Risk Factors Comparison 2023-03-31 to 2022-03-30 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all **of the** other information in this Annual Report **on Form 10- K**, before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. Additional risks that we currently do not know about, or that we currently believe immaterial, may also impair our business. Risks Related to Drug Discovery, Development, Regulatory Approval and Commercialization We ~~depend~~ **are** heavily **dependent** on the success of our lead product candidate, ELX- 02. If ELX- 02 ~~fails~~ **does not achieve positive results** during development or suffers any material development delays, it may adversely impact the commercial viability of ELX- 02 and our business. We currently have no products approved for sale. We have invested substantial efforts and financial resources primarily in the research and development of ELX- 02, which is currently our only product candidate in clinical development. We have increased investment in our preclinical candidate portfolio but have yet to advance other molecules into clinical development **. In September 2022, we announced topline results from our Phase 2 combination clinical trial of ELX- 02 for Class 1 CF patients with at least one nonsense mutation. The combination trial of ELX- 02 with ivacaftor did not achieve statistical significance for its efficacy endpoints and as a result we have paused all development of ELX- 02 in CF. ELX- 02 is now being evaluated in a Phase 2 trial in Alport syndrome patients with nonsense mutations. This is the first known clinical study in Alport syndrome and there can be no assurances of its success. We are heavily dependent on favorable efficacy results from this study in the near term for our continued development and funding for of ELX- 02 and the Company** . Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing ELX- 02 and any future product candidates, either alone or with third parties. The success of ELX- 02 and any other product candidates will depend on several factors, including the following: • our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements and timing ~~due to the ongoing COVID- 19 pandemic~~ ; • successful completion of preclinical studies; • receipt of allowances to proceed under INDs and similar applications outside the United States for our planned clinical trials or future clinical trials; • successful patient enrollment in and completion of clinical trials; • safety and efficacy data for our product candidates that are satisfactory to the FDA, European Medicines Agency (" EMA "), or any other comparable foreign regulatory authority for marketing approval; • receipt of marketing approvals for our product candidates from applicable regulatory authorities; • completion of any required post-marketing approval commitments to applicable regulatory authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved; • establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • obtaining and maintaining third- party coverage and adequate reimbursement; and • maintaining a continued acceptable safety profile of our products following any approval. Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for ELX- 02 or any other product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which would materially adversely affect our business. The success of our business, including our ability to finance our Company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and any eventual commercialization of the product candidates we develop. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost- effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with current Good Manufacturing Practices (" cGMP ") or similar regulatory requirements outside the United States, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy. We have not previously submitted a new drug application (" NDA "), to the FDA or similar submissions to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product

candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights for each product candidate, as well as the availability of competitive products, whether there is sufficient third- party reimbursement and adoption by physicians. Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays or may never advance, which would adversely affect **our** ability to **further advance clinical development,** obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business. Before obtaining regulatory approval for the commercial distribution of our therapeutic product candidates, we or a collaborator must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA, EMA and other applicable regulatory agencies in the jurisdictions in which we intend to market our product candidates. Clinical testing is expensive, time- consuming, and subject to uncertainty. Of the large number of drugs in development, only a small percentage successfully complete clinical testing and an even smaller portion obtain FDA or similar foreign regulatory authority approval and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research, development and clinical programs, we cannot assure you that ELX- 02 **, ZKN- 013,** or any of our future product candidates will be successfully developed or commercialized. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. Accordingly, we, or any development partners, may ultimately be unable to provide regulatory agencies with satisfactory data on clinical safety and efficacy sufficient to obtain approval for any indication. Further, we may experience delays in clinical trials of our product candidates. We do not know whether ongoing clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. We also cannot be sure that submission of an **Investigational New Drug (“** IND **”)** or similar application will result in the FDA, or other regulatory authority allowing clinical trials to begin in a timely manner, if at all. Moreover, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Clinical trials can be delayed for a variety of reasons, including delays related to: • inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; • failure in obtaining regulatory authorization to commence a clinical trial; • reaching agreement on acceptable terms with prospective contract research organizations (“ CROs ”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • obtaining institutional review board (“ IRB ”), or ethics committee approval at each clinical trial site; • identifying, recruiting and training suitable clinical investigators; • manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials; • insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials; • recruiting, screening and enrolling suitable patients to participate in a clinical trial; • having patients complete a clinical trial or return for post- treatment follow- up; • clinical trial sites deviating from trial protocol or dropping out of a clinical trial; • adding new clinical trial sites; • failure by our CROs, other third parties or us to adhere to clinical trial protocols; • failure to perform in accordance with the FDA’ s good GCPs, or similar regulatory guidelines in other countries; • occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in clinical trials of the same class of agents conducted by other companies; • changes in regulatory requirements or guidance that require amending or submitting new clinical trial protocols; • changes to the standard of care on which a clinical development plan was based, which may require new or additional studies or clinical trials; • selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; • costs of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates; • transfer of manufacturing processes to larger- scale facilities operated by a contract manufacturing organization (“ CMO ”) and delays or failure by our CMOs or us to make any necessary changes to such manufacturing processes; • third parties being unwilling or unable to satisfy their contractual obligations to us; or • unforeseen factors beyond our control, including public health concerns such as the COVID- 19 pandemic. In addition, disruptions caused by the COVID- 19 pandemic, including temporary pauses in our clinical trial enrollment in response to the COVID- 19 pandemic have and may in the future increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. **The design** ~~While we believe that we have enrolled a sufficient number~~ of **our Phase 2 Alport syndrome trial may not achieve efficacy results in** patients ~~to assess biological activity of ELX- 02~~ , and ~~expect to present data from the first four treatment arms of the study in the fourth quarter of this year,~~ we cannot provide assurances as to whether we will incur significant additional costs, expend additional resources or be subject to additional regulatory requirements, including COVID- 19 related disruptions, any of which may have a material adverse impact on our financial condition and results of operations. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities’ legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical

trial or by the FDA or any other regulatory authority, or if the IRBs or ethics committees of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, significant adverse events with respect to individuals who are not enrolled in any of our clinical trials but who receive our drug candidate under our compassionate use policy (typically under a single- patient IND administered by the individual' s treating physician) may result in a partial or full clinical hold on our ongoing clinical trials. A clinical hold may result in the inability to enroll new patients in our studies until the hold is removed and may make it more difficult to enroll patients thereafter. Additionally, a clinical hold may also result in, among other things, protocol redesign, changes in eligibility criteria and increased costs, any of which could adversely affect our projected development timelines and jeopardize successful completion of our clinical programs. Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. If we experience delays in the completion of any clinical trial of our product candidates, the commercial prospects of our product candidates and the ability to generate revenues may be impaired. In addition, any delays in completing our clinical trials may increase our costs, slow down our product development and approval process and may jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may have an adverse impact on our business, financial condition and prospects. Further, the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates **. In addition, the FDA' s and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union (" EU ") recently evolved. The EU Clinical Trials Regulation (" CTR ") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application (" CTA ") to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three- year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as clinical research organizations (" CROs "), may impact our developments plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted** . We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, healthcare facilities and institutions, physicians, and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with our collaborators, healthcare professionals, healthcare facilities and institutions, principal investigators, consultants, customers, and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and regulation with respect to drug pricing payments and other transfers of value made to physicians and other health care professionals by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following: • The U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U. S. federal healthcare program, such as Medicare and Medicaid. The term " remuneration " has been broadly interpreted to include anything of value, including stock options. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti- Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and

prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Any arrangements with prescribers must be for bona fide services and compensated at fair market value. • The U. S. federal civil and criminal false claims laws, including without limitation, the civil False Claims Act, which can be enforced by private citizens on behalf of the U. S. federal government through civil whistleblower or qui tam actions, and the federal civil monetary penalties law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U. S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U. S. federal government by, among other things, engaging in impermissible marketing practices, such as the off- label promotion of a product for an indication for which it has not received FDA approval. Further, pharmaceutical manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. • The U. S. federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. • The U. S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (as defined by statute), certain non- physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and • Analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives, and similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time- consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Our product candidates, including ELX- 02 ~~,~~ **and ZKN- 013** may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance. Undesirable side effects caused by our product candidates, such as ELX- 02 **and ZKN- 013** , could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large- scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. It is possible that, during the course of the clinical development of ELX- 02 **, ZKN- 013,** or other product candidates, results of our clinical trials (or significant adverse events experienced by individuals receiving drug under our compassionate use policy) could reveal an unacceptable severity and prevalence of side effects. For example, in preclinical testing of ELX- 02, we observed renal toxicities in the animals we tested following administration of this compound at doses in excess of the doses we expect to administer in our clinical trials. As a

result of this or any other side effects, our clinical trials could be suspended or terminated or not even allowed to commence, and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one or more of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product or impose restrictions on its distribution in the form of a new or modified risk evaluation and mitigation strategy; • regulatory authorities may require additional labeling, such as additional warnings or contraindications, which may negatively impact sales; • regulatory authorities may issue safety alerts, letters to healthcare providers, press releases or other communications containing warnings or other safety information about the product; • we may be required to change the way the product is administered or to conduct additional clinical studies; • we may be required to create a risk evaluation and mitigation strategy (" REMS ") which could include a medication guide outlining the risks of such side effects for distribution to patients; • we may be subject to fines, injunctions o the imposition of criminal penalties; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Even though we have received orphan drug designation from the FDA for ELX- 02 for the treatment of cystic fibrosis, cystinosis, MPS I, and Rett syndrome, we may not be able to maintain the benefits of orphan drug designation or obtain orphan drug marketing exclusivity for ELX- 02 or any of our other product candidates for **Alport syndrome or** other indications. Regulatory authorities in some jurisdictions, including the ~~Unites~~ **United** States ~~and European Union~~ (" ~~EU~~ **U. S.** ") **EU** , may designate drugs for relatively small patient populations as orphan drugs in the U. S. and orphan medicinal products in the EU. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the U. S., or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting an NDA. Similarly, in the EU, a medicinal product may receive orphan designation. This applies to products that are intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition and either the condition affects no more than five in 10, 000 persons in the EU when the application is made, or the product, without the benefits derived from orphan status, would unlikely generate sufficient return in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU, it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition authorized for marketing in the EU, or if such a method exists, that the product will be of significant benefit to those affected by the condition. The applicable exclusivity period is ten years in the EU. The European exclusivity period can be reduced to six years, if, at the end of the fifth year a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. The FDA has granted orphan drug designation for ELX- 02 for the treatment of cystic fibrosis, MPS I, Rett syndrome, and cystinosis. We may seek orphan drug designation for our other product candidates, and with respect to **Alport syndrome and** other indications. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a drug with an orphan drug designation subsequently receives the first FDA marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for that time period. The applicable period is seven years in the U. S. Orphan drug exclusivity may be lost in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity, if the underlying NDA authorizing the sale of the drug is withdrawn, or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the drug candidate from competition because different drugs can be approved for the same disease or condition. In addition, even after an orphan drug is approved, the applicable regulatory authority can subsequently approve the same or a similar drug from another sponsor for the same condition if it concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. On August 27, 2021 we received Fast Track Designation for ELX- 02 for the treatment of cystic fibrosis patients with nonsense mutations. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for Fast Track Designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA has broad discretion whether or

not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain approval. We may find it difficult to recruit and enroll patients in our clinical trials, which could cause significant delays in the completion of such trials or may cause us to abandon one or more clinical trials. Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of enrollment taking longer than anticipated, subject withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. The protocols for our clinical trials generally require that patients may not be enrolled in more than one clinical trial for the same indication, which will limit the pool of available subjects. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure and that their disease is not too advanced. Specifically, some of the diseases that our product candidates are designed to treat are rare and ultra- rare and we expect only a subset of the patients with these diseases will be eligible for our clinical trials. Because ELX- 02 is designed to target small populations and patient numbers have not been determined definitively, we must be able to identify patients in order to complete our development programs, potentially secure regulatory approval for, and if approved, successfully commercialize ELX- 02. We cannot guarantee that any of our programs will identify a sufficient number of patients to complete clinical development, pursue regulatory approval and market our product candidates, if approved. The combined number of patients in the U. S., Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with ELX- 02, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business. An inability to recruit and enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which could impact our ability to develop our product candidates and may have a material adverse effect on our business, results of operations and financial condition. Patient enrollment depends on many factors, including: • the size and nature of the patient population; • the severity of the disease under investigation; • eligibility criteria for the trial; • the proximity of patients to clinical sites; • the design of the clinical protocol; • the ability to obtain and maintain patient consents; • the ability to recruit clinical trial investigators with the appropriate competencies and experience; • the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion; • the availability of competing clinical trials; • the availability of new drugs approved for the indication the clinical trial is investigating; and • clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. In addition, the ongoing COVID- 19 pandemic has and may ~~continue to~~ **in the future** adversely affect enrollment in our clinical trials. ~~On March 25, 2020, we announced that~~ **We experienced significant delays in our recently completed Phase 2 monotherapy study with ELX- 02 in CF as a result of having to pause** enrollment ~~in our clinical trials had been paused temporarily~~ in response to the COVID- 19 pandemic in order to avoid unnecessary exposure in at- risk populations, to maintain the integrity of our study data and to support global healthcare providers in their commitment to ensure patient safety. On ~~June 17~~ **November 1** , ~~2020~~ **2022** , **we announced that** enrollment in our Phase 2 clinical trial in **Alport syndrome commenced** ~~cystic fibrosis had resumed in Israel and Europe and, on August 12, 2020 had resumed in the United States~~ . ~~COVID- 19 is continuing~~ **We experienced delays in starting the trial related** to **staffing challenges in** ~~evolve and we continue to work closely with~~ our clinical trial sites and ~~investigators to ensure that patient enrollment will continue as quickly as is feasible in a safe environment for our patients. We also evaluated~~ --- **related** ~~additional clinical~~ **lack of resources at these** sites ~~in other countries where patient enrollment may be feasible, such as Australia and Canada~~ . **Any future** ~~Additionally, significant~~ additional costs as a result of ~~this delay~~ **delays** in enrollment or failure to complete enrollment in accordance with our objectives **could be significant and** may have a material adverse impact on our financial condition and results of operations. Interim, " topline " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all available data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top- line or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with

