Risk Factors Comparison 2025-03-26 to 2024-03-11 Form: 10-K

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

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical and commercialization activities, the manufacturing of our product candidates, intellectual property, third- party relationships, competition factors, product and environmental liability, and common stock. These risks are discussed more fully below and include, but are not limited to, risks related to: Risks Related to Our Business ● substantial additional funding is needed to complete the development **and commercialization** of our product candidates **within and outside the United States** ; ● the Company has incurred significant losses and may never be profitable; ● the occurrence of security breaches, improper access to or disclosure of our data or user data, and other cyber incidents or undesirable cyber activity related to our, or our third- party vendor' s systems and data; and ● we may not have adequate personnel and may not be able to attract or retain personnel needed to develop our products. Risks Related to Clinical and Commercialization Activities ● our success depends upon the viability of our product candidates, all of which require regulatory approval to commercialize and we cannot be certain any of them will receive regulatory approval to be commercialized; ● delays in commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates; ● **we may not be able** ~~our exosome technologies are unproven in their ability~~ to ~~achieve~~ **manufacture deramiocel in** sufficient **quantities** ~~biological activity or scale in development~~ to ~~date~~ **meet market demand** ; ● product candidates can fail to meet their efficacy endpoints at any time during the clinical development process, which would likely make them ineligible for becoming commercial products; ● we may not be able to ~~use our facilities to manufacture CAP- 1002 product for commercial purposes; ● we may be required to obtain consent from CSMC in order to sell commercial product from our Los Angeles facility; ● we may not be able to~~ satisfy clinical and / or regulatory requirements necessary for the approval of our product in the U. S. ~~or~~ **, Europe,** Japan **or other select territories** ; ● we may not be able to reach the milestones set forth in our distribution agreements therefore preventing us from receiving the financial benefits of those agreements **; ● our exosome technologies are unproven in their ability to achieve sufficient biological activity or scale in development to date** ; and ● our partners may not perform as expected and therefore deny us the financial benefits of those agreements. Risks Related to the Manufacturing of our Product Candidates ● the manufacturing of our product candidates is heavily reliant on supply chain requirements including the availability of donor hearts and other raw materials that are critical for the manufacturing of our product candidates; ● we may need to rely upon third- party manufacturers for the expansion of our manufacturing capabilities for later- stage clinical trials and for ultimate commercialization; ● we may not have adequate manufacturing facilities required for any scale- up of manufacturing which may be required in the future; ● we may not be able to replicate our manufacturing processes; ● we may not be able to comply with cGMP regulations; ● we may not be able to identify or retain necessary manufacturing personnel; ● the FDA may not accept the viability or comparability of our manufacturing processes; and ● the FDA may not approve our manufacturing facilities for the manufacture of commercial products. Risks Related to Our Intellectual Property ● we may not be able to obtain, maintain, protect, and enforce our intellectual property rights; ● we may face potential challenges to the validity, enforceability, or scope of our intellectual property; ● we may experience claims from third parties that we are infringing their patents or other intellectual property rights; and ● we may not be able to satisfy our obligations under our licensing agreements. Risks Related to Our Relationships with Third Parties ● we depend on our relationships with our licensors, collaborators, and other third parties and there is no guarantee that such relationships will continue; and ● we will depend on the ability of Nippon Shinyaku to perform according to the terms of the U. S. Distribution and Japan Distribution Agreements and all applicable laws, and to successfully commercialize our lead product **deramiocel** ~~CAP- 1002~~ in DMD. Risks Related to Competitive Factors ● our products **, if approved,** will likely face intense competition; and ● any of our product candidates for which we receive regulatory approval may not achieve broad market acceptance, which could limit the revenue that we will generate from their sales, if any. Risks Related to Product and Environmental Liability ● our products may expose us to potential product liability. Risks Related to Our Common Stock ● we expect that our stock price will continue to fluctuate significantly; and ● we have never paid dividends and we do not anticipate paying dividends in the future. Risks Related to Our BusinessWe need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business. Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities **and commercialization infrastructure** , is expensive. As of December 31, ~~2023~~ **2024** , we had cash, cash equivalents, and marketable securities totaling approximately $ ~~39~~ **151** . 5 million. Additionally, we received a milestone payment of $ 10. 0 million in the first quarter of ~~2024~~ **2025** under the terms of our U. S. Distribution Agreement with Nippon Shinyaku and we may potentially receive other additional development and sales- based milestones. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities. From inception, we have financed our operations through private and public sales of our equity securities, government grants and payments from distribution agreements and collaboration partners. **We** ~~As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our long- term plans for clinical trials and new product development. 31We~~ may seek to raise additional funds through various potential sources,

such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive ~~covenants~~ **29covenants** . To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. The inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future. Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this " Risk Factors " section. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to: ● **our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States; ● the next steps in the regulatory and commercial development of our DMD program; ●** the scope, rate of progress, cost and results of our research and development activities, especially our **deramiocel** ~~CAP- 1002~~ and exosomes programs ~~; ● the next steps in the development of our DMD program, which includes our HOPE- 3 clinical trial for our CAP- 1002 product candidate for DMD; ● the availability of funding from government programs including the NIH, DoD, and CIRM, if applicable~~ ; ● the costs of developing adequate manufacturing processes and facilities; ● the costs associated with and timing of regulatory approval; ● the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; ● the costs and risks involved in conducting clinical trials and manufacturing operations in the U. S. and internationally; ● the **availability of funding and clinical trial sponsorship from government programs including NIAID, the NIH, DoD, and CIRM, if applicable; ● the** effect of competing technological and market developments; ● the terms and timing of any collaboration, licensing or other arrangements that we may establish; ● our ability to manufacture commercial- scale GMP **deramiocel** ~~CAP- 1002~~ product at our San Diego manufacturing facility; ● the cost and timing of technology transfer for, and completion of, clinical and commercial- scale outsourced manufacturing activities; ~~and~~ ● the costs of establishing sales, marketing and distribution capabilities, as applicable, for any product candidates for which we may receive regulatory approval **;** ~~. If our business plans are not successful, we may not be able to continue operations as a going concern~~ and ~~● our stockholders may lose their~~ -- **the impact, if any, of any new programs initiated by** ~~entire investment in us. Our audited financial statements include a statement that there~~ -- **the Trump administration** ~~is substantial doubt about our ability to continue as a going concern. We have historically incurred substantial losses to fund our business operations including our research~~ and **the reduction** ~~development activities and more recently manufacturing scale- up activities. We will,~~ in ~~all likelihood, sustain operating expenses without corresponding revenues for~~ **force** ~~the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence~~ of **government staffing** ~~which cannot be assured. While we have historically been able to adjust the timing associated with our R & D efforts~~ , as well as **proposed** ~~reducing~~ **reductions** ~~headcount and implementing certain budget restrictions, to alleviate~~ ~~uncertainties surrounding our ability to continue as a going concern, if ultimately we cannot continue as a going concern, our stockholders may lose their entire investment~~ in ~~us~~ **funding for programs in support of research and development of product and vaccine candidates** . We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance. We have a history of net losses, expect to continue to incur substantial net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter- to- quarter and year- to- year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors: ● our need for substantial additional capital to fund our trials and development programs; ● delays in the commencement, enrollment, and timing of clinical testing; ● the viability of **deramiocel** ~~CAP- 1002~~ as a potential product candidate and its development through all stages of clinical development; **30** ● the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through all stages of its preclinical and clinical development; ● any delays in regulatory review and approval of our product candidates in clinical development; ● our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States; ● potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment to be taken off the market; ● market acceptance of our product candidates; ● our ability to establish an effective sales and marketing infrastructure once our products are commercialized, as necessary or to establish partnerships with other companies who have greater sales and marketing capabilities; ● the ability of our distribution partner, Nippon Shinyaku, to successfully market and sell our **deramiocel** ~~CAP- 1002~~ product if and to the extent it is approved; ● our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for **deramiocel** ~~CAP- 1002~~ outside of DMD and our ~~exosomes~~ **exosome** technologies; ● our ability and third parties' abilities to obtain and protect intellectual property rights; ● competition from existing products or new products that may emerge; ● guidelines and recommendations of therapies published by various organizations; ● the ability of patients to obtain coverage of, or sufficient reimbursement for, our product candidates; ● our ability to maintain adequate insurance policies; ● our ability to

successfully manufacture our product candidates in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand; ● our dependency on third parties to formulate and manufacture our product candidates, as necessary; ● our ability to maintain and staff our current manufacturing facilities; ● our ability to build or secure new manufacturing facilities, if necessary, and achieve and maintain cGMP and obtain required certifications as required; ● costs related to and outcomes of potential intellectual property litigation; ● compliance with obligations under intellectual property licenses with third parties; ● our ability to implement additional internal systems and infrastructure; ● our ability to adequately support future growth; ● if our products are approved for commercial sale, the ability to secure adequate reimbursement levels for our products; ● our ability to attract and retain key personnel to manage our business effectively; and ● the ability of members of our senior management to manage our business and operations. ~~33The Company' s technology is not yet proven and each of our product candidates is still in clinical or preclinical development.~~ The Company' s ~~product candidates, CAP~~ **cell therapy technology (deramiocel) is in late** ~~- 1002~~ **stage development but not yet** ~~and~~ **an** ~~our~~ **approved product, and its** exosome ~~technologies~~ **technology** ~~, are~~ **is still** in **preclinical** development **. The Company' s deramiocel technology is in late- stage development** and ~~each~~ **may** ~~requires~~ **require** further ~~and, in some cases, extensive~~ clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The Company' s failure to establish ~~the~~ efficacy of **deramiocel** ~~its technologies~~ would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our ongoing Phase 3 trial of our **deramiocel** ~~CAP- 1002~~ product candidate for DMD. Additionally, we cannot predict with any certainty if, or when, we might commence any ~~additional~~ clinical trials of our **exosome** product candidates, whether we will be able to secure additional strategic partners, or whether our current trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our **exosome** product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agencies ~~. We are also unable to predict whether our preclinical studies of our exosomes products will result in a viable clinical development program~~ . Our business depends entirely on the successful development and commercialization of our product candidates. We currently have no products approved for sale and generate no revenues from sales of any products, and we may never be able to develop a marketable product. ~~Our~~ **We are not permitted to market or promote our** product candidates **before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. We are also unable to predict whether our preclinical studies of our exosomes products will result in a viable clinical development program. 31Our product candidates may, or in some cases,** will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales ~~. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals~~ . The success of our product candidates will depend on several factors, including the following: **● our ability to demonstrate our products' safety, tolerability and efficacy to the FDA or any comparable foreign regulatory authority for marketing approval;** ● successful and timely completion of our clinical trials; ● initiation and successful patient enrollment and completion of additional clinical trials on a timely basis ~~; ● the impact of COVID- 19 or some other infectious disease outbreak on our operations, ability to conduct clinical trials and on the ability of our regulators to review and approve or authorize our products; ● our ability to demonstrate our products' safety, tolerability and efficacy to the FDA or any comparable foreign regulatory authority for marketing approval~~ ; ● timely receipt of marketing approval for our products; ● obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; ● avoiding and successfully defending against any claims that we have infringed, misappropriated or otherwise violated any intellectual property of any third- party; ● the performance of our current and future distributors or collaborators, if any; ● the extent of, and our ability to timely complete, any required post-marketing approval commitments imposed by FDA or other applicable regulatory authorities; ● successfully developing a companion diagnostic test on a timely and cost effective basis, if required; ● establishment of supply arrangements with third-parties for raw materials and product supplies and potential manufacturers who are able to manufacture clinical trial and commercial quantities of drug substance and drug products; ● our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand; ● establishment of arrangements with potential manufacturers who are able to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing, if necessary ~~; ● establishment of scaled production arrangements with third- party manufacturers to obtain finished products that are compliant with cGMP and appropriately packaged for sale~~ ; ● successful launch of commercial sales following marketing approval; ● a continued acceptable safety profile following marketing approval; ● commercial acceptance by patients, the medical community and third- party payors; ~~34~~ ● the availability of coverage and adequate reimbursement and pricing by third- party payors and government authorities; ● the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments **; ● the impact of infectious disease outbreaks or pandemics on our operations, ability to conduct clinical trials and on the ability of our regulators to review and approve or authorize our products** ; ● our ability to compete with other therapies; and ● our ability to conduct post- marketing surveillance and comply with requirements of FDA and other comparable regulatory authorities after product approval. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of **our partner or of** any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of our products. If we are not successful in marketing or commercializing our products, or are significantly delayed in doing so, our business will be materially harmed. Business disruptions such as natural disasters, widespread infectious diseases,

