDA challenging the patent. Protection under the Hatch- Waxman Act will not prevent the filing or approval of another full NDA. However, the NDA applicant would be required to conduct its own pre- clinical and adequate and well- controlled clinical trials to independently demonstrate safety and effectiveness. ~~48Generic~~ -- **Generic** drug companies may submit applications seeking approval to market generic versions of our products. In connection with these applications, generic drug companies may seek to challenge the validity and enforceability of our patents through litigation and / or with the USPTO. Such challenges may subject us to costly and time- consuming litigation and / or USPTO proceedings) ~~. Such challenges may subject us to costly and time- consuming litigation and / or USPTO proceedings~~ . As a result of the loss of any patent protection from such litigation or USPTO proceedings, or the " at- risk " launch by a generic competitor of our products, our products could be sold at significantly lower prices, and we could lose a significant portion of sales of that product in a short period of time, which could adversely affect our business, financial condition, operating results and prospects. Enforcing our proprietary rights is difficult and costly and we may be unable to ensure their protection. The degree of future protection for our proprietary rights is uncertain, as legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; ● our licensors might not have been the first to file patent

applications for these inventions; ● others may independently develop similar or alternative technologies or duplicate our products or **any** ~~our current or~~ future product candidates' technologies; ● it is possible that none of the pending patent applications licensed to us will result in issued patents; ● the issued patents covering our products or any ~~current or~~ future product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged and defeated by third parties; ● we may not develop additional proprietary technologies that are patentable; or ● patent rights of others may have an adverse effect on our business. Furthermore, competitors may infringe our issued patents or other intellectual property (collectively, our " IP "), which may require us to file infringement claims, which is expensive and time consuming, and the outcome uncertain. Any claims we assert against perceived infringers could provoke counterclaims alleging that our IP rights are invalid, unenforceable, or not infringed or that we have infringed upon misappropriated others' intellectual property. In response, a court may decide that a patent of ours is wholly or partially invalid or unenforceable, construe the patent' s claims narrowly, or refuse to stop the accused party from using the technology at issue. Additionally, some of our products, including Accutane, Targadox and Exelderm, do not have patent protection because they are not eligible or qualify for such protection. This creates greater risk of competition with generic drug manufacturers and may otherwise adversely affect our business or result of operations. Further, we rely on trade secrets, including unpatented know- how, to maintain our competitive position. We enter into non- disclosure and confidentiality agreements to protect these trade secrets but cannot guarantee that counterparties will not breach the agreements and disclose our proprietary information, including trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated trade secrets is costly, difficult, and time consuming, and we may be unable to obtain adequate remedy. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. ~~If~~ **47If** we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business. Our ability to develop, manufacture, market and sell our products or any ~~current or~~ future product candidates **for which we receive marketing authorization** depends upon our ability to avoid infringing the proprietary rights of third parties. There are many U. S. and foreign issued patents and pending patent applications owned by third parties in the dermatology field that cover numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending against intellectual property claims raised by third parties, which could have a material adverse effect on our results of ~~49operations~~ -- **operations** . Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our commercial activities relating to our products or ~~current or~~ future product candidates may infringe. There could also be existing patents of which we are not aware that our products ~~or current~~ or future product candidates may inadvertently infringe. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, in addition to costly and time- consuming litigation, we could face a number of issues, including: ● diversion of management' s attention from our core business; ● substantial damages for past infringement; ● injunctions prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do; ● requirements that we pay substantial royalties or grant cross licenses under our patents; ● redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time; and ● harm to our reputation and subsequent adverse effect on the valuation of our securities and revenue. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the valuation of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. The occurrence of any of the above- described risks could materially adversely affect our business, results of operations, financial condition or cash flows. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. ~~We~~ **48We** may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our products or ~~current or~~ future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products or ~~current or~~ future product candidates **for which we receive marketing authorization** , in which case we would be required to obtain a license from these third parties, if available, on commercially reasonable terms, or our business could be harmed, possibly materially. Our inability to obtain such rights on acceptable terms, or at all, could materially adversely affect our business, results of operations, financial condition or cash flows. ~~50If~~ **If** we fail to

comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or if we breach an agreement under which we license rights to any product or future product candidate, we could lose rights that are important to our business. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture, or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Further, any uncured, material breach under our license agreement with any current or future licensor could result in our loss of rights to our products or **any** ~~current or~~ future product candidates and may lead to a complete termination of any future product development efforts. Risks Related to our Platform and DataOur business and operations would suffer in the event of computer system failures, cyber- attacks, or deficiencies in our or third parties' cybersecurity. We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk. While we **maintain** ~~recently implemented~~ internal security and business continuity measures, our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us. For example, in 2021, we were the victim of a cybersecurity incident that affected our accounts payable function and led to approximately $ 9. 5 million in wire transfers being misdirected to fraudulent accounts. The ~~matter was reported to the FBI and remains under their investigation. The~~ cybersecurity incident does not appear to have compromised any personally identifiable information or protected health information. ~~Fortress, as our controlling stockholder and supporting partner in our back- office functions, provided us with $ 9. 5 million to ensure our accounts payable operations continued to function smoothly. The $ 9. 5 million of support was in the form of a related party note which the boards of both companies have agreed and converted into 1, 476, 044 shares of our common stock upon the consummation of our IPO in November 2021 at the IPO price.~~ The federal government **was** ~~has been~~ able to trace and seize the fraudulently transferred cryptocurrency associated with the breach. ~~Once~~ **On September 19, 2024,** the ~~cryptocurrency~~ **United States District Court Southern District of New York through the United States Marshalls notified the Company that it** has ~~been converted~~ -- **recovered and will be returning** ~~back into U. S. dollars, we expect~~ to ~~receive~~ **the Company** a **portion** ~~notification letter to initiate the return~~ of the **misappropriated** cash **in connection** ~~to the Company. This process could take as long as six months or more to complete. Given the recent market declines, volatility, and liquidity issues~~ with ~~cryptocurrency, there~~ -- **the previously disclosed September 2021** ~~is no certainty as to the amount we will ultimately recover. We may incur additional expenses and losses as a result of this~~ cybersecurity incident ~~, including related to investigation fees and remediation costs~~. ~~In~~ **49In** addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to ~~51their~~ -- **their** systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber- attacks 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. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective

action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow- up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach. The costs related to significant security breaches or disruptions could be material and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Risks Related to Our Finances and Capital RequirementsWe have incurred net losses in recent fiscal years, and we may incur losses for the foreseeable future and may not be able to achieve or maintain profitability. Even though we are a cash generating, commercial organization, we have a limited operating history. We have focused primarily on in- licensing, developing, commercializing and / or manufacturing and selling our products. Potential future losses, among other things, will have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with commercialization and / or developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or if we will be able to maintain profitability. Any future net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if: ● ~~our current or~~ any future product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities; ● we acquire or in- license new products for development and / or sale; **50** ● we are required by the FDA, or foreign regulatory authorities, to perform studies in addition to those currently expected; ~~52~~ ● there are any delays in completing our clinical trials or the development of ~~our current or~~ any future product candidates; ● we execute other collaborative, licensing or similar arrangements that require us to make payments and / or expend funds; ● there are variations in the level of expenses related to our future development programs; ● there are any product liability or intellectual property infringement lawsuits in which we may become involved; ● there are any regulatory developments affecting our products ~~,~~ ~~current~~ or future product candidates, or the product candidates of our competitors; or ● the level of underlying demand for our products and wholesalers' buying patterns. Our ability to maintain profitability depends upon our ability to generate and sustain revenue. Our ability to generate and sustain revenue depends on a number of factors, including, but not limited to, our ability to: ● obtain and maintain regulatory approval for our products, or any other ~~current or~~ future product candidates that we may license or acquire; ● manufacture commercial quantities of our current products or ~~current or~~ future product candidates, if approved, at acceptable cost levels; and ● maintain and / or expand our commercial organization and the supporting infrastructure required to successfully market and sell our products ~~or current~~ or future product candidates, if approved. Even if we do achieve sustainable profitability, we may not be able to maintain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain or initiate any research and development efforts, diversify our product offerings or even continue our operations. A decline in our value could also cause you to lose all or part of your investment. We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate any future product development programs or commercialization, manufacturing and / or sales efforts. Selling and developing products for dermatological use, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We may need to raise additional capital to: ● fund our operations and continue our efforts to hire additional personnel; ● qualify and outsource the commercial- scale manufacturing of our products under cGMP; and ● acquire, in- license and / or develop additional product candidates. Our future funding requirements will depend on many factors, including, but not limited to: ● the potential for delays in our efforts to seek regulatory approval for any current or future product candidates, and any costs associated with such delays; ● the costs of maintaining and / or establishing a commercial organization to sell, market and distribute our products and / or **any** ~~current or~~ future product candidates **for which we receive marketing authorization** ; ● the rate of progress and costs of our efforts to prepare for the submission of NDA or BLA for any product candidates that we may in- license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval; ~~53~~ **51** ● the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with any ~~current or~~ future product candidates, including any such costs we may be required to expend if licensors are unwilling or unable to do so; ● the cost and timing of securing sufficient supplies of our products and ~~current or~~ future product candidates from our contract manufacturers in preparation for commercialization, manufacture, and / or sale; ● the effect of competing technological and market developments; ● the terms and timing of any collaborative, licensing, co- promotion or other arrangements that we may establish; ● the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to