our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions or interpretations reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could negatively impact our business, operating results, prospects or financial condition. The regulatory approval processes of the FDA and comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. Similarly, in the EU, our product candidates can only be placed on the market after obtaining a marketing authorization. Prior to obtaining approval to commercialize a product candidate in the United States, Europe or other jurisdictions, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA or other regulatory authority may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval, or it may object to elements of our clinical development program. The FDA or any foreign regulatory authorities or bodies can delay, limit or deny approval of our drug product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for a variety of reasons, including the following: • regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the applicable regulatory authority that a product candidate is safe or effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by regulatory authorities for approval; • serious and unexpected drug- related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States, the EU, or elsewhere, and we may be required to conduct additional clinical studies; • the applicable foreign regulatory authority may disagree regarding the formulation, labeling and / or the specifications of our product candidates; • applicable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. . Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS program, which may be required to assure safe use of the drug after approval. Regulatory authorities may also approve a product candidate for a more limited indication or patient population than we originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any of our product candidates that obtain regulatory approval, we may be unable to generate any revenue. We have no experience selling and marketing our product candidates or any other products. To successfully commercialize any products that may result from our clinical development programs and obtain regulatory approval, we will need to develop these capabilities, either on our own or with the assistance of others. We may seek to enter into collaborations with other entities to utilize their marketing and distribution capabilities, but we may be unable to do so on favorable terms, if at all. If any future collaborative partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies or successfully commercialize any of our product candidates. Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups,

warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or other regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as ongoing compliance with cGMP requirements and GCPs for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and similar standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with applicable regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: • delays in or the rejection of product approvals; • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers or manufacturing process; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • product seizures, detentions or import bans; • voluntary or mandatory product recalls and publicity requirements; • total or partial suspension of production; and • imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Disruptions at the FDA and other government agencies and foreign regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s and foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA relocation to Amsterdam and resulting staff changes may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, in March 2020, the FDA ~~announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA~~ temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on- site inspections of domestic **and foreign** manufacturing facilities subject to a risk- based prioritization system. The FDA utilized this risk- based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In ~~May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in~~ July 2021, the FDA resumed standard inspectional operations of domestic facilities. More recently, the FDA has continued to monitor and implement changes to its

inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Developments by competitors may render our products or technologies obsolete or non- competitive which would have a material adverse effect on our business, results of operations and financial condition. We compete with pharmaceutical companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Our product candidates will have to compete with existing therapies and potential therapies under development by our competitors. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our product candidates. Other companies have product candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors. Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, staff and facilities, and have substantially greater financial resources than we do, as well as significantly greater experience in: • developing drugs; • undertaking preclinical testing and human clinical trials; • obtaining marketing approvals from the FDA and other regulatory authorities; • formulating and manufacturing drugs; and • launching, marketing and selling drugs. These organizations also compete with us to attract qualified personnel, for acquisitions and joint venture candidates and for other collaborations. Efforts to compete and the pursuit of activities of our competitors may impose unanticipated costs on our business, which would have a material adverse effect on our business, results of operations and financial condition. If we are unable to develop and commercialize our product candidates, our business will be adversely affected. A key element of our strategy is to develop and commercialize a portfolio of new products. We seek to do so through our internal research programs and strategic collaborations for the development of new products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including: • a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all; • a product candidate that is developed and approved may not be accepted by patients, the medical community or third- party payors; • competitors may develop alternatives that render our product candidates obsolete; • the research methodology used may not be successful in identifying potential product candidates; or • a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be safe or effective or otherwise does not meet applicable regulatory approval requirements. Any failure to develop or commercialize any of our product candidates may have a material adverse effect on our business, results of operations and financial condition. Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. In the United States, no uniform policy for coverage and reimbursement exists, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. There may be significant delays in obtaining reimbursement for newly- approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drugs product will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Increasingly, the third- party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for

drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely. Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third- party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician- administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used. Our inability to promptly obtain coverage and adequate reimbursement from both third- party payors for the product candidates that we may develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations, and prospects. Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, or ACA, which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers. The ACA, among other things, expanded Medicaid program eligibility and access to commercial health insurance coverage, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. The ACA also appropriated funding to comparative clinical effectiveness research, although it remains unclear how the research will affect Medicare coverage and reimbursement or how new information will influence other third- party payer policies. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures of the Biden administration, if any, will impact our business. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 ~~and a~~ **. Under current legislation, the actual reduction in Medicare payments varies from** 1 % ~~reduction~~ from April 1, 2022 through June 30, 2022, **up to 3 % in the final fiscal year of this sequester** unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, beginning January 1, 2024. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost- effectiveness of our product candidates to other therapies that are considered the local standard of care. It is also possible that additional governmental action is taken in response to address the COVID- 19 pandemic. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, particularly as a result of the recent presidential election, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability. We have a history of net losses and negative cash flows from operating activities since inception and, as of December 31, ~~2021~~ **2022** , had an accumulated deficit of $ ~~238~~ **274** . ~~3~~ **4** million. We have financed our operations primarily through equity securities, and to a lesser extent from loans and grants. We have devoted substantially all of our financial resources and efforts to research and development. We expect that it will be several years, if ever, before we receive regulatory approval for commercialization of a product candidate. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we: • advance ELX- 02 **, ZKN- 013,** and / or other product candidates further into clinical development; • ~~continue to~~ experience **any further** delays in enrollment and completion of our clinical trials due to the COVID- 19 pandemic or otherwise; • continue the preclinical development of our research programs and advance candidates into clinical trials; • pursue regulatory authorization to conduct clinical trials of additional product candidates; • seek marketing approvals for our product