or pandemics or geopolitical conflicts could seriously harm our future revenues and financial condition and increase our costs and expenses. Our corporate headquarters and our manufacturing and research facilities are located in San Diego and in the greater Los Angeles, California area, a region known for seismic activity, as well as being susceptible to drought and fires. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or manufacturing facilities, or at the facilities of any third- party manufacturer or vendor, could have a material adverse effect on our business, financial condition and results of operations. In addition, outbreaks of viruses, infectious diseases or pandemics (including, for example, the outbreak of the novel coronavirus (COVID- 19) **)** , terrorist acts or acts of war targeted at the United States, and specifically in the California region, or geopolitical conflicts, such as the Russia- Ukraine conflict and the conflicts in ~~the~~ **32the** Middle East, could cause damage or disruption to us, our employees, facilities, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations. A breakdown, corruption or breach of our information technology systems or computer systems, or those used or hosted by our CROs, contractors, consultants or third- party vendors could subject us to liability or interrupt the operation of our business. We are increasingly dependent upon information technology systems, computer systems and data, as well as the information technology systems, computer systems and data of our current and future clinical research organizations (“ CROs ”), contractors, consultants and third- party vendors, especially if we expand our clinical trials and therefore our databases of patient information. Our information technology systems, computer systems and data (and those of our current and future CROs, contractors, consultants and third- party vendors) are potentially vulnerable to breakdown, corruption, deliberate attacks, malicious intrusion or software, as well as unintentional cybersecurity incidents, such as system misconfigurations, misuses or human error. Likewise, data privacy or security breaches by individuals authorized to access our information technology systems or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, customers or other business partners, may be exposed to unauthorized persons or to the public. We utilize and rely on services of third parties in connection with our clinical trials, which services involve the collection, use, storage and analysis of personal health information. While we receive assurances from these third parties that their systems and services are compliant with HIPAA and other applicable privacy and cybersecurity laws, there can be no assurance that such third parties will comply with applicable laws or regulations. Non- compliance by such third parties or weaknesses in their cybersecurity programs may result in liability for us which would have a material adverse effect on our business, financial condition and results of operations. Despite the implementation of security measures, our information technology systems and computer systems, and those of our current and future CROs, contractors, consultants and other third parties are potentially vulnerable to breakdown, corruption, disruption or cybersecurity incidents. Cyber- attacks are increasing in their frequency, sophistication and intensity and are becoming increasingly difficult to detect. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of ~~35clinical~~ -- **clinical** trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be significantly delayed. We continue to build and improve our information systems and infrastructure and believe we have taken appropriate security measures to minimize these risks to our data, information technology systems and computer systems, and we intend to defend against and respond to data security incidents. There can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or adequately contain and mitigate risks from a data security incident, which could result in a material disruption of our development programs and business operations, and our business, financial condition, results of operations and prospects could be adversely impacted. If we achieve our near- term product development milestones, we may not be able to manage any subsequent growth. Should we achieve our near- term product development milestones, of which no assurance can be given, our long- term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources, especially if we expand our business and operations internationally. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed. ~~Risks~~ **33Risks** Related to Clinical and Commercialization ActivitiesOur success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized. We will need FDA approval to market and sell any of our product candidates in the United States and approvals from FDA- equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we ~~must submit~~ **submitted** to the FDA **a** ~~an NDA or~~ BLA ~~demonstrating that the product candidate is safe~~ for ~~humans and effective~~ **potential approval of deramiocel, which BLA has been accepted by the FDA** for **review** ~~its intended use~~ . This ~~demonstration~~ **application** requires significant research and animal testing, which are referred to as preclinical studies, as well as human testing, which are referred to as clinical trials. Satisfaction of the FDA’ s regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, testing and manufacturing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA and other foreign regulatory agencies have substantial discretion in the approval process and may require us to conduct additional preclinical and clinical testing or to perform post- marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our **BLAs or** NDAs ~~or BLAs~~ , as applicable. We cannot be sure that we will ever obtain regulatory clearance for our

product candidates. Failure to obtain FDA approval of any of our product candidates will reduce our number of potentially salable products, if any, and, therefore, corresponding product revenues, and will have a material and adverse impact on our business. We have limited experience in conducting late- stage clinical trials, which are complex and subject to strict regulatory oversight. We have limited late- stage clinical trial experience with respect to ~~its~~ **our** product candidates. The clinical testing process is governed by stringent regulations and is highly complex, costly, time- consuming, and uncertain as to outcome, and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies. Our failure or the failure of our collaborators to conduct clinical trials successfully or our failure to capitalize on the results of clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not sufficiently enroll or produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates. ~~36To~~ **To** receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well- controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and / or non- clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. Furthermore, negative, delayed or inconclusive results may result in: ● the withdrawal of clinical trial participants; ● the termination of clinical trial sites or entire trial programs; ● costly litigation arising out of the trials; ● substantial monetary awards to patients or other claimants; ● the requirement that additional trials be conducted; ● impairment of our business reputation; ● loss of **potential** revenues **resulting from** ~~; and ●~~ the inability to commercialize our product candidates. ~~As~~ **34As** the results of earlier preclinical studies or clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if our preclinical studies and clinical trials are completed as planned, we cannot be certain that their results will support the claims of our product candidates. Positive results in preclinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay or cause us to refrain from the filing of our **BLAs and / or** NDAs ~~and / or BLAs~~ with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results. Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase 2, Phase 3 or other clinical trial which we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase 2 or Phase 3 clinical trials, even after seeing promising results in earlier clinical trials. Our exosome technologies are based on a novel therapeutic approach which makes it difficult to predict the time and cost of development and the probability of subsequently obtaining regulatory approval, if at all. Our exosome technologies involve a relatively new therapeutic approach which will face both clinical and regulatory challenges. To date, and to the best of our knowledge, no products based on exosomes have been approved in the United States for therapeutic use. It is therefore difficult to accurately predict the developmental challenges we may face for our exosome technologies as they proceed through preclinical studies and clinical trials. In addition, because we have only conducted preclinical studies with our exosome technologies, we have not yet been able to assess their safety in humans, and there may be short- term or long- term effects from treatment with our exosomes that we cannot predict at this time. Also, animal models for the indications we may explore may not exist or may be difficult to obtain for our preclinical studies. As a result of these factors, we are unable to predict the time and cost of development of our exosome technologies and we cannot predict whether the application of our exosome technologies, or any similar or competitive exosome technologies, will result in regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our exosomes or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all. ~~37The~~ -- **The** clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity and intended use and market of the product candidate. As a result, the regulatory approval process for our exosomes is uncertain and may be more expensive and take longer than the approval process for other product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our exosomes in either the United States or the European Union or other regions of the world or how long it will take to commercialize our product candidates, if at all. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be adversely impacted. Negative developments in the field of exosomes could damage public perception of any product candidates that we develop, which could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates. Exosome- based therapeutics and vaccines are novel and unproven therapies which may not gain the acceptance of the public, patients or the medical community. To date, efforts by others to leverage natural exosomes have generally ~~demonstrated~~ **35demonstrated** an

inability to generate exosomes with predictable biologically active properties or to manufacture exosomes at suitable scale to treat more than a small number of patients. Our success will depend on our ability to demonstrate that our exosome technologies can overcome these challenges. Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by our exosomes prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our exosomes or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of exosome therapeutics, could result in a decrease in demand for any products that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of, or modification to, our clinical trials. Any future negative developments in the field of exosomes and their use as therapies could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our exosomes or other potential future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our exosomes or any other product candidates which we may develop in the future. Advancing product candidates based on our exosome platform as novel products creates significant challenges for us, including: ● to our knowledge, obtaining marketing approval from the FDA or comparable foreign regulatory authorities has never been done before; ● educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens; and ● establishing the sales and marketing capabilities to gain market acceptance, if approved. We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to do so, the FDA may not permit us to proceed. We hope to file additional INDs over the next several years, including with respect to our exosome technologies in one or more indications. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our preclinical studies, having sufficient processes in place in connection with the manufacturing of the exosomes and the availability of necessary funding for any potential clinical trial. We cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Any IND we submit could be denied by the FDA or the FDA could place any future investigation of ours on clinical hold until we provide additional information, either before or after clinical trials are initiated. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trial set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. The FDA may also impose clinical holds at any time before or during clinical trials due to unacceptable and significant risks to clinical trial subjects or non- compliance with FDA requirements. Unfavorable future trial results or other factors, such as insufficient capital to continue development of a product candidate or program, could also cause us to voluntarily withdraw an effective IND. ~~38Delays~~ -- **Delays** in the commencement, enrollment, and completion of clinical testing **, as well as reduced government funding of certain clinical trials,** could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates. Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. Additionally, a clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials require us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may otherwise be resource constrained. We may be required to withdraw from a clinical trial as a result of changing standards of care, or we may become ineligible to participate in clinical studies **. In addition, clinical trials which were due to receive support from the U. S. government, such as the NIAID clinical trial using our StealthXTM vaccine candidate, may be impacted by staffing reductions as well as changes in government priorities with a new U. S. presidential administration** . We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to: **36** ● findings in preclinical studies; ● reaching agreements on acceptable terms with prospective CROs, vendors and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites; ● obtaining regulatory clearance to commence a clinical trial; ● complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials; ● obtaining IRB approval to conduct a clinical trial at numerous prospective sites; ● recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size of the patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the inability of the sites to conduct trial procedures properly, the inability of the sites to devote their resources to the trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications; ● the impact of ~~COVID- 19~~ **infectious disease outbreaks or pandemics** on site personnel availability, patient screening and patient enrollment; ● competition from other companies operating in the same disease setting; ● developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so; ● patients failing to comply with the clinical trial protocol or dropping out of a trial; ● clinical trial sites failing to comply with the clinical trial protocol or dropping out of a trial; ● addressing any conflicts with new or existing laws or regulations; ● the need to add new clinical trial sites; ● retaining patients who have initiated their participation in a clinical trial but may withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow- up; ● manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis; ● obtaining advice from regulatory authorities regarding the statistical analysis plan to be used to evaluate the clinical trial data or other trial design issues; ● demonstrating the bioequivalence of products we manufacture to prior products manufactured by us; ● complying with design protocols of any applicable special protocol assessment we receive from the FDA; ● severe or unexpected drug- related side effects experienced by patients in a clinical trial; ● collecting, analyzing and reporting final data from the clinical trials; ● breaches in quality of

