Risk Factors Comparison 2025-03-14 to 2024-03-22 Form: 10-K

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

Risks Related to our Financial Position and Capital Needs We have incurred recent losses and our future profitability is uncertain. We have incurred an operating loss of approximately $ 5. ~~6~~ **7** million for the year ended December 31, ~~2023~~ **2024** , and a loss of approximately $ ~~10~~ **5** . ~~0~~ **6** million ~~(which included a $ 5. 0 million investment for the research tools referenced in Note 3)~~ for the year ended December 31, ~~2022~~ **2023** , respectively. We expect our operating losses to continue until such time, if ever, that product sales, licensing fees, royalties and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved. 22Even with the proceeds from our recent securities offerings, we will need additional capital to fund our operations as planned. For the year ended December 31, ~~2023~~ **2024** , our operations used approximately $ ~~8~~ **5** . ~~0~~ **3** million in cash. Cash used in operations consisted primarily of cash on hand and cash raised in our December 2021 public offering ~~and~~ **,** our May 2022 private offering **and our December 2024 private offering** . At December 31, ~~2023~~ **2024** , we had a combined cash, ~~certificates of deposit~~ and short- term U. S. ~~Treasuries~~ **treasuries** balance of approximately $ ~~10~~ **5** . ~~0~~ **9** million. Although we generated gross proceeds in excess of $ ~~30~~ **32** million from our 2021 ~~and~~ **,** 2022 **and 2024** securities offerings, we will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings and other sources. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings could also have a material and adverse effect on the price of our common stock. We have generated minimal revenues from our products **and do not expect to generate revenues for the foreseeable future** . We will not achieve profitability unless we generate increased revenues from our current or proposed products or therapies. Revenues generated from sales of our CaverStem ® ~~and FemCelz ®~~ kits were only $ **11, 000 and $** 9, 000 ~~and $ 88, 600~~ for the years ended December 31, ~~2023~~ **2024** , and December 31, ~~2022~~ **2023** , respectively. To sustain our operating costs and generate profits, we will need to **generate** ~~significantly increase~~ revenues from our ~~CaverStem ® and FemCelz ® products or from our other~~ products or therapies that have not yet been commercialized. We expect to continue to incur significant financial losses in the future as we seek to proceed with our Type I Diabetes (CELZ- 201 CREATE- 1) clinical trial, our AlloStemSpine ® Chronic Lower Back Pain (CELZ- 201 ADAPT) clinical trial, and our other planned clinical trials. We have received the necessary regulatory approval for our Type I Diabetes (CELZ- 201 CREATE- 1) clinical trial and our AlloStemSpine ® Chronic Lower Back Pain (CELZ- ~~202~~ **201** ADAPT) clinical trial. In addition, we are further developing our cell platforms, and file INDs for additional indications that utilize our cell platforms. We anticipate that our expenses will increase substantially as we: · initiate, conduct, and complete ongoing, anticipated, or future preclinical studies and clinical trials for our current and future product candidates; · seek marketing approvals for product candidates that successfully complete clinical trials; and · establish a sales, marketing, and distribution infrastructure to commercialize products for which we may obtain marketing approval. Risks Related to Product Development, Regulatory Approval and Commercialization Our product candidates' commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals, and the risks generally inherent in the development of biopharmaceutical products. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed. In the near term, failure to successfully advance the development of our proposed products may have a material adverse effect on us. To date, other than limited sales generated from our CaverStem ~~® and FemCelz ®~~ products, we have not successfully developed or commercially marketed, distributed, or sold any product candidate. The success of our business may depend upon our ability to successfully advance the development of our current and future product candidates through preclinical studies and clinical trials, where applicable, have the product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidates successfully commercialized by us or a commercial partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive the necessary approvals from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates. 23We may not be successful in our commercialization efforts for our proposed products and therapies, which may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. To the extent we possess or obtain the necessary regulatory approval for our proposed products and therapies, we still may not be successful in our commercialization efforts or in gaining sufficient market acceptance by physicians, patients, third- party payors, and others in the medical community. Market acceptance will require us to build and maintain strong relationships with healthcare professionals that treat the indications our therapies are intended to address. A failure to build or maintain these important relationships with these healthcare professionals and treatment centers could result in lower market acceptance. Our efforts to educate physicians, patients, third- party payors, and others in the medical community on the benefits of our products and therapies may require significant resources and may never be successful. The degree of market acceptance of our products and therapies will depend on a number of factors, including: · their efficacy; · limitations or warnings or any restrictions on use, and the prevalence and