candidates; • establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, regulatory, management and scientific personnel; • add operational, financial and management information systems and personnel; • acquire or in- license other product candidates and technologies; and • operate as a public company **and maintain our compliance with Nasdaq listing requirements** . We have never generated any revenue from product sales and may never be profitable. To become and remain profitable, we and our collaborators must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, securing coverage and reimbursement for those product candidates for which we may obtain marketing approval, and satisfying any post- marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of the company could also cause investors to lose all or part of their investment. We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for ELX- 02, and as we become obligated to make milestone payments pursuant to our outstanding license agreements. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution of the approved product. ~~Further, we expect to incur additional costs related to the Zikani Merger.~~ Our future capital requirements will depend on many factors, including: • the scope, progress, results and costs of drug discovery, clinical development, laboratory testing and clinical trials for ELX- 02 **, ZKN- 013,** and other product candidates; • the costs, timing and outcome of any regulatory review of ELX- 02 **, ZKN- 013,** and other product candidates; • the cost of any other product candidate programs we pursue; • the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, and securing coverage and reimbursement for any product candidates that receive marketing approval; • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; • our ability to establish and maintain collaborations on favorable terms, if at all; and • the extent to which we acquire or in- license other product candidates and technologies. Identifying potential product candidates and conducting preclinical studies and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval or achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, despite our prior public equity offerings and debt ~~financing~~ **financings** , we will need substantial additional funding in connection with our continuing operations and to achieve our goals. However, our existing cash and cash equivalents may prove to be insufficient for these activities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or future commercialization efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans. If we are unable to obtain adequate financing, we will evaluate options, which may include reducing or deferring operating expenses, including by downsizing our workforce and curtailing certain development programs, which could have a material adverse effect on our operations and financial results **. Changing circumstances and market conditions, some of which may be beyond the Company' s control, could impair our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others. We maintain our cash and cash equivalents in accounts with major financial institutions, and our deposits these institutions can and do exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, we could lose our deposits in excess of the federally insured or protected amounts and there can be no assurance that we will be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position** . Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. For the ~~years~~ **year** ended December 31, ~~2021~~ **2022** ~~and 2020~~ , our net losses were $ **36** ~~(66~~ . **1** ~~7)~~ million ~~and $ (34. 6) million, respectively,~~ and as of December 31, ~~2021~~ **2022** , we had an accumulated deficit of $ **274** ~~(238~~ . **4** ~~3)~~ million. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital. **We believe that our cash and cash equivalents at December 31, 2022 are not sufficient to fund our current and planned operations for at least the next twelve months.** These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of the issuance of the **consolidated** financial statements included in this Annual Report **on Form 10- K** . We are exploring various sources of funding such as strategic collaborations and the issuance of equity to fund our operations. If we raise additional funds through strategic collaborations and alliances, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. To the extent that we raise additional capital through the sale of equity, the ownership interest of our existing ~~shareholders~~ **stockholders** will

be diluted and other preferences may be necessary that adversely affect the rights of existing stockholders. If we are unable to raise sufficient capital through the transactions discussed above, we may need to curtail expenses contemplated by our current operating plan, and we may be required to delay, limit, reduce or terminate our product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If the foregoing plans are unsuccessful and we are unable to continue as a going concern, you could lose all or part of your investment in the ~~company~~ **Company** . Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, as well as entering into new collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity, such as our public offering of shares of our common stock in May 2021 or issuances of common stock under our at- the- market program (" ATM Program "), or convertible debt securities, an investor' s ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect an investor' s rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. Further, the availability of funding under the Hercules Term Loan is conditioned on us meeting certain clinical and equity milestones during defined time periods. **For example, because the Company did not meet the milestone requirements for the Tranche 2 Advance under the Hercules Term Loan as of August 15, 2022, this funding was not available to the Company.** Any debt agreements we may enter into in the future may contain similar restrictions on funding. If we raise funds by entering into new collaborations, strategic alliances 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 or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may not be able to maintain compliance with our debt covenants in the future. The Hercules Term Loan **Agreement** contains customary affirmative and negative covenants which, among other things, ~~requires~~ **required** the Company to maintain at all times a minimum qualified cash balance equaling amounts ranging from $ 6. 3 million to $ 10. 0 million **($ 10. 0 million effective as of August 15, 2022 and at December 31, 2022)** and limits our ability to (i) incur additional indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of our assets, grant liens or encumber our assets or (iv) fundamentally alter the nature of our business. These covenants are subject to a number of exceptions and qualifications. **Subsequent to year end, on March 7, 2023, this minimum qualified cash balance was reduced to $ 2. 25 million as of March 7, 2023 with the amendment of the terms and our repayment of $ 7. 5 million of principal.** If we breach these financial covenants and fail to secure a waiver or forbearance from the third- party lender, such breach or failure could accelerate the repayment of the outstanding borrowings under the Hercules Term Loan ~~agreement~~ or the exercise of other rights or remedies the third- party lender may have under applicable law. No assurance can be provided a waiver or forbearance will be granted or the outstanding borrowings under the Hercules Term Loan ~~agreement~~ , will be successfully refinanced on terms that are acceptable to the Company. We do not intend to pay dividends for the foreseeable future. We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Further, the terms of the Hercules **Term** Loan Agreement limit us from paying dividends or making certain distributions. Any determination to pay dividends in the future will be at the discretion of our board of directors. Our indebtedness and debt service obligations may adversely affect our cash flow. We intend to fulfill our debt service obligations, including repayment of the principal of the Hercules Term Loan, from cash generated from our **future** operations, from our existing cash, and potential additional cash proceeds from our ATM Program or other future equity financings. Our indebtedness could have significant additional negative consequences, including requiring the dedication of a substantial portion of our expected cash flow to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes and limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash in order to fund our debt service obligations, including repayment of the principal, we may have to delay or curtail research and development programs. Risks Related to Our Business and Operations ~~Our stockholders may not realize a benefit from the Zikani Merger commensurate with the ownership dilution they will experience in connection with the Zikani Merger. If we are unable to realize the strategic and financial benefits currently anticipated from the Zikani Merger, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies and we may not manage these processes successfully. We are making substantial investments of resources to support this acquisition, which will result in significant ongoing operating expenses and may divert resources and management attention from other areas of our business. Delays in this process could adversely affect the combined company' s business, financial results, financial condition and stock price. Even if we are able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time. It is also possible that undisclosed, contingent or other liabilities or problems in connection with the acquired company may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and prospects.~~ We continue to seek opportunities to expand our business through strategic initiatives. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful,

and we may not realize the anticipated benefits of any completed acquisition, collaboration or other strategic transaction. Our business strategy includes expanding our product candidates and capabilities. We regularly evaluate potential merger, acquisition, partnering and in- license opportunities that we expect will expand our pipeline or product offerings, and enhance our research or development programs. We may engage in future strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. Any such transactions will be dependent on our ability to appropriately evaluate the potential risks and uncertainties, integrate any new technology, product and / or business, and generate revenues (including through up- front payments, milestones and / or royalties) sufficient to meet our underlying objectives. Any strategic transaction undertaken ~~, including the Zikani Merger,~~ may result in unforeseen development costs, timeline delays, regulatory approval challenges and uncertainties relating to the commercial market opportunity, any of which could cause us to fail to realize the anticipated value of the transaction and may have a material adverse effect on our business and financial condition. To manage effectively our current and future potential growth, we must also continue to enhance and develop our global employee base, and our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research, development, sales and marketing, manufacturing and other areas of our operations. The development or expansion of our business, any acquired business or any acquired or in- licensed products may require a substantial capital investment by us. We may not have these necessary funds, or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our Company. Our business could be affected by litigation, government investigations and enforcement actions. We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the U. S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, Qui Tam, false claims, privacy, anti- kickback, anti- bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. Any of these actions or proceedings may result in significant costs, fines, penalties or imposition of burdensome restrictions on the company, any of which could have a material adverse effect on our business, results of operations and financial condition. We could be subject to additional tax liabilities. We are subject to federal, state and local taxes in the ~~Unites~~ **United** States and Israel. Significant judgment is required in evaluating our tax positions and our worldwide provision for taxes. During the ordinary course of business, there are many activities and transactions for which the ultimate tax determination is uncertain. In addition, our tax obligations and effective tax rates could be adversely affected by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations, including those relating to income tax nexus, by our earnings being lower than anticipated in jurisdictions where we have lower statutory rates and higher than anticipated in jurisdictions where we have higher statutory rates, by changes in foreign currency exchange rates, or by changes in the valuation of our deferred tax assets and liabilities. We may be audited in various jurisdictions, and such jurisdictions may assess additional taxes against us. Although we believe our tax estimates are reasonable, the final determination of any tax audits or litigation could be materially different from our historical tax provisions and accruals, which could have a material adverse effect on our operating results or cash flows in the period or periods for which a determination is made. Our business could be adversely affected by the effects of widespread public health epidemics and other factors beyond our control. Public health epidemics or widespread outbreaks of contagious diseases could adversely impact our business. Any outbreak of contagious diseases, and other adverse public health developments, such as the COVID- 19 pandemic, could impact our operations depending on future developments, which are highly uncertain, largely beyond our control and cannot be predicted with certainty. These uncertain factors include the duration of the outbreak, new information which may emerge concerning the severity of the disease and the actions to contain or treat its impact, could adversely impact our operations, including among others, conduct of our clinical trials, employee mobility and productiveness, temporary closure of facilities, including clinical trial sites, our manufacturing capabilities, and third party service providers such as CROs, any of which could have an adverse impact on our business and our financial results. The COVID- 19 pandemic has also adversely affected the conduct of our clinical trials. For example, on March 25, 2020, we announced that enrollment in our clinical trials had been paused temporarily in response to the COVID- 19 pandemic in order to avoid unnecessary exposure in at- risk populations, to maintain the integrity of our study data and to support global healthcare providers in their commitment to ensure patient safety. On June 17, 2020, we announced that enrollment in our Phase 2 clinical trial in cystic fibrosis had resumed in Israel and Europe, and on August 12, 2020, had resumed in the ~~Unites~~ **United** States. As the COVID- 19 pandemic continues in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials. We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage, and adversely affect our financial condition and results of operations. We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U. S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. Any actual or perceived failure by us to comply with applicable laws and regulations could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition and results of operation. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U. S., HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder (collectively, " HIPAA ") imposes, among other things, certain standards relating

to the privacy, security, transmission and breach reporting of individually identifiable health information. While we do not believe that we are currently acting as a " covered entity " or " business associate " as such terms are defined under HIPAA, and therefore are not directly regulated under HIPAA, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. Further, certain states have also adopted privacy and security laws and regulations, which govern the privacy, processing and protection of health- related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (" CCPA ") went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (" CPRA ") recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia **, Utah, Connecticut,** and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Numerous other countries have also developed, or are developing, laws governing the collection, use and transmission of personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, in May 2018, the General Data Protection Regulation (" GDPR ") went into effect, which imposes strict requirements for processing the personal data of individuals within the European Economic Area (" EEA "). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU (" CJEU ") limited how organizations could lawfully transfer personal data from the EU / EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (" SCCs "). The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom ~~; the~~ **. The** United Kingdom' s Information Commissioner' s Office ~~launched a public consultation on its draft revised~~ **has published new data transfer standard contracts for transfers from the United Kingdom under the United Kingdom GDPR. This new documentation will be mandatory for relevant** data transfers ~~mechanisms in August~~ **from September 21,** ~~2021~~ **2022 ; existing standard contractual clauses arrangements must be migrated** ~~and laid its proposal before Parliament, with the United Kingdom SCCs expected~~ to ~~come into force in~~ **the new documentation by** March **21,** ~~2022~~ **2024** ~~, with a two- year grace period~~ . There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non- EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Since the beginning of 2021, after the end of the transition period following the United Kingdom' s departure from the EU, we are also subject to the United Kingdom ~~data protection regime~~ **GDPR (" UK GDPR ")** , which **together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR** imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £ 17. 5 million or 4 % of a noncompliant company' s global annual revenue for the preceding financial year, whichever is greater. **The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and the European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re- assesses and renews or extends that decision. In September 2021, the United Kingdom government launched a consultation on its proposals for wide- ranging reform of United Kingdom data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes which are made to the United Kingdom data protection regime could result in the European Commission reviewing the United Kingdom adequacy decision, and the United Kingdom losing its adequacy decision if the European Commission deems the United Kingdom to no longer provide adequate protection for personal data.** As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws

and regulations that may affect how we conduct business **. The EU has also proposed a Regulation on Privacy and Electronic Communications, (" ePrivacy Regulation"), which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials. Failure or perceived failure to comply with the GDPR, the UK GDPR, the ePrivacy Regulation, the EU Clinical Trials Regulations, and other countries' privacy or data security- related laws, rules or regulations could result in significant regulatory penalties and fines, affect our compliance with contracts entered into with our partners, collaborators and other third- party payors, and could have an adverse effect on our reputation, business and financial condition** . Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business, financial condition and results of operations. Security breaches, cyber- attacks, or other disruptions could expose us to liability and affect our business and reputation. We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, " hacktivists, " patient groups, disgruntled current or former employees, and others. Cyber- attacks are of ever- increasing levels of sophistication, and despite our security measures, our information technology systems and those of our third- party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e. g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. The COVID- 19 pandemic has caused us to modify our business practices, including permitting our employees to work from home. As a result, we are increasingly dependent upon our **information** technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our **information** technology systems and data, which includes use of cloud technologies. This increased remote usage of information systems increases the risks that our business may be disrupted due to a variety of reasons, including security breaches, power outages, unavailability of employees, use of non- company secured equipment and increased phishing and hack activity. However, despite these measures, and due to the ever- changing information cyber- threat landscape, we may be subject to data breaches through cyber- attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Even if a compromise were identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Like other companies in our industry, we **and our service providers are from time to time subject to cyberattacks and security incidents, including malware and computer viruses. While we do not believe that we** have experienced **any significant** ~~attacks to our data and systems~~ **system failure** , **accident,** ~~including malware and computer viruses. If our~~ **or** ~~systems failed or~~ **security breach to date, if such an event** were ~~breached~~ **to occur and cause interruptions in** ~~or~~ **our** ~~disrupted~~ **operations** , **it could result in** patient and other data and information **becoming** ~~may become~~ compromised, **and** we could lose sales for approved products, if any, and suffer reputational damage and loss of confidence by patients, investors and business partners. Such incidents may result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events, or similar events occurring through one of our vendors that maintain such information on our behalf, could cause our business to be materially harmed and our results of operations to be adversely impacted **. Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks) and the mishandling of data by our employees and third- party service providers, then our reputation, business, results of operations and financial condition could be adversely affected** . We currently rely, and plan to rely on in the future, third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, consultants and strategic partners to conduct and support our preclinical studies and clinical trials. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed. Nevertheless, we are

responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP 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 regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations. Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development, or if approved, eventual commercialization. We rely, and expect to continue to rely, on third- party manufacturers for the production of our product candidates for preclinical studies and clinical trials. We do not have long- term supply agreements with these manufacturers. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single- source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID- 19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID- 19 or treat its effects. We expect to continue to rely on third- party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the failure of the third party to manufacture our product candidates according to our schedule; • the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms; • the termination or nonrenewal of agreements at a time that is costly or inconvenient for us; • the failure to comply with contractual obligations; • the failure to comply with applicable regulatory requirements; • the failure to manufacture our product candidates according to our specifications; • clinical supplies not being delivered to clinical sites on time; • disruptions to the operations of our third- party manufacturers or suppliers, testing facilities, or research sites caused by conditions unrelated to our business or operations, including unrelated regulatory action against or the bankruptcy of the manufacturer or supplier, testing facility, or research site, or the unavailability of essential personnel to conduct or complete our research or clinical trials, such as, for example, a result of the COVID- 19 pandemic; and • the misappropriation of our proprietary information, including our trade secrets and know- how. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory

requirements of the FDA others, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or comparable regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel. The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. Intense competition exists in the biopharmaceutical industry for these types of personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the highly qualified personnel necessary for developing, manufacturing and commercializing our product candidates. If we are unsuccessful in our recruitment and retention efforts, or if our recruitment efforts take longer than anticipated, our business may be harmed. We may face difficulty in attracting and retaining key talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more late- stage programs, recruitment by competitors or delays in the recruiting and hiring process as a result of the COVID- 19 pandemic **or otherwise** . We cannot ensure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any such personnel will not have a material impact on our financial condition and results of operations. We are highly dependent on principal members of our senior management. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives. If we fail to attract and retain highly qualified personnel, we may not be able to successfully develop, manufacture or commercialize our product candidates. We have experienced recent changes in management and other key personnel in critical functions across our organization, including in connection with the Zikani Merger. Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition or results of operations. In addition, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs. Further, if members of our management and other key personnel in critical functions across our organization are unable to perform their duties ~~or have limited availability due to COVID- 19~~ , we may not be able to execute on our business strategy and / or our operations may be negatively impacted. Risks Related to Intellectual Property If we fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, the value of our intellectual property rights would diminish, and our business, competitive position and results of operations would suffer. As of December 31, ~~2021~~ **2022** , we owned or licensed ~~41~~ **66** issued patents and ~~105~~ **101** pending patent applications in the U. S. and abroad, not including U. S. provisional applications. However, with regard to the pending applications, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a currently pending patent application may delay the approval of such patent application which could have a material adverse effect on our business, results of operations and financial condition. In addition, there are a number of factors that could cause our current or future issued patents to become invalid or unenforceable or that could cause our pending patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or lack of originality of the technology. Our competitive position and future revenue will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. However, we cannot predict: • the degree and range of protection any patents will afford us against competitors and those who infringe upon our patents, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents; • if and when patents will issue; • whether or not others will obtain patents claiming aspects similar to those covered by our owned or licensed patents and patent applications; or • whether we will need to initiate litigation or administrative proceedings, which may be costly, and whether we win or lose. If patent rights covering our products or technologies are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the U. S. Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors and those who infringe upon our patents. Furthermore,

the lives of our patents are limited. With regard to our lead compound ELX- 02, patents that have issued or that may issue in the future from our primary composition of matter patent family are currently set to expire in 2031. We have pending patent families directed to specific methods of manufacturing ELX- 02 and using ELX- 02 to treat various ocular conditions, and any patents that may issue from these families would be expected to expire in 2038 and 2039, respectively. However, these applications may not issue, and even if they do issue the resultant patents may not provide adequate coverage to meaningfully block competitors from launching their products. We will likely pursue additional patent protection relating to ELX- 02 in the future, including for example additional methods of use or manufacture, specific formulations, or combinations of ELX- 02 with other therapeutic agents. However, as with our pending patent families, any applications we file in the future may not issue or may not result in adequate coverage to adequately protect our assets. Depending upon the timing, duration, and conditions of any FDA marketing approval for ELX- 02, one or more of our patents may be eligible for patent term extension of up to five years under the Hatch- Waxman Act. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply for an extension within applicable deadlines, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, an approved method of using the approved drug, or a method of manufacturing the approved drug may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for ELX- 02 will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our business could be harmed. If we cannot obtain new patents, maintain our existing patents and protect the confidentiality and proprietary nature of our trade secrets and other intellectual property, our business and competitive position may be harmed. Our success will depend in part on our ability to obtain and maintain patent and regulatory protections for our product candidates, to preserve our trade secrets and other proprietary rights, to operate without infringing the proprietary rights of third parties, and to prevent third parties from circumventing our rights. Due to the time and expense of bringing new product candidates through development and regulatory approval to the marketplace, there is particular importance in obtaining patent and trade secret protection for significant new technologies, products and processes. We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the U. S. or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Our product candidates are expensive and time- consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our products from copycat products. Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the U. S. and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will issue as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the U. S. and other countries. Such proceedings include re- examinations, inter partes reviews, post- grant reviews and interference proceedings before the U. S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office and other non- U. S. patent offices. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights. In addition, our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other biopharmaceutical companies. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects. If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and / or obtain a license to continue the manufacture, sale or development of our product candidates. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our product candidates, which would adversely affect our business. If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business, results of operations and financial condition. We have not received to date any claims of infringement by any third parties. However, as our product candidates progress into clinical trials and commercialization, if at all, our public profile and that of our product candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we may incur substantial costs and we may have to: • obtain licenses, which may not be available on commercially reasonable terms, if at all; • redesign our products or processes to avoid infringement, which could significantly impede development and impair or block our ability to secure regulatory approval of any redesigned product or process; • stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our

product candidates; • defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or • pay damages. Any costs incurred in connection with such events or the inability to develop or sell our products may have a material adverse effect on our business, results of operations and financial condition. We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position. Our policy is to enter agreements relating to the non- disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the rights belong to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors and other third parties. Despite the protective measures we employ, we still face the risk that: • these agreements may be breached; • these agreements may not provide adequate remedies for the applicable type of breach; or • our trade secrets or proprietary know- how will otherwise become known. Any breach of our confidentiality agreements or our failure to effectively enforce such agreements may have a material adverse effect on our business and competitive position. If we cannot meet requirements under our license agreement, we could lose the rights to our product candidates, which could have a material adverse effect on our business. We depend on the license agreement with TRDF to maintain the intellectual property rights to certain of our product candidates. Our license agreement requires us to make payments and satisfy performance obligations in order to maintain our rights under this agreement. This agreement lasts either throughout the life of the patents that are the subject of the agreement, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product. In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreement in a timely manner, we could lose the rights to our proprietary technology, which could have a material adverse effect on our business, results of operations and financial condition. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have an adverse effect on the success of our business. Competitors or other third parties may infringe, misappropriate or otherwise violate our patents or other intellectual property. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description, or non- enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products and product candidates, which may allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our products, product candidates or technologies without infringing third- party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Moreover, 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 our product candidates. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. We may be subject to third-party claims including infringement, interference or derivation proceedings, post- grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe such claims are without merit, a court could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product or product candidates unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products, product candidates or technologies may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court to cover aspects of our products, product candidates or technologies, the holders of any such patents may be able to prohibit our commercialization of the applicable product or product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party' s patent rights. These damages potentially include royalties, increased damages (possibly treble damages) and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us, our development,