manufacturing runs that compromise all or some of the doses made; positive results in FDA- required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source; ● availability of materials provided by third parties necessary to manufacture our product candidates; ● availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products; ● requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company' s CROs and other third parties; and ● meeting logistical requirements for the delivery of investigational product. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain or maintain, clinical or marketing approval for these product candidates. We may not be able to obtain approval for ~~39indications~~ **indications** that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different from those indications for which we sought approval. Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. In August 2023, the FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA' s new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Further, in December 2023, the FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. ~~Modifications~~ **37Modifications** to informed consent or other clinical trial requirements may affect enrollment or retention of patients, require modifications to trial documents and may cause delays to the trial. Amendments may require us to resubmit our clinical trial protocols to IRBs for re- examination which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed or will not be realized. In addition, many of 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 a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and already established a competitive advantage. Any delays in obtaining regulatory approvals may: ● delay commercialization of, and our ability to derive product revenues from, our product candidates; ● impose costly procedures on us; or ● diminish any competitive advantages that we may otherwise enjoy. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: ● we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; ● clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; ● the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors, including our CROs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● we, our investigators, or any of the overseeing IRBs or ethics committees might decide to suspend or terminate clinical trials of our product candidates for various reasons, including non- compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; ● the cost of clinical trials of our product candidates may be greater than we anticipate; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; ● regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and ● any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. ~~40If~~ **If** we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are insufficiently positive to support marketing approval, or if there are safety concerns, we may: ● incur unplanned costs; ● be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; ● obtain marketing approval in some countries and not in others; ● obtain marketing approval for indications or patient populations that are narrower or more limited in scope than intended or desired; ● obtain marketing approval subject to significant use or distribution restrictions or with labeling that includes significant safety warnings, including boxed warnings; ● be subject to additional post- marketing testing requirements; or ● have the drug removed from the market after obtaining marketing approval. ~~Our~~ **38Our** drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Furthermore, we rely on third- party CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations **. The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and "**

may not defer to an agency interpretation of the law simply because a statute is ambiguous. ” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by U. S. Department of Health and Human Services, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny. In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current presidential administration’ s commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as the U. S. Department of Health and Human Services, CMS and FDA. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict . The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. We currently have no products approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through adequate and well- controlled clinical trials that our product candidates are safe and effective for use in treating specific conditions in order to obtain marketing approvals for their commercial sale. Success in preclinical studies and early- stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate safety and efficacy to the satisfaction of the FDA and non- U. S. regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. Product candidates that have shown promising results in preclinical studies and early- stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials. From time to time, we may publish or report interim or preliminary data from our clinical trials, once initiated. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and 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. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited ~~experience~~ **39experience** in designing late- stage clinical trials and may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in preclinical studies and earlier clinical trials. ~~41In~~ **In** some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials, once initiated, **or in a clinical trial conducted by a third party sponsor or investigator using the same product candidate,** such event could adversely affect our other clinical trials ~~using the same product candidate~~ **and ability to obtain marketing approval** . Moreover, there is a relatively limited safety data set for product candidates using an exosome platform. An adverse safety issue or other adverse finding in a clinical trial conducted by a third- party with a product candidate similar to ours could adversely affect our clinical trials. Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or comparable foreign regulatory authorities. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. In addition, the FDA or other comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Before obtaining marketing approval for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and adequate and well- controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and elsewhere to the satisfaction of other comparable foreign regulatory authorities, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or other comparable foreign regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our

product candidates for any indication. The FDA and other comparable foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective. If we are required to conduct additional clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval in our target markets, including the United States and Japan. The regulatory pathway for COVID- 19 or other infectious disease vaccines is continually evolving and may result in unexpected or unforeseen challenges. The speed at which select parties have acted to create and test many therapeutics and vaccines for COVID- 19 or other infection diseases is atypical. Further, changing plans or priorities within the FDA **, other government departments,** or the regulatory authorities in other jurisdictions, including changes based on new knowledge of COVID- 19 or other infectious diseases, and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals. We cannot anticipate or predict with certainty the timelines or regulatory processes that may be required for the development of our potential COVID- 19 vaccine that may be developed to fight against variants of the SARS- CoV- 2 virus. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target. ~~We~~ **40We** may not be successful in our efforts to identify or discover additional potential product candidates or additional indications for our existing product candidates. Our research programs may initially show promise in identifying potential product candidates or potential additional indications for existing product candidates, yet fail to lead to successful clinical development for a number of reasons, including: ● the research methodology used may not be successful in identifying potential product candidates; ● potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and / or achieve market acceptance; and ● potential product candidates may not be safe or effective in treating their targeted diseases. ~~42Rescearch~~ -- **Research** programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, our business would be harmed. If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future distributors or collaborators, to market the drug could be compromised. Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of the drug or seize the drug; ● we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials; ● additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug; ● we may be subject to fines, injunctions or the imposition of civil or criminal penalties; ● regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; ● we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients; ● we, or any future collaborators, could be sued and held liable for harm caused to patients; ● the drug may become less competitive in the marketplace; and ● our reputation may suffer. Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price. Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success. If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient revenues from sales of drugs to cover our costs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: ● the efficacy and safety of the product; **41** ● the potential advantages of the product compared to alternative therapies; ● the prevalence and severity of any side effects; ● whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third- line therapy; ● our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices; ● the product' s convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments; ● the willingness of the target patient population to try, and of physicians to prescribe, the product; ● limitations or warnings, including distribution or use restrictions and safety information contained in the product' s approved labeling; ● the strength of sales, marketing and distribution support; ● the performance of third- party distributors, such as our exclusive distributor for our lead product candidate, **deramiocel** ~~CAP- 1002~~ ; ~~43~~ ● changes in the standard of care for the targeted indications for the product; and ● the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third- party payors. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly advancing technologies, evolving understanding of disease etiology and a strong emphasis on proprietary drugs. We face competition with respect to any product candidates that we may seek to discover and develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies. Potential competitors also include academic institutions and governmental agencies and public and private research institutions. Many of the companies that we compete or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Small or early- stage companies may also prove to be significant competitors, particularly through collaborative

arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of DMD which includes competitors both in the United States and internationally. ~~We have competitors both in the United States and internationally.~~ With **deramiocel** ~~CAP- 1002~~ , we expect to face competition from existing products and products in development. **At** ~~In addition, at~~ this time, there are four FDA conditionally approved exon skipping drugs: EXONDYS 51 (eteplirsen), AMONDYS 45 (casimersen) and VYONDYS 53 (golodirsen), which are PMOs approved for the treatment of DMD patients amenable to Exon 51, Exon 45 and Exon 53 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., and VILTEPSO (vitolarsen), a PMO approved for the treatment of DMD patients amenable to Exon 53 skipping, which is marketed by Nippon Shinyaku ~~(~~ **through its** U. S. subsidiary ~~:~~ **,** NS Pharma, Inc. **Currently** ~~). In June 2023~~ , ~~the FDA approved~~ Sarepta' s **microdystrophin gene therapy,** ~~BLA application seeking accelerated approval of~~ Elevidys (delandistrogene moxeparvovec) ~~, its~~ **is approved** ~~microdystrophin gene therapy,~~ for the treatment of **ambulant individuals with Duchenne who are at least 4 years of age and conditionally approved for non-** ambulant individuals with Duchenne. There are multiple other companies focused on developing genetic based therapies that target dystrophin mechanisms and non- dystrophin mechanisms for the treatment of DMD. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other comparable foreign regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third- party payors. ~~The~~ **42The** FDA has granted orphan drug status and an RMAT designation to **deramiocel** ~~CAP- 1002~~ for the treatment of DMD, but we may be unable to maintain or receive the benefits associated with orphan drug status, including market exclusivity, or an RMAT designation. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a biological product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. ~~44We~~ **We** have received orphan drug status for **deramiocel** ~~CAP- 1002~~ for the treatment of DMD. Even though we have received orphan drug designation (**"** ODD **"**) as described above, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. For any product candidate for which we have been or will be granted ODD in a particular indication, it is possible that another company also holding ODD for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company' s period of exclusivity expires. In addition, our exclusive marketing rights in the United States, if obtained, may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Even though we have obtained **ODD** ~~orphan drug designation~~ for **deramiocel** ~~CAP- 1002~~ for a select indication, we may be unable to seek or obtain **ODD** ~~orphan drug designation~~ for our future product candidates and we may not be the first to obtain marketing approval for any particular orphan indication. In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects. We have also obtained an RMAT designation for **deramiocel** ~~CAP- 1002~~ for the treatment of DMD. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long- term clinical benefit, or may be able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT designation does not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges. Even if we were to obtain approval for **deramiocel** ~~CAP- 1002~~ for the treatment of DMD with the rare pediatric disease designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval. **Deramiocel** ~~CAP- 1002~~ has

received rare pediatric disease designation from the FDA for the treatment of DMD. The FDA generally define a" rare pediatric disease" as a serious or life- threatening disease that affects fewer than 200, 000 individuals in the U. S. primarily under the age of 18 years old. Under the FDA' s Rare Pediatric Disease Priority Review Voucher program, upon the approval of a **BLA or** NDA ~~or BLA~~ for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a ~~subsequent~~ **43subsequent BLA or** NDA ~~or BLA~~. The Priority Review Voucher may be sold or transferred an unlimited number of times, as long as the sponsor making the transfer has not yet submitted the application. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U. S. within one year following the date of approval. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for **deramiocel** ~~CAP- 1002~~ and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval. ~~45Providing~~ -- **Providing** product for use in third- party trials or for compassionate use poses risks to our product candidates. In addition to manufacturing **deramiocel** ~~CAP- 1002~~ for its own clinical trials, Capricor provided **deramiocel** ~~CAP- 1002~~ for investigational purposes in two clinical trials sponsored by CSMC. Additionally, we recently were selected to be part of Project NextGen, an initiative by the U. S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines for COVID- 19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX ™ vaccine, subject to regulatory approval. NIAID' s Division of Microbiology and Infectious Diseases (**“** DMID **”**) would oversee the study. Providing product for clinical trials sponsored by third parties poses significant risks for the Company as we will not have control over the conduct of the trial even though we have used our commercially reasonable efforts to ensure that the investigative sites are contractually bound to follow the protocol and other procedures established by Capricor. Similarly, providing product for compassionate use can pose risks for the Company as its use will not be subject to the same protocol and procedures established in our clinical trials. Additionally, even though the investigative sites have experience in conducting clinical trials, any adverse event that may occur during the trial may have a negative impact on our efforts to obtain regulatory approval for our product. There are no assurances that the clinical trial sites will perform the studies in accordance with the protocol, the manuals provided by Capricor or the sponsor’ s instructions, or otherwise act in accordance with applicable law. There is no assurance that if research injuries are sustained, any insurance carrier will compensate Capricor for any liabilities or other losses sustained by Capricor arising out of these injuries. We have been informed by CSMC that both of the **deramiocel** ~~CAP- 1002~~ (REGRESS and ALPHA) trials have ceased enrollment and that the trials have been concluded. Notwithstanding their cessation, there is a risk that injuries could result from the use of the product or other claims may arise. Our products face a risk of failure due to adverse immunological reactions. A potential risk of an allogeneic therapy such as that being tested by the Company with **deramiocel** ~~CAP- 1002~~ is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety and efficacy of the Company’ s products and the success of our trials. Additionally, if research subjects have pre- existing antibodies or other immune sensitization to our cells, our cells and the therapy could potentially be rendered ineffective which could have a negative impact on the regulatory pathway for our product as well as the viability for other potential indications. After a patient in the HOPE- 2 trial had a serious adverse event in the form of anaphylaxis, we put a voluntary hold on dosing in December 2018 to develop a plan to manage potential allergic reactions. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including possibly an excipient, or inactive ingredient, in the formulation. To reduce the risk of future events, we initiated a pre- medication strategy commonly used by physicians to prevent and treat allergic reactions. We cannot provide any assurances that ~~this~~ **similar events** will not happen again in our current trials or in any future studies. If these or other reactions continue to occur, it could have a material adverse impact on the effectiveness of the product, our ability to receive approval of our product candidates, and could result in substantial delays, increased costs and potentially termination of the trial. Our business faces significant government regulation, and there is no guarantee that our product candidates will receive regulatory approval. Our research and development activities, preclinical studies, clinical trials, and manufacturing and marketing of our potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, ~~as~~ **44as** well as by regulatory authorities in other countries. In the United States, our product candidates are subject to regulation as biological products or as combination biological products / medical devices under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other statutes, and as further provided in the Code of Federal Regulations. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries including determinations that our manufacturing processes being utilized in the United States are not compliant with the regulations adopted in those foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations ~~46would~~ -- **would** delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations. Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, other federal agencies and