market generic versions of our branded products; and ● the success of sales efforts of our current products and / or the commercialization of any ~~current or~~ future product candidates **for which we receive marketing authorization** . Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions. We may need to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of future development programs, acquisition plans or our future commercialization efforts, which could materially adversely affect our business, prospects and the trading price of our common stock. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate future product development or current or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we fail to raise the additional funds needed to complete the development **and commercialization** of our current products or **any** ~~current or~~ future ~~product~~ **products** ~~candidates, or the funds needed to complete the development of our~~ **or** ~~current or future~~ product candidates, we will be unable to execute our current business plan. Risks Related to Owning our Common StockIf we fail to maintain or implement effective internal controls, we may not be able to report financial results accurately or on a timely basis, or to detect fraud, which could have a material adverse effect on our business and the per share price of our common stock. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal control over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting. ~~54Our~~ **52Our** current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and ineffective 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 market price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Capital Market (“ Nasdaq ”). Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an “ emerging growth company ” (“ EGC ”), as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock. Our charter documents and Delaware law could discourage takeover attempts and other corporate governance changes. Our Third Amended and Restated Certificate of Incorporation and **Amended and Restated** ~~bylaws~~ **Bylaws** contain provisions that could delay or prevent a change in control of our Company. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions include certain provisions that: ● permit the board of directors to establish the number of directors and fill any vacancies and newly created directorships; ● provide that, after a removal for cause, vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; ● prohibit cumulative voting in the election of directors; ● require majority voting to amend our certificate of incorporation and bylaws; ● authorize the issuance of “ blank check ” preferred stock that our board of directors could use to implement a stockholder rights plan; ● restrict the forum for certain litigation against us to Delaware or federal courts; ● establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and ● bestow majority control of the stockholder vote to Fortress by virtue of their exclusive ownership of our Class A Common Stock. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a period of time without the approval of our board of directors. In addition, our **amended and restated** credit facility includes, and other debt

instruments we may enter into in the future may include, provisions entitling the lenders to demand immediate repayment of all borrowings upon the occurrence of certain change of control events relating to our company, which also could discourage, delay or prevent a business combination transaction. ~~55Our~~ **53Our** Third Amended and Restated Certificate of Incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware is the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a chosen judicial forum for disputes with us or our directors, officers, employees or stockholders. Our Third Amended and Restated Certificate of Incorporation requires to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions must be brought in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our certificate of incorporation. In addition, our Third Amended and Restated Certificate of Incorporation provides that the federal district courts of the United States are the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act and the Exchange Act. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Third Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition. The requirements of being a public company may strain our resources, divert our management' s attention and affect our ability to attract and retain qualified board members. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and are required to comply with the applicable requirements of the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations. Compliance with these rules and regulations increases our legal and financial compliance costs, makes some activities more difficult, time- consuming or costly and increases demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and operating results and maintain effective disclosure controls and procedures and internal controls over financial reporting. Significant resources and management oversight is required to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard. As a result, management' s attention may be diverted from other business concerns, which could harm our business and operating results. Although we hired additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses. Reduced reporting and disclosure requirements applicable to us as an EGC could make our common stock less attractive to investors. We are an EGC and, as long as we continue to be an EGC, we may continue to avail ourselves of exemptions from various reporting requirements applicable to other public companies. Consequently, we are not required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act, and we are subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of the dates such pronouncements are effective for public companies. We could be an EGC for up to five years following the completion of our November 2021 public offering. We will cease to be an EGC upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of the aforementioned offering, (ii) the first fiscal year after our annual gross revenue is $ 1. 