manufacturing or sales activities relating to the product, product candidate or technology that is the subject of the suit may be delayed or terminated, as parties making claims against us may obtain injunctive or other equitable relief. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross- license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our products or product candidates, or forced to modify such products or product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our products, product candidates or technologies so that we no longer infringe the third- party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products or product candidates. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace and could have an adverse impact on our business and financial condition. Risks Related to Our Regional Operations Potential political and economic instability in regions where we conduct business may adversely affect our results of operations. In addition to our operations in the United States, we currently conduct certain research and clinical development activities through our regional operations located in Israel ~~,~~**. We also maintain a legal presence** and **contract with vendors located in Australia. We** may, in the future, expand **our presence and** operations to other ~~regional~~ locations ~~in Europe and elsewhere~~ as circumstances require. Accordingly, political and economic conditions in **any** ~~Israel and the~~ **other** ~~surrounding~~ **country or** region ~~in particular,~~ **where we do business** may directly affect our operations. **In particular,** ~~Regional~~ **regional** instability **in the Middle East** may lead to a deterioration in the political and trade ~~relationships~~ **relationship** that ~~exist~~ **exists** between countries in the region, making it more difficult to conduct operations. In addition, our insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East or for any resulting disruption in our operations. Although the Israeli government has in the past covered the reinstatement value of direct damages that were caused by terrorist attacks or acts of war, we cannot provide assurance that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred. Furthermore, in the past, Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with Israel and with Israeli companies. These restrictive laws and policies, even though we are a U. S.- based company, may have an adverse impact on our operating results, financial conditions or the expansion of our business. We received Israeli government grants for our research and development activities and programs. The terms of such grants may require us, in the future, to pay royalties and under certain circumstances, penalties in addition to payment of royalties. Our research and development efforts were initially financed, in part, through royalty- bearing grants from the Israel Innovation Authority, or IIA. We received an aggregate of $ 2. 6 million from the IIA for the development of our technologies. With respect to such grants we are required to pay certain royalties (including accrued interest) up to $ 2. 8 million. We are required to comply with the requirements of the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744- 1984, as amended, and related regulations ~~, or~~ **("** the R & D Law ~~,~~ **")** with respect to these past grants. If we fail to comply with the R & D Law, we may be required to refund certain grants previously received and / or to pay interest and penalties and we may become subject to criminal charges. With respect to such grants we are obligated to pay royalties at a rate in the low to middle single digit percentage from the revenue generated from the sale of any products or services developed using IIA grants up to a maximum amount equal to repayment of the grant proceeds received plus accrued interest. We have not commenced the payment obligation of these royalties since we have not yet generated revenue, and we have a contingent obligation with respect to such future royalty payments including interest, of $ 2. 8 million. The R & D Law and terms of the prior grants restrict the transfer of certain know- how, and the transfer of manufacturing or manufacturing rights of products developed with grant funds, outside of Israel, without the prior approval of the IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIA funding according to the R & D Law, the discretionary approval of the IIA may be required for any assignment and / or transfer to third parties inside or outside of Israel of know- how or transfer outside of Israel of manufacturing or manufacturing rights and may result in payment of increased royalties and / or payment of additional amounts to the IIA. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development outside of Israel. Such approvals may not be granted by the IIA and any conditions imposed may not be acceptable to the Company. The R & D Law and the regulations promulgated thereunder provide that the transfer of IIA- supported technology or know- how outside of Israel may involve the payment of additional amounts depending upon the value of the transferred technology or know- how, the amount of IIA support, the time of completion of the IIA- supported research project and other factors, up to a maximum of six times the amount of grants received. These restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our stockholders in a transaction involving the transfer outside of Israel of technology or know- how developed with IIA funding may be reduced by any amounts that we are required to pay to the IIA. Our obligations and limitations pursuant to the R & D Law are not limited in time and may not be terminated by us at will. As of the date hereof, we have not been required to pay any royalties with respect to the IIA grants. We may become

subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business. We enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment or engagement are assigned to us or owned exclusively by us, without the employee retaining any rights. A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727- 1967 (the " Patent Law "), inventions conceived by an employee during the scope of his or her employment with a company are regarded as " service inventions, " which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the " Committee "), a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions. Previous decisions by the Committee have created uncertainty in this area regarding whether the right to receive remuneration for service inventions can be voluntarily waived by an employee and whether such waiver is enforceable. In addition, the Committee determined that even if such right to receive compensation and royalties for service inventions may be waived, the waiver should be specific. Subsequent court cases have not provided significant clarity on these matters. Risks Related to Our Common Stock Our stock price may be volatile, and purchasers of our common stock could incur substantial losses. The trading price of our common stock has been volatile and may continue to be volatile and subject to wide fluctuations in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors' operating results, clinical trial results or adverse events associated with our product candidates, product development by us or our competitors, changes in laws, including healthcare, regulatory, tax or intellectual property laws, intellectual property developments, acquisitions or other strategic transactions ~~(including the Zikani Merger)~~, changes in financial or operational estimates or projections and the perceptions of our investors that we are not performing or meeting expectations ~~. The market price of our common stock may decline as a result of the Zikani Merger for a number of reasons, including, our failure to achieve the perceived benefits of the Zikani Merger as rapidly or to the extent anticipated by financial or industry analysts, or investors react negatively to the Zikani Merger and its impact on our business and prospects~~. The trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. In addition, the securities market has from time- to- time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock. Our failure to meet the continued listing requirements of The Nasdaq ~~Global~~ **Capital** Market could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of The Nasdaq ~~Global~~ **Capital** Market, such as the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. ~~Under Nasdaq rules, the closing bid price for our common stock must remain at or~~ **For example, on** ~~above $ 1. 00 per share to comply with Nasdaq' s minimum bid requirement for continued listing. On~~ January 3, 2022, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market **(" Nasdaq Listing Qualifications")** notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock has been below the minimum $ 1. 00 per share required for continued listing on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450 (a) (1) (the " Minimum Bid Price Requirement "). Under Nasdaq Listing Rule 5810 (c) (3) (A), the Company **was** ~~has been~~ granted a 180 calendar day grace period, or until July 5, 2022, to regain compliance with the minimum bid price requirement. The minimum bid price requirement will be met if our common stock has a minimum closing bid price of at least $ 1. 00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. ~~If we fail to~~ **Because the Company did not** regain compliance with the Minimum Bid Price Requirement before July 5, 2022, ~~then~~ **the Company applied** ~~we may be eligible~~ to ~~have~~ **transfer its listing to the Nasdaq Capital Market and for an extension of** an additional 180 calendar days, or until January 2, 2023 ~~,~~to regain compliance with the Minimum Bid Price Requirement. **On July 7** ~~To qualify for the additional grace period~~, ~~we are required to submit a transfer~~ **2022, Nasdaq notified us that our** application for ~~transfer between~~ **listing on the** Nasdaq **Capital** ~~market~~ **Market** ~~tiers~~ **was approved and that Nasdaq had approved the Company' s extension request. On December 1, 2022, we effected a 1- for- 40 reverse stock split of our common stock (the " Reverse Stock Split "). At a special meeting of stockholders held on November 30, 2022 (the " Special Meeting "), the stockholders of the Company approved a proposal to authorize the Company' s Board of Directors, in its discretion following the Special Meeting to** ~~and~~ **amend** ~~pay~~ **the Company' s Amended and Restated Certificate of Incorporation, as amended (the " Certificate of Incorporation "), to effect** a ~~$~~ **reverse stock split of all of the outstanding shares of the Company' s common stock. On November 30, 2022, following the Special Meeting, the Company' s Board of Directors approved the Reverse Stock Split at a ratio of 1- for- 40. On December 1, 2022, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment (the " Certificate of Amendment ") with the Secretary of State of the State of Delaware to amend the Company' s Certificate of Incorporation to effect the Reverse Stock Split. The Reverse Stock Split became effective at** 5 ~~,~~**:** ~~000~~ **00 p** ~~application fee~~ **m., Eastern** ~~In order to be eligible for consideration for such additional time~~ **Time** , **on December 1, 2022. On December 19, 2022,** we **were notified by** ~~will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The~~ Nasdaq **Listing Qualifications that** ~~Global Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of its intention to cure the deficiency during the second compliance period. We are monitoring~~ the closing bid price of ~~its~~ **the our** common stock ~~;~~ ~~however~~ **had been at $ 1. 00 per share or greater for the 11 consecutive business days** , **from December 2, 2022 to December 16, 2022. Accordingly, the Company has regained compliance with Listing Rule 5550 (a) (2) and this matter is now closed. Although we regained compliance with Listing Rule 5550 (a) (2)** there can be no **guarantee that we can continue to remain compliant. Further, on October 11, 2022, we received a letter from Nasdaq Listing Qualifications notifying us that for the last 30 consecutive business days, the Company' s Minimum Value of Listed Securities, as**