corresponding state agencies to ensure strict compliance with good manufacturing practices, and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards, nor can we guarantee that we will maintain compliance with such regulations in regards to our own manufacturing processes. Other risks include: ● regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies; ● regulatory authorities may withdraw their approval of the IND or the product or require us to take our approved products off the market; ● we may be required to change the way the product is manufactured or administered, and we may be required to conduct additional clinical trials or change the labeling of our products; ● we will be required to manufacture on our own behalf or retain the services of a commercial manufacturer to develop product suitable for commercial sale in compliance with cGMP requirements; ● we may have limitations on how we or our distributor promote our products; ● we may be subject to litigation or product liability claims; and ● the products we manufacture may experience failures in the manufacturing process. There are additional risks involved in conducting clinical trials internationally. If we decide to expand or conduct one or more of our clinical trials to investigative sites in Europe, Japan, or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. For example, if we decide to conduct our trials in Europe, we may have to move our manufacturing facility to a facility located in Europe, enter into an agreement with a European manufacturer to manufacture our product candidates for us, enter into an agreement with a domestic manufacturer who maintains an acceptable cGMP facility or ensure that our facility meets Japanese, European or other foreign specifications. Any of those options would involve a significant monetary investment, time delays, and increased risk and may impact the progress of our clinical trials and regulatory approvals. Further, we have entered into the Japanese Distribution Agreement with Nippon Shinyaku for the distribution of **deramiocel** ~~CAP- 1002~~ in Japan. In order for us to be able to sell **deramiocel** ~~CAP- 1002~~ in Japan, we will be required to satisfy the requirements of and get approval from the **Pharmaceuticals and Medical Devices Agency (“** PMDA **”)** . At this time, we are uncertain as to the type or types of trials that may be required, whether the PMDA in Japan will accept product manufactured at our facilities, if approved, the price at which our product may be sold and market acceptance. To the extent we conduct business in the European Union (“ EU ”), or receive information about EU residents, we will also have to comply with the EU General Data Protection Regulation (the “ GDPR ”), which **governs** ~~was officially adopted in April 2016 and went into effect in May 2018. The GDPR introduces new~~ data protection requirements in the EU ~~, as well as~~ **. Failure to comply with the requirements of the GDPR can result in (among other things)** substantial fines for breaches of data protections rules. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non- compliance with the GDPR may result in monetary penalties of up to € 20 million or 4 % of worldwide ~~revenue~~ **45revenue** , whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate. Additionally, the U. S. Foreign Corrupt Practices Act (“ FCPA ”) prohibits U. S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti- corruption laws and / or regulations. As we expand our business outside of the United States, ensuring compliance with the FCPA and the laws of other countries will involve additional monetary and time commitments on behalf of the Company. ~~47Even~~ -- **Even** if our product candidates receive regulatory approval, we may still face future development and FDA regulatory difficulties. Even if U. S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product' s indicated uses or marketing, or impose ongoing requirements for potentially costly post- approval studies. If any of our products were granted accelerated approval, the FDA could require post- marketing confirmatory trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. **Additional delays may result if an FDA Advisory Committee, EMA' s Committee for Medicinal Products for Human Use, or CHMP, or other regulatory authority recommends non- approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. The** FDA may withdraw approval of a drug or indication approved under the accelerated approval pathway if any of the following were to occur: a trial required to verify the predicted clinical benefit of the product fails to verify such benefit; other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; the applicant fails to conduct any required post- approval trial of the drug with due diligence; or the applicant disseminates false or misleading promotional materials relating to the product. In addition, the FDA currently requires as a condition for accelerated approval the pre- approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Given the number of recent high- profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre- approval of promotional materials, and restrictions on direct- to- consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA' s drug approval process and the FDA' s efforts to assure the safety of marketed drugs have resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post- approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to

become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications. Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record- keeping, and submission of safety and other post- market information on the drug. New issues may arise during a product lifecycle that did not exist, or were unknown, at the time of product approval, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured. Since approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections, these new issues post- approval may result in voluntary actions by Capricor or may result in a regulatory agency imposing restrictions on that product or us, including requiring withdrawal of the product from the market or for use in a clinical trial. If our product candidates fail to comply with applicable regulatory requirements, such as good manufacturing practices, a regulatory agency may: ● issue warning or untitled letters; ● require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance **; ● impose other civil or criminal penalties; ● suspend regulatory approval; ● suspend any ongoing clinical trials; 46 ● refuse to approve pending applications or supplements to approved applications filed by us; ● impose restrictions on operations, including costly new manufacturing requirements; or ● seize or detain products or require a product recall. In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries, or any delay or setback in obtaining such approval, could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post- marketing follow- up studies. If we or current or future collaborators, manufacturers, or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and substantial penalties, which could affect our ability to develop, market and sell our products and may harm our reputation. Although we do not currently have any products on the market, if our therapeutic candidates or clinical trials become covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal, state and foreign governments of the jurisdictions in which we conduct our business. Healthcare providers, physicians and third- party payors play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse, transparency, and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our therapeutic candidates for which we obtain marketing approval. Some of our pre- commercial activities also may be subject to some of these laws. For more information on potentially applicable healthcare laws and regulations, See Part I, Item 1 – Other Healthcare Fraud and Abuse Laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of these or any other healthcare regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely impact our ability to operate our business and our results of operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation, even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, could result in negative publicity, a drop in our share price, or other harm to our business, financial condition and results of operations. Defending against any such actions could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. 47Any drugs we develop may become subject to unfavorable pricing regulations, third- party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our future business prospects. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require**

approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical 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 and negatively impact the revenues we are able to generate from the sale of the product in that country. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. However, there may be significant delays in obtaining coverage for newly- approved drugs. Moreover, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution costs. Also, interim payments for new drugs, if applicable, may be insufficient to cover our costs and may not be made permanent. Thus, even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary or cost- effective, and the amount reimbursed for any products may be insufficient to allow our products to be sold on a competitive basis. Because our programs are in early stages of development or have otherwise not been approved for commercial sale, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. In addition, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our product on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we develop. Increasingly, the third- party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates and other concessions to reduce the prices for pharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected. We currently expect that certain drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U. S. law, certain drugs that are not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Specifically, Medicare Part B coverage may be available for eligible beneficiaries when the following, among other requirements have been satisfied: ● the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which the product is administered according to accepted standards of medical practice; ● the product is typically furnished incident to a physician' s services; ● the indication for which the product will be used is included or approved for inclusion in certain Medicare- designated pharmaceutical compendia (when used for an off- label use); and ● the product has been approved by the FDA. Average prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. Reimbursement rates under Medicare Part B would depend in part on whether the newly approved product would be eligible for a unique billing code. Self- administered outpatient drugs are typically reimbursed under Medicare Part D, and drugs that are administered in an inpatient hospital setting are typically reimbursed under Medicare Part A under a bundled payment. It is difficult for us to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different 48federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program. Third- party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement rates. These coverage policies and limitations may rely, in part, on compendia listings for approved therapeutics. Our inability to promptly obtain relevant compendia listings, coverage, and adequate reimbursement from both government- funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition. There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality of care and / or expanding access to care and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. See Part I, Item 1 – Healthcare Reform for additional detail on recent legislative and regulatory

changes that could affect our operations. Our risk mitigation measures cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U. S. federal and state regulations and all potentially applicable foreign regulations and other requirements. The development, manufacturing, distribution, pricing, sale, marketing and reimbursement of our product candidates, together with our general operations, are subject to extensive federal and state regulation in the United States and may be subject to extensive regulation in foreign countries. In addition, our business is complex, involves significant operational risks and includes the use of third parties to conduct business. While we intend to implement numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. We cannot guarantee that we, our employees, our consultants, our contractors or other third parties are or will be in compliance with all potentially applicable U. S. federal and state regulations and / or laws, and all potentially applicable foreign regulations and / or laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Any of these occurrences could have a material and adverse effect on our business and results of operations. Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such 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 be in compliance with such 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 material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us. 49Our ability to obtain reimbursement or funding for our programs from the federal government may be impacted by possible reductions in federal spending. U. S. federal government agencies currently face potentially significant spending reductions. For example, as a result of the Budget Control Act of 2011, the Bipartisan Budget Act (" BBA "), and the Coronavirus Aid, Relief, and Economic Security Act (the " CARES Act "), an annual 2 % reduction to Medicare payments took effect on April 1, 2013, and has been extended into through the first eight months of the fiscal year 2032 sequestration order. The U. S. federal budget remains in flux, which could, among other things, result in additional cuts to Medicare payments to providers and otherwise affect federal spending on clinical and preclinical research and development. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact which the actions of the current Trump administration and the U. S. Congress may have on the federal budget. If federal spending is reduced, and staffing reductions are put into effect, these actions will also impact the ability of relevant agencies, such as the FDA, CMS, HHS, or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations. We are planning to potentially develop vaccine candidates using our exosome technologies. The successful development, testing, manufacturing and commercialization of vaccines is a long, complex, expensive and uncertain process. There are unique risks and uncertainties associated with vaccines, including: ● There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, media pathogens, bacteria, viral strains, synthesized nucleic acids, including mRNA and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States, Japan and the EU, could result in restricted access to, or the transport or use of, such materials. If the Company in unable to access sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research or product development activities as planned and may incur additional costs. ● The development, manufacturing and marketing of vaccines are subject to regulation by the FDA, the EMA, PMDA and other regulatory bodies that are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot. ● Vaccines are frequently costly to manufacture because production ingredients are inactive biological materials derived from virus, animals, or plants and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines. ● Changes in leadership, especially within the U. S. Department of Health and Human Services, have the potential to significantly impact vaccine- related policies and public health initiatives. Changes, including those resulting from the 2024 U. S. election and resulting changes in the Department of Health and Human Services may impact funding for vaccine research and development, reimbursement for vaccines and their