235 billion or more, (iii) the date on which we have, during the previous three- year period, issued more than $ 1. 0 billion in nonconvertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non- affiliates exceeded $ 700 million as of the end of the second quarter of that fiscal year. We cannot predict whether investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock, and the price of our common stock may be more volatile. ~~56Our~~ **54Our** shares of common stock are subject to potential delisting if we do not continue to maintain the listing requirements of Nasdaq. We list our shares of common stock on Nasdaq under the symbol " DERM. " Nasdaq has rules for continued listing, including, without limitation, minimum market capitalization and other requirements. Failure to maintain our listing, or de- listing from Nasdaq, would make it more difficult for shareholders to sell our securities and more difficult to obtain accurate price quotations on our securities. This could have an adverse effect on the price of our common stock. Our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future, may also be materially and adversely affected if our common stock is not traded on a national securities exchange. 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 gains. We currently intend to retain any earnings to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors. In addition, the terms of our existing debt arrangements preclude us from paying dividends and our future debt agreements, if any, may contain similar restrictions. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases. The trading price of the shares of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses. The trading price of our common stock fluctuates substantially. These fluctuations could cause you to incur substantial losses, including all of your investment in our common stock. Factors that could cause fluctuations in the

trading price of our common stock include the following: ● significant volatility in the market price and trading volume of companies in our industry; ● announcements of new solutions or technologies, commercial relationships, acquisitions, or other events by us or our competitors; ● price and volume fluctuations in the overall stock market from time to time; ● changes in how customers perceive the benefits of our products and future offerings; ● the public' s reaction to our press releases, other public announcements, and filings with the SEC; ● fluctuations in the trading volume of our shares or the size of our public float; ● actual or anticipated changes or fluctuations in our results of operations or financial projections; ● changes in actual or future expectations of investors or securities analysts; ● litigation involving us, our industry, or both; ● governmental or regulatory actions or audits; ● regulatory developments applicable to our business, including those related to privacy in the United States or globally; ● general economic conditions and trends; ● major catastrophic events in our domestic and foreign markets; and ● departures of key employees. ~~57Risks~~ **55Risks** Related to our Relationship with Fortress Biotech, Inc. Fortress controls a voting majority of our common stock, which could be detrimental to our other shareholders. Pursuant to the terms of the Class A Common Stock held by Fortress, Fortress **is** ~~will be~~ entitled to cast, for each share of Class A Common Stock held by Fortress, the number of votes that is equal to 1. 1 times a fraction, the numerator of which is the number of shares of our outstanding common stock and the denominator of which is the number of shares of outstanding Class A Common Stock (the " Class A Common Stock Ratio "). Thus, Fortress will at all times have voting control of Journey **so long as it continues to be the sole holder of our Class A Common Stock** . Further, for a period of ten (10) years from the date of the first issuance of shares of Class A Common Stock, the holders of record of the shares of Class A Common Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Common Stock), exclusively and as a separate class, shall be entitled to appoint or elect the majority of the directors of Journey **; however, the Company and Fortress waived application of this provision of the certificate of incorporation, and the holders of the Common Stock voted together with the holders of the Class A Common Stock for all directors, at our most recent annual meeting of stockholders, with the holders of the Class A Common Stock utilizing the super- voting rights described above. In any case, the 10- year period is expiring during the year ending December 31, 2025** . This concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of Journey or our assets, and might affect the prevailing market price of our common stock. We are a " controlled company " within the meaning of Nasdaq listing standards and, as a result, qualify for exemptions from certain corporate governance requirements. Although we do not presently intend to take advantage of these exemptions, we may do so in the future. We are a " controlled company " within the meaning of Nasdaq listing standards. Under these rules, a company of which more than 50 % of the voting power is held by an individual, a group or another company is a " controlled company " and may elect not to comply with certain corporate governance requirements of Nasdaq, including (i) the requirement that a majority of the Board of Directors consist of independent directors, (ii) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities and (iii) the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities. Although we presently are not taking advantage of these exemptions, we may do so in the future. Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may have received better terms from unaffiliated third parties than the terms we receive in our arrangements with Fortress. We have arrangements with Fortress in connection with management and administration services for the Company. While we believe the terms of these arrangements are reasonable, they might not reflect terms that would have resulted from arm' s- length negotiations between unaffiliated third parties. The terms of the arrangement relate to, among other things, systems, insurance, accounting, legal, finance, tax and human resources. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business. The ownership by our executive officers and some of our directors of shares of equity securities of Fortress and / or rights to acquire equity securities of Fortress might create, or appear to create, conflicts of interest. Because of their current or former positions with Fortress, some of our executive officers and directors own shares of Fortress common stock and / or options to purchase shares of Fortress common stock. Their individual holdings of common stock and / or options to purchase common stock of Fortress may be significant compared to their total assets. Ownership by our directors and officers, after our separation, of common stock and / or options to purchase common stock of Fortress might appear to create conflicts of interest when these directors and officers are faced with decisions that could have different implications for Fortress than for us. ~~58Fortress~~ **56Fortress** ' current or future financial obligations and arrangements, or an event of default thereon, may change the ownership dynamic of us by Fortress. Any default or breach by Fortress under any current or future credit agreement or arrangements may have an adverse effect on our business. Fortress has pledged as collateral to certain of its creditors equity in the Company. If Fortress were to default on its obligations to any such creditor, that creditor, whose interests may not align with those of our other stakeholders, could acquire a controlling interest in the Company. In addition, Fortress' current credit agreement with Oaktree Capital (the " Oaktree Credit Agreement ") contains certain affirmative and negative covenants and events of default that apply in different instances to Fortress itself, its private subsidiaries, its public subsidiaries, or combinations of the foregoing. Although we are not a party to the Oaktree Credit Agreement, because Fortress controls our stockholder vote, Fortress may not permit us to effect certain actions which we feel would be in the Company' s best interests, but which Fortress cannot allow so as to remain in compliance with the Oaktree Credit Agreement. General RisksFailure to manage our growth effectively could cause our business to suffer and have an adverse effect on our business, operating results and financial condition. We have experienced significant growth in a short period of time. To manage our

growth effectively, we must continually evaluate and evolve our organization. We must also manage our employees, operations, finances and capital investments efficiently. Our efficiency, productivity and the quality of our products may be adversely impacted if we do not train our new personnel, particularly our sales and support personnel, quickly and effectively, or if we fail to appropriately coordinate across our organization. Additionally, our rapid growth may place a strain on our resources, infrastructure and ability to maintain the quality of our products. You should not consider our revenue growth and levels of profitability in recent periods as indicative of future performance. In future periods, our revenue or profitability could decline or grow more slowly than we expect. Failure to manage our growth effectively could cause our business to suffer and have an adverse effect on our operating results and financial condition. If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research reports about our business, our share price and trading volume could decline. The trading market for our common stock partially depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us should downgrade our shares or change their opinion of our business prospects, our share price would likely decline. If one or more of these analysts ceases coverage of our company or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States. If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our results of operations could be adversely affected. U. S. generally accepted accounting principles (" GAAP ") are subject to interpretation by the Financial Accounting Standards Board (" FASB "), the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported results of operations and could affect the reporting of transactions already completed before the announcement of a change. **57** ~~59The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes appearing elsewhere in this report on Form 10- K. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates. " The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of revenue and expenses that are not readily apparent from other sources. Significant estimates, judgments, and assumptions used in our financial statements include, but are not limited to, those related to revenue recognition, accounts receivable and related reserves, useful lives and realizability of long- lived assets, research and development costs, assumptions used in the valuation of warrants, accounting for share- based compensation, and valuation allowances against deferred tax assets. These estimates are periodically reviewed for any changes in circumstances, facts, and experience. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock. Global and national financial events may have an impact on our business and financial condition in ways that we currently cannot predict. A credit crisis, turmoil in the global or U. S. financial system, recession or similar possible events in the future could negatively impact us. A financial crisis or recession may limit our ability to raise capital through credit and equity markets. The prices for the products and services that we intend to provide may be affected by a number of factors, and it is unknown how these factors may be impacted by a global or national financial event. If our estimates or judgments relating to our critical accounting policies are erroneous or based on assumptions that change or prove to be incorrect, our operating results could fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on our best judgment, historical experience, information derived from third parties and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our judgments prove to be wrong, assumptions change or actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, share- based compensation and income taxes. Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. For example, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15 % of the adjusted financial statement income of certain large corporations, as well as a 1 % excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. 60~~