severity of any side effects; · the availability and efficacy of alternative treatments; · the effectiveness of sales and marketing efforts and the strength of marketing and distribution support; · their cost- effectiveness compared to alternative therapies; and · availability and amount of coverage and reimbursement from government payors, managed care plans and other third- party payors. The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate' s profile. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Our CaverStem ® and FemCelz ® products are exempt from the FDA premarket review and approval process as these autologous therapies involve treating the patient with his or her own cells. However, we will require FDA approval of CELZ- 201 CREATE- 1 for the treatment of Type I diabetes, AlloStemSpine (CELZ 201 – ADAPT) treatment for chronic lower back pain, and other indications. We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, in part, on consultants and third- party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive non- clinical and clinical data and supporting information to the FDA for each therapeutic indication to establish a product candidate' s safety and efficacy for each indication. If third parties we rely on fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, our efforts to secure regulatory approval of our product candidates may be delayed or prove unsuccessful. 24Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we will encounter problems with any of our completed, ongoing, or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of Type I Diabetes (CELZ- 201 CREATE- 1) and AlloStemSpine ® Chronic Lower Back Pain (CELZ- 201 ADAPT) will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to: · delays in securing clinical investigators or trial sites for the clinical trials; · delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial; · slower than anticipated patient recruitment and enrollment; · negative or inconclusive results from clinical trials; · unforeseen safety issues; · uncertain dosing issues; · an inability to monitor patients adequately during or after treatment; and · problems with investigator or patient compliance with the trial protocols A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. We do not know whether any clinical trials we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market ImmCelzTM (CELZ-100). Our autologous products are currently not eligible for reimbursement from public or private insurers. Currently, our CaverStem ® and FemCelz ® products and related medical procedures are paid for by patients and are not eligible for reimbursement from public or private insurers. As a general rule, reimbursement is available only for products and therapies that have been approved by the FDA. Our CaverStem ® and FemCelz ® products were exempt from the FDA premarket review and approval process as these autologous therapies involve treating the patient with his or her own cells. While we believe that the requirement that patients directly pay the cost for our **autologous** ~~CaverStem ® and FemCelz ®~~ products and procedures make these procedures more attractive to doctors, these treatments are only available to patients that can afford to pay for them. Our success and the extent of our growth will depend in part on the extent to which reimbursement for the costs of our products and related treatments will be available from third party payers, such as public and private insurers and health systems. ~~25The~~ -- **The** pharmaceutical business is subject to increasing government regulation and reform, including with respect to price controls, reimbursement, and access to therapies, which could adversely affect our future revenues and profitability. Our existing and proposed products may not be considered cost- effective, and third- party or government reimbursement might not be available or sufficient. Globally, governmental, and other third- party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U. S. to continue. ~~Our~~ **25Our** existing and proposed products are and will be subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and the implementation of U. S. health care reform legislation that is increasing these pricing pressures. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, instituted comprehensive health care reform, and includes provisions that, among other things, reduce and / or limit Medicare reimbursement, and impose new and / or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time. The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as