administration, vaccine mandates and recommendations and public perception of vaccine importance. Risks Related to the Manufacturing of our Product CandidatesWe have limited manufacturing capability and may not be able to maintain our manufacturing licenses. In 2022, we completed construction of our new primary manufacturing facility located within our Research and Development Facility in San Diego, California as we prepare for potential commercial launch. This facility is designed to produce GMP deramiocel product for clinical and potential commercial use, subject to FDA approval. It is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. We are using product manufactured from our San Diego facility to support Cohort B of the ongoing HOPE- 3 trial and supporting our OLE trials. We recently entered into an amendment to our lease adding an additional approximate 22, 000 square feet of space for continued 50manufacturing expansion. We plan to build additional cleanrooms in this expanded space suitable for commercial manufacturing, subject to FDA approval. Additionally, we also maintain a portion of our laboratories, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. In that portion of the leased premises where we manufacture deramiocel, we believe that we follow current good manufacturing practices to the extent that they are applicable to the stage of our clinical programs, although our facility at CSMC is not current Good Manufacturing Practices (" cGMP ") qualified for commercial manufacturing. Capricor has been manufacturing deramiocel in this facility for our current and previous studies including Cohort A of the HOPE- 3 trial. Our plans to use the CSMC facility for future trials could change if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, our CSMC Facilities Lease is scheduled to expire on July 31, 2026. We have been given no assurances that the CSMC Facilities Lease for the manufacturing space will be continued beyond July 31, 2026. In addition, the FDA may consider the data we provide as part of our BLA is insufficient to prove that the drug used in our San Diego facility is comparable to the drug produced in our Los Angeles facility and used in our prior clinical studies. This could result in us being required to conduct further testing and may result in us being required to conduct additional clinical and / or nonclinical studies prior to BLA approval. Even if we do complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree with our determination that the trial is sufficient to support the approval of our BLA application. We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations (" OPOs "). There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or, in that case, that an alternative OPO will be available to us. If those OPOs or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs or CDC- exosomes and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPOs are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPOs provide donor hearts will not change, making it more difficult or even impossible for the OPOs to continue to supply us with the hearts we need to produce our product candidates. There are also no guarantees that the OPOs which supply hearts have followed federal or state regulations addressing the donation of human organs and other regulatory matters. We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. There is no guarantee that any licenses issued to us will not expire, be revoked, or forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, if a serious adverse event in any of our clinical trials were to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license. Other states may impose additional licensing requirements upon us which, until obtained, would limit our ability to conduct our trials in such states. The process of manufacturing our products is complex and we may encounter difficulties in production, particularly with respect to process development or scaling- up of our manufacturing capabilities. We are currently producing doses of deramiocel in order to conduct our ongoing clinical trials as well as prepare for potential commercial launch. The process of manufacturing our products is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing adequate supply of our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with preclinical and clinical trials, along with additional costs. We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical trials or at earlier portions of a trial to the product used in later clinical trials or later portions of the trial. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product 51used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and / or undertake additional clinical and / or nonclinical testing, which could significantly delay the clinical development or

commercialization of the associated product candidate. Although we continue to build on our experience in manufacturing our product candidates, we have no experience, as a company, manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for commercial use. Our manufacturing capabilities could be affected by cost- overruns, unexpected delays, equipment failures, labor shortages, operator error, natural disasters, unavailability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. Furthermore, compliance with cGMP requirements and other quality issues may arise during our internal efforts to scale- up manufacturing, and with our current suppliers, or any future CMOs. If contaminants are discovered in our supply of our product candidates or in our manufacturing facilities or those of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized. We will need to increase our manufacturing capacity in the future and we may encounter problems at our current manufacturing facilities. In order to manufacture deramiocel in quantities sufficient to meet our anticipated commercial opportunity in the U. S. and other global markets, we will need to continue to increase our manufacturing capabilities. We may encounter technical challenges to increasing the scale at which we manufacture deramiocel, including with respect to material procurement and quality control and assurance. An increase in production could make it more difficult for us to comply with quality system regulations or other applicable requirements that are currently enforced by the FDA and other regulatory authorities, or that may be introduced in the future, in both the United States and in other countries. Commercial scale production of deramiocel on a continuing basis also will require us to continue to hire and retain additional management and technical personnel who have the necessary manufacturing experience and skills. We might not successfully identify, hire or retain qualified personnel on a timely basis or at all. Our inability to increase the scale of our manufacturing of deramiocel could impair our ability to generate revenue and adversely affect market acceptance of our product. In addition, we are planning to conduct our commercial manufacturing operations at our facility in San Diego, California. Any interruption in operations at this location could result in our inability to satisfy product demand. Despite our efforts to safeguard this facility, including acquiring insurance on commercially reasonable terms, adopting environmental health and safety protocols, a number of factors could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses, including: ● operating restrictions, partial suspension or total shutdown of production imposed by regulatory authorities; ● equipment malfunctions or failures; ● technology malfunctions; ● work stoppages; ● damage to or destruction of the facility due to natural disasters or other events; or ● regional or local power shortages. Our insurance may not cover our losses in any particular case, or insurance may not be available on commercially reasonable terms to cover certain of these catastrophic events. In addition, regardless of the level of insurance coverage, damage to our facilities or any disruption that impedes our ability to manufacture deramiocel in a timely manner could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. 52Additionally, we rely on third- party vendors for certain tests (sterility, etc.) required for product release. If these vendors are unable to perform the services, whether due to capacity, availability of materials, regulatory or other constraints, including federal and state regulations, we will not be able to sell deramiocel until we can retain an alternative vendors to supply these services. We may be unable to transition to alternative methods in a timely or cost- effective manner or at all, which could harm our business and results of operations. We are subject to a number of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by supply chain issues, equipment failures, labor shortages, natural disasters, power failures and numerous other factors. Cell therapy medicines are novel and any product candidates we develop may be complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates we may develop, or otherwise harm our business. Our product candidates being developed will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we intend to develop generally cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, including even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures,

product recalls, product liability claims, insufficient inventory, or potentially delay progression of our potential regulatory filings. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical- grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. In addition, the FDA, the EMA, and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects. Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations, and prospects. Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. 53We may need to rely exclusively on third parties to formulate and manufacture our product candidates and provide us with the devices and other products necessary to administer such a product. Our resources and expertise to formulate or manufacture our product candidates on a large or commercial scale basis are still very limited. If we need to secure an additional manufacturer of our product candidates, demand for third- party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third- party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our products. If deramiocel or any of our exosome technologies receives FDA approval, we may need to ultimately rely on one or more third- party contractors to manufacture supplies of these products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third- party manufacturers exposes us to the following risks: ● We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all because the number of potential manufacturers is limited, and subsequent to approval of an BLA or NDA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any. ● Our third- party manufacturers may not be able to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any. ● Our third- party manufacturers may not be able to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates. ● Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials needed to manufacture or utilize our product candidates. ● Our contract manufacturers may elect to terminate our agreements with them. ● Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues. Disruptions in our supply chain or failure to adequately forecast product demand could result in significant delays or lost sales. The loss of a material supplier could significantly disrupt our business. In some cases, we obtain components used in certain of our products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non- compliant with the FDA, EMA or other comparable applicable foreign bodies, then qualifying and obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which production could be delayed and we could lose sales. Our sources of supply for raw materials may be threatened by shortages and other market forces, tariffs and other trade barriers, by natural disasters, climate impacts, public health crises or other disruptive events, by the supplier' s failure to maintain adequate quality, or a recall initiated by the supplier. Even when substitute suppliers are available, the need to verify the substitute supplier' s regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales. Any failure by us to forecast demand for, or to maintain an adequate supply of, raw material and finished product could result in an interruption in the supply of certain products, which could impact potential sales of that product. If we or our suppliers are unable or our suppliers are unwilling to meet our increased manufacturing requirements, we may not be able to produce enough materials or products in a timely manner, which could impact our sales. Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties. 54Our product candidates, if approved, will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market

information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as cGMPs, a regulatory agency may: ● issue warning letters or untitled letters; ● require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non- compliance ; ● impose other civil or criminal penalties; ● suspend regulatory approval; ● suspend any ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications filed by us; ● impose restrictions on operations, including costly new manufacturing requirements; or ● seize or detain products or require a product recall. ~~In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries, or any delay or setback in obtaining such approval, could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, 48and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post- marketing follow- up studies. If we or current or future collaborators, manufacturers, or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and substantial penalties, which could affect our ability to develop, market and sell our products and may harm our reputation. Although we do not currently have any products on the market, if our therapeutic candidates or clinical trials become covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal, state and foreign governments of the jurisdictions in which we conduct our business. Healthcare providers, physicians and third- party payors play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse, transparency, and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our therapeutic candidates for which we obtain marketing approval. Some of our pre- commercial activities also may be subject to some of these laws. For more information on potentially applicable healthcare laws and regulations, See Part I, Item 1 – Other Healthcare Fraud and Abuse Laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of these or any other healthcare regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely impact our ability to operate our business and our results of operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation, even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, could result in negative publicity, a drop in our share price, or other harm to our business, financial condition and results of operations. Defending against any such actions could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Any drugs we develop may become subject to unfavorable pricing regulations, third- party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our future business prospects. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical 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 and negatively impact the revenues we are able to generate from the sale of the product in that country. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.~~

However, there may be significant delays in obtaining coverage 49for newly- approved drugs. Moreover, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution costs. Also, interim payments for new drugs, if applicable, may be insufficient to cover our costs and may not be made permanent. Thus, even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary or cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. In addition, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our product on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we develop. Increasingly, the third- party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates and other concessions to reduce the prices for pharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected. We currently expect that certain drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U. S. law, certain drugs that are not usually self- administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Specifically, Medicare Part B coverage may be available for eligible beneficiaries when the following, among other requirements have been satisfied: ● the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which the product is administered according to accepted standards of medical practice; ● the product is typically furnished incident to a physician' s services; ● the indication for which the product will be used is included or approved for inclusion in certain Medicare- designated pharmaceutical compendia (when used for an off- label use); and ● the product has been approved by the FDA. Average prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. Reimbursement rates under Medicare Part B would depend in part on whether the newly approved product would be eligible for a unique billing code. Self- administered, outpatient drugs are typically reimbursed under Medicare Part D, and drugs that are administered in an inpatient hospital setting are typically reimbursed under Medicare Part A under a bundled payment. It is difficult for us to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program. Third- party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement rates. These coverage policies and limitations may rely, in part, on compendia listings for approved therapeutics. Our inability to promptly obtain relevant compendia listings, coverage, and adequate reimbursement from both government- funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition. There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality of care and / or expanding access to care and 50the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. See Part I, Item 1 — Healthcare Reform for additional detail on recent legislative and regulatory changes that could affect our operations. Our risk mitigation measures cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U. S. federal and state regulations and all potentially applicable foreign regulations and other requirements. The development, manufacturing, distribution, pricing, sale, marketing and reimbursement of our product candidates, together with our general operations, are subject to extensive federal and state regulation in the United States and may be subject to extensive regulation in foreign countries. In addition, our business is complex, involves significant operational risks and includes the use of third parties to conduct business. While we intend to implement numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. We cannot guarantee that we, our employees, our consultants, our contractors or other third parties are or will be in compliance with all potentially applicable U. S. federal and state regulations and / or laws, and all potentially applicable foreign regulations and / or laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a

product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Any of these occurrences could have a material and adverse effect on our business and results of operations. Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such 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 be in compliance with such 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 material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us. Our ability to obtain reimbursement or funding for our programs from the federal government may be impacted by possible reductions in federal spending. U. S. federal government agencies currently face potentially significant spending reductions. For example, as a result of the Budge Control Act of 2011, the Bipartisan Budget Act (" BBA "), and the Coronavirus Aid, Relief, and Economic Security Act (the " CARES Act "), an annual 2 % reduction to Medicare payments took effect on April 1, 2013, and has been extended into through the first six months of the fiscal year 2032 sequestration order (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1 % from April 1, 2022 until June 30, 2022). The U. S. federal budget remains in flux, which could, among other things, result in additional cuts to Medicare payments to providers and otherwise affect federal spending on clinical and preclinical research and development. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact which the actions of President Biden' s administration and the U. S. Congress may have on the federal budget. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or 51eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations. We are planning to potentially develop vaccine candidates using our exosome technologies. The successful development, testing, manufacturing and commercialization of vaccines is a long, complex, expensive and uncertain process. There are unique risks and uncertainties associated with vaccines, including: ● There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, media pathogens, bacteria, viral strains, synthesized nucleic acids, including mRNA and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States, Japan and the EU, could result in restricted access to, or the transport or use of, such materials. If the Company in unable to access sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research or product development activities as planned and may incur additional costs. ● The development, manufacturing and marketing of vaccines are subject to regulation by the FDA, the EMA, PMDA and other regulatory bodies that are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot. ● Vaccines are frequently costly to manufacture because production ingredients are inactive biological materials derived from virus, animals, or plants and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines. Risks Related to the Manufacturing of our Product CandidatesWe have limited manufacturing capability and may not be able to maintain our manufacturing licenses. In 2022, we completed construction of our new primary manufacturing facility located within our Research and Development Facility in San Diego, California as we prepare for potential commercial launch. This facility is designed to produce commercial- scale GMP CAP- 1002 product for clinical and potential commercial use, subject to FDA approval. Additionally, we also maintain a portion of our laboratories, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. Currently, in the area of our leased premises at CSMC where we manufacture CAP- 1002 and may potentially manufacture our exosome technologies, we believe that we follow good manufacturing practices sufficient for an investigational stage product. Capricor has been manufacturing CAP- 1002 in this facility for our current and previous studies including Cohort A of the HOPE- 3 trial. We are using product manufactured from our San Diego facility to support Cohort B of the ongoing HOPE- 3 trial and supporting our OLE trials. Furthermore, it is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. Our plans to use the CSMC facility for future trials could change if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, our CSMC Facilities Lease is scheduled to expire on July 31, 2026. There can be no assurance that the Facilities Lease for the manufacturing space will be continued beyond July 31, 2026 or whether the facility will be approved by the FDA for commercial manufacturing following approval of the BLA. In the third quarter of 2023, we met with the FDA, where we affirmed alignment with respect to our Phase 3, HOPE- 3 program where the FDA agreed to allow us to submit a BLA supported by results using product manufactured at our Los Angeles manufacturing site. At this time, we can provide no assurance that the FDA will ultimately approve this facility for commercial use, or that CMSC will allow us to market

commercial product from this facility. Should this facility ultimately not be approved to manufacture commercial product, this may result in delays and significant expenses which would materially impact our business and product development. In addition, FDA may consider the data we provide are insufficient to prove that the drug used in Cohort B of our HOPE- 3 study is comparable to the drug produced in our Los Angeles facility and used in our prior clinical studies. This could result in us being required to conduct further comparability testing and may result in us being required to conduct 52additional clinical and / or nonclinical studies before we are able to submit a BLA for approval. Additional testing or clinical trial requirements could lead us not to pursue an application for approval. Conducting a clinical trial may prove too difficult or too expensive, and the process of designing a clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we do complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree with our determination that the trial is sufficient to support the submission and approval of a BLA application. We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations (" OPOs "). There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or, in that case, that an alternative OPO will be available to us. If those OPOs or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs or CDC- exosomes and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPOs are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPOs provide donor hearts will not change, making it more difficult or even impossible for the OPOs to continue to supply us with the hearts we need to produce our product candidates. We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. For example, we have recently entered into Azzur License Agreement with Azzur Cleanrooms- on- Demand – San Diego, LLC pursuant to which we have been granted an exclusive license to use certain space and the non- exclusive right to use certain equipment and property for our early phase clinical and / or pre- clinical manufacturing purposes. We are planning to use this facility to manufacture our exosome- based vaccine for potential clinical use. There is no guarantee that any licenses issued to us will not expire, be revoked, forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, if a serious adverse event in any of our clinical trials were to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license. Other states may impose additional licensing requirements upon us which, until obtained, would limit our ability to conduct our trials in such states. The process of manufacturing our products is complex and we may encounter difficulties in production, particularly with respect to process development or scaling- up of our manufacturing capabilities. We are currently producing doses of CAP- 1002 in order to conduct our ongoing clinical trials at both of our facilities. The process of manufacturing our products is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing adequate supply of our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with preclinical and clinical trials, along with additional costs. We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical trials or at earlier portions of a trial to the product used in later clinical trials or later portions of the trial. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and / or undertake additional clinical and / or nonclinical testing, which could significantly delay the clinical development or commercialization of the associated product candidate. Although we continue to build on our experience in manufacturing our product candidates, we have no experience, as a company, manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for commercial use. Our manufacturing capabilities could be affected by cost- overruns, unexpected delays, equipment failures, labor shortages, operator error, 53natural disasters, unavailability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. Furthermore, compliance with cGMP requirements and other quality issues may arise during our internal efforts to scale- up manufacturing, and with our current suppliers, or any future CMOs. If contaminants are discovered in our supply of our product candidates or in our manufacturing facilities or those of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of

patients once approved, would be jeopardized. We are subject to a number of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by supply chain issues, equipment failures, labor shortages, natural disasters, power failures and numerous other factors. We may need to rely exclusively on third parties to formulate and manufacture our product candidates and provide us with the devices and other products necessary to administer such a product. Our resources and expertise to formulate or manufacture our product candidates on a large or commercial scale basis are still very limited. If we need to secure an additional manufacturer of our product candidates, demand for third- party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third- party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our products. If CAP- 1002 or any of our exosome technologies receives FDA approval, we may need to ultimately rely on one or more third- party contractors to manufacture supplies of these products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third- party manufacturers exposes us to the following risks: ● We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any. ● Our third- party manufacturers may not be able to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any. ● Our third- party manufacturers may not be able to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates. ● Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials needed to manufacture or utilize our product candidates. ● Our contract manufacturers may elect to terminate our agreements with them. ● Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards. 54Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues. Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties. Our product candidates, if approved, will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as cGMPs, a regulatory agency may: ● issue warning letters or untitled letters; ● require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non- compliance; ● impose other civil or criminal penalties; ● suspend regulatory approval; ● suspend any ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications filed by us; ● impose restrictions on operations, including costly new manufacturing requirements; or ● seize or detain products or require a product recall. The third parties we use in the manufacturing process for our product candidates may fail to comply with cGMP regulations. If we decide to transfer the manufacturing of our product candidates for future clinical trials or for commercial supply, our contract manufacturers will be required to produce our products in compliance with cGMP. These contract manufacturers are subject to periodic unannounced inspections by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign requirements. We do not have control over a third- party manufacturer' s compliance with these regulations and requirements. In addition, changes in cGMP could negatively impact the ability of our contract manufacturers to complete the manufacturing process of our product candidates in a compliant manner on the schedule we require for clinical trials or for potential commercial use. The failure to achieve and maintain high quality compliance, including failure to detect or control anticipated or unanticipated manufacturing errors, could result in patient injury or death or product recalls. Any difficulties or delays in our contractors' manufacturing and supply of product candidates, or any failure of our contractors to maintain compliance with the applicable regulations and requirements could increase our costs, make us postpone or cancel clinical trials, prevent or delay regulatory approvals by the FDA and corresponding state and foreign authorities, prevent the import and / or export of our products, cause us to lose revenue, result in the termination of the development of a product candidate, or have our product candidates recalled or withdrawn from use. Risks Related to Our Intellectual PropertyWe may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights. Our success will depend in large part on our ability to obtain, maintain, and defend patents on our product candidates, obtain

licenses to use third- party technologies, protect our trade secrets and operate without infringing the valid and enforceable proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, in- licensed or Company- owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed- in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and enforce against infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we have rights or obtain access to our know- how. In addition, the laws of certain countries ~~55may --~~ **may** not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our product candidates. There can also be no assurance that our proposed technology will not infringe upon valid and enforceable patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such ~~litigation~~ **55litigation** , if instituted, could have a material adverse effect, potentially including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes. Some of our technology has resulted and / or will result from research funded by agencies of the U. S. government and the State of California. As a result of such funding, the U. S. government and the State of California have certain rights in the technology developed with the funding. These rights may include a non- exclusive, non- transferable, irrevocable, paid- up, worldwide license to practice or have practiced for or on behalf of the government (s) such inventions. In addition, the government (s) has the right to " march in " and require us to grant third parties licenses to such technology, in certain circumstances, such as if we fail to take effective steps to achieve practical application of such inventions. The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non- patented proprietary know- how and trade secrets. There can be no assurance that we can adequately protect our rights in such non- patented proprietary know- how and trade secrets, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know- how and trade secrets. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know- how or other proprietary information were to be disclosed, or misappropriated, the value of our trade secrets, know- how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. In September 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a " first **inventor** to file " system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U. S. Patent and Trademark Office (" USPTO "), and may become involved in derivation, post- grant review, or inter partes review, proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or ~~invalidate~~ **render unpatentable** , our or our licensors' patent rights, which could adversely affect our competitive position. It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights and product candidates would diminish. Our commercial viability will depend, in part, on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture **and utilize** them, as well as successfully defending these patents against third- party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these **products and** activities. We have licensed certain patent and other intellectual property rights that cover cardiospheres ~~(CSps)~~ , and cardiosphere- derived cells ~~(CDCs)~~ , (including our **deramiocel** ~~CAP- 1002~~ product candidate) from the University of Rome, JHU, and CSMC. We have also licensed certain patent and other intellectual property rights from CSMC that cover extracellular vesicles, such as exosomes and microvesicles. Under the license agreements with the University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Under our Amended and Restated Exclusive License Agreement with CSMC and our Exclusive License Agreement with CSMC, as the same have been amended, we have assumed, in coordination with CSMC, financial responsibility for the prosecution and maintenance of certain patents and patent applications ~~56thereunder --~~ **thereunder** . Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity and / or unenforceability of these patents would also be subject to the cooperation of the University of Rome, JHU, and / or CSMC. The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain ~~unresolved~~ **uncertain and unclear** . No ~~consistent~~ **clear statutes or common** ~~laws~~ **law** regarding the breadth of claims allowed in biopharmaceutical patents has **clearly** emerged to date in the ~~United~~ **56United** States. The biopharmaceutical patent situation outside the United States ~~is even~~ **may be** more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed **,** or ~~enforced~~ **remain valid or enforceable** in the patents we own or that are in- licensed. Further, if any of our owned or in- licensed patents are determined by legal

authority to be invalid or unenforceable, it could impact our ability to commercialize or license our technology. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ● others may be able to make products that are similar to our product candidates but that are not covered by the claims of any of our patents; ● we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have); ● we might not have been the first to file patent applications for these inventions; ● it is possible that any pending patent applications we may have will not result in issued patents; ● any issued patents may not provide us with any competitive advantage, or may be held invalid or unenforceable as a result of legal challenges by third parties; ● we may not develop additional proprietary technologies that are patentable or protectable under trade secrets law; and ● the patents of others may have an adverse effect on our business. We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts **as proscribed in state and federal statutes** to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know- how. If any of our trade secrets, know- how or other proprietary information is improperly disclosed, the value of our trade secrets, know- how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. Our viability also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know- how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit unauthorized disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements are often limited in duration and may not provide adequate protection for our trade secrets, know- how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. In addition, enforcing a claim that a third- party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets, know- how or other proprietary information is improperly disclosed, the value of our trade secrets, know- how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. We may incur substantial costs as a result of litigation or other adversarial proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology. If we choose to go to court to stop a third- party from using the inventions covered by our patents, that individual or company has the right to ask the court to rule that such patents are invalid and / or should not be enforced against that third- party. These lawsuits are expensive and would consume time and other resources, even if we were successful in ~~57discontinuing~~ -- **discontinuing** the infringement of our patents. In addition, there is a risk that the court will determine that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party' s activities do not infringe our rights to these patents. In addition, the U. S. Supreme Court has modified certain legal tests so as to make it harder to obtain patents from the USPTO, and to defend issued patents against invalidity challenges. As a consequence, issued patents may be found **by federal courts** to contain invalid claims according to the revised legal ~~standards~~ **57standards** . Some of our own or in- licensed patents may be subject to challenge and subsequent invalidation in a variety of post- grant proceedings, before the Patent Trial and Appeal Board ~~(the PTAB)~~ of the USPTO or in litigation under the revised legal standards, which make it more difficult to defend the **patentability or** validity of claims in already issued patents. Furthermore, a third- party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third- party' s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect the results of our operations and divert the attention of managerial and technical personnel. There is a risk that a court could determine that we or our commercialization partners are infringing the third- party' s patents and order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court could order us or our partners to pay the other party damages for having violated the other party' s patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products, manufacturing processes or methods of use. The coverage of patents is subject to claim construction by the courts, which is not always predictable or ~~reasonable~~ **favorable** . If we are sued for patent infringement, we would need to demonstrate that our products, manufacturing processes or methods of use either do not infringe the patent claims of the relevant patent and / or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires ~~a~~ proof by clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent applications may have priority over our patent applications or patents, which could further require us to obtain licenses to these issued patents covering such technologies. For patent applications filed before the Leahy- Smith Act, if another party has filed a United States patent application on inventions

similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U. S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation or inter partes review proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Some jurisdictions in which we operate have enacted legislation which allows members of the public to access information under statutes similar to the U. S. Freedom of Information Act. Even though we believe our information would be excluded from the scope of such statutes, there are no assurances that we can protect our confidential information from being disclosed under the provisions of such laws. If any confidential or proprietary information is released to the public, such disclosures may negatively impact our ability to protect our intellectual property rights. We may be subject to claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used, misappropriated or disclosed confidential information of these third parties or our employees' former employers. Litigation ~~58may~~ -- **may** be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. ~~We~~ **58We** depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business. We are dependent on patents, trade secrets, know- how and proprietary technology, both our own and that licensed from others. We have several license agreements, including with the University of Rome, JHU and CSMC. These licenses may be terminated upon certain conditions, including in some cases, if we fail to meet certain minimum funding or spending requirements, fail to take certain developmental actions, fail to **attain certain developmental milestones, fail to** pay certain minimum royalties, or fail to maintain the licensed intellectual property. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other contract interpretation- related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. Risks Related to Our Relationships with Third PartiesWe will depend on our exclusive distributor, Nippon Shinyaku, for the commercial sale of our lead product **deramiocel** ~~CAP- 1002~~ in DMD in the United States and Japan, if we receive regulatory approval in those territories. We believe that a substantial portion of our revenue for the foreseeable future will depend on milestones and other payments received from our distributor, Nippon Shinyaku. Nippon Shinyaku has exclusive distribution rights for **deramiocel** ~~CAP- 1002~~ in the United States and Japan for a significant period of time, with only limited rights of either party to terminate these agreements **. In the event that Nippon Shinyaku fails to adequately commercialize deramiocel in the United States or Japan because it lacks financial or other resources, decides to focus on other initiatives or otherwise, our ability to successfully commercialize deramiocel in the United States and Japan would be limited, which would adversely affect our business, financial condition and results of operations. Our results of operations could be materially harmed if we or our distributor are unable to accurately forecast customer demand for our products and manage our inventory. We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions and to support the projected demand for our product candidates, but keep limited materials on hand. To ensure adequate inventory supply and manage our operations with our suppliers, we forecast anticipated materials requirements and demand for our products (if commercialized) in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for deramiocel could be negatively affected by many factors, including, product recalls, labor shortages, the failure to accurately manage our commercial strategy, product introductions by competitors, an increase or decrease in demand for our products, our failure or the failure of our distributor to accurately forecast demand, unanticipated changes in general market conditions or regulatory matters, insurance reimbursement levels, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of product demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write- downs or write- offs. Conversely, if we underestimate patient demand for deramiocel or our own requirements for materials, our manufacturing partners and suppliers may not be able to deliver components or other materials to meet our requirements and our manufacturing may be affected by the impact of inflation and labor shortages on our suppliers, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries, any of which would damage our reputation and business. In addition, several materials incorporated into our products require lengthy order lead times and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be 59able to allocate sufficient capacity in**

order to meet our increased requirements, any of which could have an adverse effect on our ability to meet demand for our products and our results of operations . We are dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued. We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and / or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. ~~By way of example, we recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U. S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC' s purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.~~ Each of the institutions receives funding from independent sources such as the NIH and other private or not- for- profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor, Inc.' s founder, Dr. Eduardo ~~59Marbán --~~ **Marbán** , who is the Director of the Smidt Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our cell therapy or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements or research agreements between those institutions and us. Further, the failure of any third- party licensor to comply with its licensing obligations under its respective agreement with us would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know- how. If requirements under our license agreements are not met, including meeting defined milestones, we could suffer significant harm, including losing rights to our product candidates. 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 agreements in a timely manner, we could lose the rights to the proprietary technology. Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties (including and other than the University of Rome, JHU and CSMC) in connection with the development and use of our product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all. We have received government grants and a loan award which impose certain conditions on our operations. Commencing in 2009, we received several grants from the NIH and DoD to fund various projects. Some of these awards remain subject to annual and quarterly reporting requirements and require us to allocate expenses to the applicable project. On June 16, 2016, Capricor ~~entered into the~~ **was granted a** CIRM Award ~~with CIRM~~ in the amount of approximately $ 3. 4 million to fund, in part, the HOPE- Duchenne trial. Pursuant to **the** terms of the CIRM Award, disbursements were tied to the achievement of specified operational milestones. The CIRM Award ~~is~~ **was** further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (**"** CCR **"**) Sections 100600- 100612, and ~~the~~ **potentially** sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. **In the first quarter of 2025, Capricor notified CIRM that it was electing to convert the CIRM Award into a loan. As a result, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements.** The **terms of the loan agreement are currently under discussion with** ~~maximum royalty on net commercial revenue that Capricor may be required to pay to~~ CIRM **. The Company accounts for this** ~~is equal to nine times the total amount awarded --~~ **award** ~~and paid to Capricor~~ **as a liability rather than income** . ~~If~~ **60If** we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us. We are actively looking into potential additional strategic partnerships for our product candidates, particularly for **deramiocel** ~~CAP- 1002~~ in additional territories outside the United States and Japan **,** and **for** our exosomes product candidates **. For example, we are in advanced negotiations pursuant to a binding term sheet with Nippon Shinyaku for the distribution of deramiocel in the European region** . If we do not establish strategic partnerships, we potentially will have to undertake development and commercialization efforts with respect to our product candidates on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life science companies, we will be subject to a number of risks, including: ● we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates; ● strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing; ● strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs; ● strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products; ● disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or

commercialization of our product candidates or that result in costly litigation or arbitration that diverts management' s attention and consumes resources; ~~60~~ ● strategic partners may experience financial difficulties; ● strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; ● business combinations or significant changes in a strategic partner' s business strategy may also adversely affect a strategic partner' s willingness or ability to complete its obligations under any arrangement; and ● strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors. We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We depend and will depend upon independent investigators and collaborators, such as universities, medical institutions, CROs, vendors and strategic partners to conduct our preclinical and clinical trials under agreements with us. We negotiate budgets and contracts with CROs, vendors and trial sites which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory 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 current good clinical practices (" cGCPs "), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP 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 that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. Further, GCP requirements may evolve. In June 2023, the FDA published a draft guidance, E6 (R3) Good Clinical Practice (GCP), which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies. Biologic products for commercial purposes must also be produced under cGMP. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat ~~clinical~~ **61clinical** 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 and regulations. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, which in some instances may be limited, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third- party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. **As we advance our programs through potential commercial launch, we have substantial fixed costs associated with third party contracts that will increase and will not be able to be terminated, even if our product candidates are not ultimately approved. As we advance our programs, in particular our lead product candidate deramiocel, we have incurred and will continue to incur substantial costs associated with those programs. For example, we are increasing our spending on manufacturing-related costs as we prepare to be able to manufacture deramiocel for a potential commercial launch following potential regulatory approval. We have continued to expand our use of real estate as we expand our capacity to manufacture and otherwise support deramiocel. While we seek to be prudent with our spending programs, many of our agreements are for agreed upon amounts with our counterparties and are not able to be terminated by us, even if we ultimately are unable to commercially launch deramiocel due to failure to receive regulatory approvals.** ~~61Risks --~~ **Risks** Related to Competitive FactorsOur products will likely face intense competition. The Company is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. We will experience intense competition with respect to our existing and future product candidates. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, greater clinical trial experience, longer drug development history in obtaining regulatory approvals, and greater manufacturing, distribution, sales and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates that we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products

based upon the principles underlying our proprietary technologies earlier than we do, obtain approvals for such products from the FDA more rapidly than we do, or develop alternative products or therapies that are safer, more effective and / or more cost effective than any product developed by us. Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours, and may also be more successful than us in manufacturing and marketing their products. Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. Existing or future therapies developed by others may render our potential ~~products~~ **62products** obsolete or noncompetitive. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations. If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our consultants render services on a part- time basis to other entities which may result in the creation of intellectual property rights in favor of those entities. Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, **as well as manufacturing and quality assurance,** and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. We have experienced employee turnover from time to time, including involving some of our key employees. The loss of any of our current key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company' s success, both to enable the Company to grow, and to allow the Company to replace any employees or consultants whose relationships with the Company have been terminated. The market for employees with experience in the cell therapy and exosome industries is especially competitive, and we may not be able to recruit employees needed to develop and manufacture our products or be able to retain the employees whom we do recruit. There has been a close working relationship between the academic lab at CSMC and our research and development team where employees and consultants of both entities from time to time have contributed time and services to the research being performed by the other. As a result, it can sometimes be unclear whether intellectual property developed out of these services for CSMC would be owned by CSMC or by the Company, although if owned by CSMC, the Company may have rights to that intellectual property under the terms of its license agreements with CSMC. ~~62The~~ -- **The** Company may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non- profit research institutions for experienced scientists. Certain of the Company' s officers, directors, scientific advisors, and / or consultants or certain of the officers, directors, scientific advisors, and / or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and / or consultants of other biopharmaceutical or biotechnology companies. The Company currently does not maintain " key man " insurance policies on any of its officers or employees. All of the Company' s employees **are and** will be employed " at will " and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific and manufacturing personnel, and attract additional qualified candidates, the Company' s business and results of operations could be adversely affected. If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product candidates. An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including having access to the cash and other resources we need for such development and potential commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates, we may be forced to curtail the development of a particular candidate, reduce, delay, or terminate its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not secure sufficient funds, we will not be able to complete our trials or bring our product candidates to market and generate product revenue. We have entered into the U. S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku for the exclusive commercialization and distribution rights ~~in~~ **63in** the United States and Japan **, respectively,** of **deramiocel** ~~CAP- 1002~~ for DMD. We continue to evaluate additional potential partners for this program in other territories outside of these territories, subject to any rights of Nippon Shinyaku. We have no experience selling, marketing, or distributing products and no current internal capability to do so. The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. As we entered into the U. S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku, we will depend upon Nippon Shinyaku' s strategic interest in our **deramiocel** ~~CAP- 1002~~ product candidate and Nippon Shinyaku' s ability to successfully market and sell any such products, if and when approved. If any of our other product candidates are cleared for commercialization, we intend to pursue collaborative arrangements regarding the sales and marketing of such products,

however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if **we are** able to do so, that such collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in- house marketing and sales force with sufficient technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third- party collaborators or develop in- house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, such as our partnership with Nippon Shinyaku, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales, if any, will be limited. The commercial viability of our product candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance among physicians, the medical community, patients, and **the availability of** coverage and reimbursement ~~of them~~ by third- party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including: ● limitations or warnings contained in a product' s FDA- approved labeling; ~~63-~~ ● changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval; ● limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions; ● ~~lower~~ demonstrated clinical safety and efficacy compared to other products; ● prevalence and severity of adverse effects; ● **the** ~~ineffective~~ -- **effectiveness of** marketing and distribution efforts; ● ~~lack of~~ availability of reimbursement from managed care plans and other third- party payors; ● ~~lack of~~ cost- effectiveness; ● timing of market introduction and perceived effectiveness of competitive products; ● availability of alternative therapies at similar costs; and ● potential product liability claims. Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any. Our development of a potential vaccine for COVID- 19 or other indications is at an early stage and is subject to significant risks. ~~Our~~ **64Our** development of a vaccine **of COVID- 19** is in early stages and we may be unable to produce a vaccine that successfully treats a particular virus in a timely manner, if at all ~~. Even if we were able to successfully develop and obtain regulatory approval for a vaccine, if the outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our vaccine, we may not be able to generate product revenues from the vaccine~~ . Additionally, a number of pharmaceutical companies have already obtained regulatory approval for COVID- 19 vaccines, and other companies with significantly more resources and visibility than us are developing COVID- 19 vaccines. Even if we were able to successfully develop and obtain regulatory approval for a COVID- 19 vaccine, vaccines produced by these other companies may be superior to our vaccine. Even if a vaccine that we develop is not inferior to other available vaccines, it could be difficult to obtain market acceptance. We are committing financial resources and personnel to the development of a COVID- 19 vaccine which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective, or for which better vaccine options may be available. Even if our product candidates are approved, our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement. Our or our collaborators' ability to generate significant sales of our products, if approved, depends on the availability of adequate coverage and reimbursement from third- party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third- party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products. Orphan drugs in particular have received negative publicity for the perceived high prices charged for them by their manufacturers, and as a result, other orphan drug developers such as us may be negatively impacted by such publicity and any U. S. or other government regulatory response. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Many third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies ~~,~~ but also have their own methods and approval processes to decide which drugs they ~~64will~~ -- **will** pay for and establish reimbursement levels. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate ~~attractive~~ **sufficient** efficacy profiles, they may not qualify for coverage and reimbursement. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan- by- plan basis. One payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time- consuming process. Each plan determines whether or not it

will provide coverage for a drug, what amount it will pay for the drug, the applicable formulary tier, and whether to require step therapy or other utilization management controls. Such decisions can strongly influence the adoption of a drug by patients and physicians ~~. Patients who are prescribed treatments for their conditions and treating healthcare providers generally rely on third- party payors to reimburse all or part of the associated healthcare costs~~. Patients may be unlikely to use and prescribers unlikely to prescribe our products unless adequate coverage is provided and reimbursement is available. Additionally, a third- party payor' s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. The process for determining whether a third- party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third- party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drug products. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop. Further, there have been a number of legislative and regulatory proposals to change the healthcare system that could affect our ability to sell any future drugs profitably. The U. S. government, state legislatures, and foreign governments ~~have~~ **65have** shown significant interest in implementing cost- containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results. There can be no assurance that any of our product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost- effective by third- party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not harm our ability to sell our product candidates profitably, if they are approved for sale. Risks Related to Product and Environmental LiabilityOur products may expose us to potential product liability, and there is no guarantee that we will be able to obtain and maintain adequate insurance to cover these liabilities. The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, biologics, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, ~~65administering~~ -- **administering** or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● withdrawal of clinical trial participants; ● termination of clinical trial sites or entire trial programs; ● costs of related litigation; ● substantial monetary awards to patients or other claimants; ● decreased demand for our product candidates; ● impairment of our business reputation; ● loss of revenues; and ● the inability to commercialize our product candidates. The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company or the levels of coverage may not be sufficient to reimburse it for expenses or losses it may suffer or for its indemnification obligations. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could significantly decrease our cash position and adversely affect our business. In addition, our clinical trial agreements and most agreements with third- party vendors contain provisions requiring us to maintain certain levels of insurance extending for multiple years beyond the termination or expiration of the agreement as well as indemnification obligations requiring us to indemnify them from any losses and claims that may be brought in connection with their provision of services, testing, manufacture or other activities in connection with the use of our products. **If we are unable to procure policies in the amounts, with suitable coverage and for the duration required, we could be in breach of our agreements with such third parties.** ~~Our~~ **66Our** business involves risk associated with handling hazardous and other dangerous materials. Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, animal tissue, biological waste, and various radioactive compounds. The risk of accidental

contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations. Our business depends on compliance with ever- changing environmental and human health and safety laws. We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations, as well as laws and regulations designed to protect employees and others who handle hazardous materials. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, the Company has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local environmental laws and regulations. However, both federal and state environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations. ~~66Risks~~ -- **Risks** Related to Our Common StockWe expect that our stock price will continue to fluctuate significantly. The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to: ● our financial condition, including our need for additional capital, as well as the impact of any terms imposed on our business and operations by the providers of additional capital; ● results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints; ● announcements concerning clinical trials and regulatory developments; ● failure or delays in entering drug candidates into clinical trials; ● failure or discontinuation of any of our research or development programs; ● developments in establishing and maintaining new strategic alliances or with existing alliances or collaborators; ● failure to meet milestone requirements under distribution agreements, including the U. S. Distribution Agreement and Japan Distribution Agreement with Nippon Shinyaku; ● failure to satisfy ~~licensing~~ **contractual** obligations, including our ability to meet milestone requirements under our license agreements; ● market conditions in the pharmaceutical, biotechnology and other healthcare related sectors; ● actual or anticipated fluctuations in our quarterly financial and operating results; ● developments or disputes concerning our intellectual property or other proprietary rights; ● introduction of technological innovations or new commercial products by us or our competitors; ● issues in manufacturing our drug candidates or drugs; ● issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates; ● FDA or other U. S. or foreign regulatory actions affecting us or our industry; ● the risks and costs of increased operations, including clinical and manufacturing operations, on an international basis; **67** ● market acceptance of our drugs when they enter the market; ● third-party healthcare coverage and reimbursement policies; ● litigation or public concern about the safety of our drug candidates or drugs or the operations of the Company; ● issuance of new or revised securities analysts' reports or recommendations; ● additions or departures of key personnel; ● potential delisting of our stock from the Nasdaq Stock Market; or ● volatility in the stock prices of other companies in our industry. We have never paid dividends and we do not anticipate paying dividends in the future. We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company' s common stock for that purpose. **Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock.** We may issue shares of blank check preferred stock without stockholder approval in the future. Our certificate of incorporation authorizes the issuance of up to 5, 000, 000 shares of preferred stock, none of which are currently issued or currently outstanding. If issued, our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti- dilution protection, and the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock. ~~67Market~~ -- **Market** and economic conditions may adversely affect our industry, business and ability to obtain financing. Recent global market and economic conditions have been unpredictable and challenging. These conditions and any adverse impact on the financial markets may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts maintain coverage of us, the trading price of our stock could decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could also decline. If one or more of these analysts cease to cover our stock altogether, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. The operational and other projections and forecasts that we may make from time to time are subject to inherent risks, many of which are beyond our control. The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult

to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. Additionally, final data may differ significantly from preliminary reported data. ~~Our~~ **68Our** certificate of incorporation and by- laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable. Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as: ● authorizing the issuance of " blank check " preferred stock without any need for action by stockholders; and ● establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings. These provisions could make it more difficult for our stockholders to affect our corporate policies or make changes in our Board of Directors and for a third- party to acquire us, even if doing so would benefit our stockholders. A significant number of shares of our common stock are issuable pursuant to outstanding stock awards and warrants, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and warrants, and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock. As of December 31, ~~2023~~ **2024**, there were approximately ~~31~~ **45**. ~~1~~ **6** million shares of common stock outstanding and approximately ~~5~~ **4**. ~~0~~ **9** million common warrants outstanding, as well as outstanding awards to purchase approximately ~~8~~ **10**. ~~2~~ **7** million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, ~~2023~~ **2024**, there were **59, 850** ~~approximately 1. 2 million~~ shares of common stock available for future issuance under our incentive plans. This number of shares available for future issuance under those plans was subsequently increased by **2, 279, 114 shares on January** 1, **2025** ~~557, 416 shares~~ in accordance with the terms of our 2021 ~~equity~~ **Equity** ~~incentive~~ **Incentive** ~~plan~~ **Plan** which include an automatic increase previously approved by our Board and stockholders. We may issue additional common stock, warrants and other convertible securities from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock, warrants or other convertible securities and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock. ~~68The~~ -- **The** Company' s ability to utilize Nile' s net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may further be limited as a result of the merger with Capricor. Federal and state income tax laws impose restrictions on the utilization of net operating loss (" NOL "), and tax credit carryforwards in the event that an " ownership change " occurs for tax purposes, as defined by Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "). In general, an ownership change occurs when stockholders owning 5 % or more of a " loss corporation " (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three- year period. If an " ownership change " occurs, Section 382 of the Code imposes an annual limitation on the amount of post- ownership change taxable income that may be offset with pre- ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation' s value immediately before the ownership change by the greater of the long- term tax- exempt rate determined by the U. S. Internal Revenue Service (" IRS ") in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built- in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post- ownership change year that can be reduced by the loss corporation' s pre- ownership change tax credit carryforwards. The merger between Nile and Capricor resulted in an " ownership change " of Nile. In addition, previous or current changes in the Company' s stock ownership may have triggered or, in the future, may trigger an " ownership change, " some of which may be outside of our control. Accordingly, the Company' s ability to utilize Nile' s NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company. The requirements of being a public company may strain our resources and divert management' s attention. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the " Exchange Act "), and other applicable securities rules and regulations, and are subject to the listing ~~requirements~~ **69requirements** of The Nasdaq Stock Market LLC (" Nasdaq "). Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time- consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight is required. In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. As a result, management' s attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired employees in order to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses. Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act of 2002 could have a material adverse effect on our business and stock price. The Sarbanes- Oxley Act of 2002, as amended (" Sarbanes- Oxley "), as well as rules implemented by the SEC, Nasdaq and any market on which the Company' s shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company' s management and other personnel will

need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company' s legal and financial compliance costs and will make some activities more time consuming and costly. Section 404 of Sarbanes- Oxley (" Section 404 ") requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10- K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other ~~69significant~~ -- **significant** deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity. You may experience future dilution as a result of future equity offerings. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by any investor. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by any investor. If our business plans are not successful, our stockholders may lose their entire investment in us. We have historically incurred substantial losses to fund our business operations including our research and development activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. If our business plans are not successful, our stockholders may lose their entire investment in us. We may be at risk of securities class action litigation or litigation initiated by individual stockholders. We may subject to securities class action litigation or litigation initiated by individual stockholders. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. Additionally, we may be subject to litigation and business challenges in the operation of our company due to actions instituted by activist stockholders. Perceived ~~uncertainties as to our future direction as a result of stockholder activism may lead to the perception of a change in the direction of the business or other instability and may affect our relationships with vendors, distributors, collaborators, prospective and current employees and others. Responding to legal and / or business challenges related to securities class action litigation, or litigation initiated by individual stockholders, including activist stockholders, could be costly and time- consuming, may not align with our business strategies, and could divert management' s attention and resources from the pursuit of our business strategies, any of which could harm our business and result in a decline in the market price of our common stock. In the event we fail to satisfy any of the listing requirements of The Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity. Our common stock is listed on The Nasdaq Capital Market. For continued listing on The Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, maintaining board diversity among other requirements. In the event that we fail to satisfy any of the listing requirements of The Nasdaq Capital Market, our common stock may be delisted. If our securities are delisted from trading on The Nasdaq Stock Market, however, and we are not able to list our securities on another exchange or to have them quoted on The Nasdaq Stock Market, our securities could be quoted on the OTC Markets or on the " pink sheets. " As a result, we could face significant adverse consequences including: ● a limited availability of market quotations for our securities; ● a determination that our common stock is a " penny stock, " which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ● a limited amount of news and analyst coverage; and ● a decreased ability to issue additional securities (including pursuant to short- form registration statements on Form S- 3) or obtain additional financing in the future.~~ 70