defined by Nasdaq (“ MVLS ”), has been below the minimum $ 35 million requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5500 (b) (2) (the “ Minimum Market Value Requirement ”). Under Nasdaq Listing Rule 5810 (c) (3) (C), the Company has 180 calendar days, or until April 10, 2023, to regain compliance with the Minimum Market Value Requirement. The Minimum Market Value Requirement will be met if our minimum MVLS closes at $ 35 million or more for a minimum of ten (10) consecutive business days during the compliance period ending April 10, 2023. If we do not regain compliance with the Minimum Market Value Requirement during the compliance period ending April 10, 2023, Nasdaq will provide written notification that the Company’ s common stock will be subject to delisting. At that time, the Company may appeal any such delisting determination to the Panel. We are actively monitoring our MVLS and evaluating available options to regain compliance with the Minimum Market Value Requirement. However, there is no assurance that we will be able to regain compliance **with the Minimum Market Value Requirement during the 180- day** ~~or that Nasdaq will grant us a further extension of time to regain~~ compliance **period** ~~, if necessary~~ . The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Minimum ~~Bid Price~~ **Market Value** Requirement ~~would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum bid price~~ required for continued listing ~~again~~ or prevent future non- compliance with Nasdaq’ s listing requirements. **There is also no assurance that we will maintain compliance with the other listing requirements of The Nasdaq Capital Market.** General Risk Factors Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert 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 Exchange Act, the Sarbanes- Oxley Act of 2002 (the “ Sarbanes- Oxley Act ”), and Nasdaq stock market rules. The requirements of these rules and regulations have increased and will continue to significantly increase our legal and financial compliance costs, including costs associated with the hiring of additional personnel, making some activities more difficult, time-consuming or costly, and may also place undue strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes- Oxley Act requires, among other things, that we maintain disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place, as well as maintaining these controls and procedures, is a costly and time- consuming effort that needs to be re- evaluated frequently. Section 404 of the Sarbanes- Oxley Act, or Section 404, requires that we annually evaluate our internal control over financial reporting to enable management to report on the effectiveness of those controls. In connection with the Section 404 requirements, we test our internal controls and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas for further attention or improvement. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting and other personnel, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, adequate internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 could result in the loss of investor confidence in the reliability of our financial statements, which in turn could cause the market value of our common stock to decline. Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations. As of December 31, ~~2021~~ **2022** , we had U. S. federal and state net operating loss carryforwards (“ NOLs ”), of $ ~~158~~ **159** . ~~8~~ **2** million and $ ~~24~~ **25** . ~~2~~ **9** million, respectively, and federal research tax credit carryforwards of $ ~~5~~ **8** . ~~9~~ **1** million. Certain U. S. NOLs will begin to expire, beginning in ~~2022~~ **2023** through 2037, and research tax credits will expire beginning in 2026 through 2041. Included in these U. S. federal NOLs are $ ~~82~~ **84** . ~~5~~ **1** million of NOLs generated after the effective date of the **Tax Cuts and Jobs Act of 2017 ("** TCJA **")** which are not subject to expiration. Under the TCJA, Federal NOLs generated in 2018 and future years may be carried forward indefinitely but may not be carried back and are only eligible to offset up to a maximum of 80 % of taxable income generated in a given year. It is uncertain if and to what extent various U. S. states will conform their net operating loss rules to the TCJA. In general, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended, (the “ Code ”), a corporation that undergoes an “ ownership change ” is subject to limitations on its ability to utilize its pre- ownership change NOLs to offset future taxable income. We may have experienced ownership changes in the past. We may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. Although we have not completed our analysis, it is reasonably possible that our federal NOLs available to offset future taxable income could materially decrease. This reduction will be offset by an adjustment to the existing valuation allowance for an equal and offsetting amount. Additionally, our state NOLs available to offset future state income could similarly decrease which would also be offset by an equal and offsetting adjustment to the existing valuation allowance. Given the offsetting adjustments to the existing valuation allowance, any ownership change is not expected to have a material adverse effect on our consolidated financial statements. As of December 31, ~~2021~~ **2022** , we had Israeli NOLs of $ ~~99~~ **101** . ~~3~~ **0** million, which carry forward indefinitely. Our ability to utilize our NOLs is dependent on attaining profitability sufficient to offset such available NOLs prior to their expiration. In addition, we may not be able to utilize a portion of the NOLs even if we attain profitability. Our directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may

make decisions that an investor may not consider to be in the best interests of our stockholders. Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, a significant percentage of our common stock, giving effect to options and other derivative securities that are held by such persons. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent the consummation of transactions favorable to other stockholders, such as a transaction in which stockholders might otherwise receive a premium for their shares over current market prices. Future sales and issuances of our securities or rights to purchase securities, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the prices of our securities to fall. Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities ~~, such as our public offering of shares of our common stock in May 2021~~ or our ATM Program pursuant to which we may sell up to $ 50. 0 million of our common stock, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in one or more transactions, existing investors may be materially diluted by subsequent sales, and new investors could gain rights superior to our existing stockholders. Pursuant to our 2018 Equity Incentive Plan, our management is authorized to grant stock options and other equity- based awards to our employees, directors and consultants. As of December 31, ~~2021~~ **2022** , individuals held share awards to purchase or receive an aggregate of ~~8~~ **249** , **403** ~~910, 707~~ shares of our common stock. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year **(5 % of the outstanding common stock)** , our stockholders may experience additional dilution, which could have a negative effect on our share price. ~~55~~