the availability of capital. United States federal and state privacy laws, and equivalent laws of other nations, may increase our costs of operation and expose us to civil and criminal sanctions. Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities. We and our collaborators may be subject to federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we knowingly use or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. ~~26Later~~ -- **Later** discovery of previously unknown problems could limit our ability to market or sell our products or therapies and can expose us to product liability claims. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: · refusals or delays in the approval of applications or supplements to approved applications; · refusal of a regulatory authority to review pending market approval applications or supplements to approved applications; **26** · restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures; · fines, warning letters, or holds on clinical trials; · injunctions or the imposition of civil or criminal penalties; · restrictions on product administration, requirements for additional clinical trials, or changes to product labeling requirements; or · recommendations by regulatory authorities against entering into governmental contracts with us. Discovery of previously unknown problems or risks relating to our product could also subject us to potential liabilities through product liability claims. If we do not obtain required approvals in other countries in which we aim to market our products, we will be limited in our ability to export or sell the products in those markets. Our lack of experience in conducting clinical trials in foreign jurisdictions may negatively impact the approval process in those jurisdictions. If we are unable to obtain and maintain required approval from one or more foreign jurisdictions where we would like to sell our products or therapies, we will be unable to market products as intended, our international market opportunity will be limited, and our results of operations will be harmed. We rely in part on third parties for research and clinical trials for our products and therapies. We rely on contract research organizations (" CROs "), academic institutions, corporate partners, and other third parties to assist us in managing, monitoring, and otherwise carrying out clinical trials and research activities. We rely or will rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. Although we rely on these third parties to manage the data from clinical trials, we will be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Our failure, or the failure of third parties on which we rely, to comply with the strict requirements relating to conducting, recording, and reporting the results of clinical trials, or to follow good clinical practices, may delay the regulatory approval process or cause us to fail to obtain regulatory approval for our proposed products and therapies. ~~27We~~ **We** currently have a very limited marketing and sales organization and may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products and therapies, we may not be able to generate sufficient revenues to support our operations. ~~Our current sales, marketing and distribution capabilities consist of independent contractors who promote the sale of our CaverStem ® and FemCelz ® products to medical doctors.~~ To generate sufficient revenues to support our operations, we will have to seek collaborators, especially for marketing and sales **in and** outside of the United States or invest significant amounts of financial and management resources to develop internal sales, distribution, and marketing capabilities. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing, and distribution functions on acceptable financial terms, or at all. In addition, our product revenues, and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Even if we determine to perform sales, marketing, and distribution functions ourselves, we could face a number of additional related risks, including: · we may not be able to attract and build an effective marketing department or sales force; · the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by our product candidates that we may develop, in- license or acquire; and · our direct sales and marketing efforts may not be successful. ~~We~~ **27We** rely upon third parties for the manufacture of our CaverStem ® and FemCelz ® disposable kits and are dependent on their quality and effectiveness. We rely upon third parties for the manufacture of our CaverStem ® and FemCelz ® disposable kits. The failure to achieve and maintain high

manufacturing standards, or to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in cost overruns, product recalls or withdrawals, patient injury or death, and other problems that could seriously hurt our business. We may be unable to compete effectively with marketed therapies or drugs targeting similar indications to our products and therapies. We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any products that are safer, more effective, have fewer side effects or are less expensive than our products and therapies. These potential competitors may also compete with us in establishing clinical trial sites, and patient enrollment for clinical trials. Our business and operations would suffer in the event of computer system failures or security breaches. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, and proprietary business information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication, and intensity. Cyberattacks could include the deployment of harmful malware, denial- of- service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property and proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID- 19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed. ~~28We~~ **We** are subject to risks arising from the global outbreak of the COVID- 19 coronavirus. The outbreak of the COVID- 19 coronavirus has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID- 19 or other public health epidemic, poses the risk that we or our employees, CROs, suppliers, manufacturers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. Another significant, outbreak of COVID- 19, a communicable disease, could disrupt our clinical trials, supply chain and the manufacture or shipment of our products, and other related activities, which could have a material adverse effect on our business, financial condition and results of operations, and may also have an adverse impact on global economic conditions which could impair our ability to raise capital when needed. ~~We~~ **28We** are subject to risks arising from the wars in Ukraine and the Gaza Strip. Although we believe we do not have any exposure to the wars in Ukraine and the Gaza Strip, we cannot predict how global supply chain activities, or the economy at large may be impacted by prolonged wars in those or other regions, or whether global conflicts, if any, may in the future adversely affect our results of operations. Risks Related to Our Intellectual Property We may not be able to protect our proprietary rights. Our commercial success will depend in large part upon our ability to protect our proprietary rights. There is no assurance, for example, that any additional patents will be issued based on our or our pending applications or, if issued, that such patents will not become the subject of a re- examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products and services incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products and services, duplicate any of our products and services, or design around any patents we obtain. Our commercial success will also depend upon our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third- party patent, we could be required to pay damages, alter our products, services or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products and / or services, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. United States and foreign patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using. In addition to patents, we rely on unpatented trade secrets and proprietary technological expertise, and confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors. Failure to obtain or maintain patent protection or to protect our trade secrets could have a substantial negative effect on our results of operations and financial condition. We are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our product candidates. There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be

prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect the Company from prior infringement. 29We may need to initiate lawsuits to protect or enforce our intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market. In order to protect or enforce our intellectual property rights, we may need to initiate patent, trademark and related litigation against third parties, such as infringement suits or requests for injunctive relief. Our ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who we believe to be infringing its rights. Any lawsuits or administrative proceedings in patent offices that we initiate or that are initiated against us could be expensive, take significant time and divert our management' s attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, or adversely affect our ability to distribute any products that are subject to such litigation. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits or administrative proceedings that we initiate, and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. Risks Related to Employee Matters We are dependent on our executive officers, and we may not be able to pursue our current business strategy effectively if we lose them. Our success to date has largely depended on the efforts and abilities of Timothy Warbington, our Chief Executive Officer and Don Dickerson, our Chief Financial Officer. Our ability to manage our operations and meet our business objectives could be adversely affected if, for any reason, such officers do not remain with us. Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards. We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) U. S. laws and regulations or those of foreign jurisdictions, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. ~~30If~~ **If** we fail to comply with the U. S. federal Anti- Kickback Statute and similar state and foreign country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations. A provision of the Social Security Act, commonly referred to as the federal Anti- Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. The federal Anti- Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the federal Anti- Kickback Statute that apply to activity in those states, and some of these laws are even broader than the federal Anti- Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti- Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs. ~~While~~ **30While** we believe our operations will be in compliance with the federal Anti- Kickback Statute and similar state laws, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time- consuming and costly to us and could divert management' s attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti- Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition. Risks Related To Our Common Stock The market price of our common stock is highly volatile, and you could lose all or part of your investment. The trading price of our common stock has been volatile. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include: · whether we achieve our anticipated corporate objectives; · termination of lock- up agreements or other restrictions on the ability of our stockholders and other security holders to sell shares; and · general economic or political conditions in the United States or elsewhere. In addition, the stock market in general, and the stock of clinical stage biotechnology companies in particular, have experienced extreme price and volume fluctuations

that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If our shares of common stock are delisted from The Nasdaq Capital Market and become subject to the penny stock rules, it will be more difficult to trade our shares. The SEC has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $ 5. 00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not maintain a listing on Nasdaq and if the price of our common stock is less than $ 5. 00, our common stock will be deemed a penny stock. The penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares. 31Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our securities. During 2023 we effected a 1- for- 10 reverse stock split in order to increase the trading price of our common stock and comply with ~~NASDAQA~~ **Nasdaq** ' s $ 1. 00 minimum bid price requirement. Although we are currently in compliance with Nasdaq' s minimum bid price requirement, if we again fail to satisfy this or any other continued listing requirement, Nasdaq may take steps to delist our securities. 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. In the event of a delisting, we would take actions to restore our compliance with Nasdaq' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Nevada law. Our bylaws provide that we will indemnify and hold harmless our officers and directors against claims arising from our activities, to the maximum extent permitted by Nevada law. If we were called upon to perform under our indemnification agreement, then the portion of our assets expended for that purpose would reduce the amount otherwise available for our business. Because we do not expect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of common stock. We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares.