Risk Factors Comparison 2024-03-27 to 2023-03-29 Form: 10-K

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

~~● Our business, financial condition and results of operations, including our preclinical studies and clinical trials, could continue to be harmed by the effect of the COVID- 19 pandemic or other health epidemics and pandemics. Risks Relating to Our Intellectual Property ● We may not be able to protect our proprietary technology in the marketplace. ● The patent protection of biotherapeutics is complex and uncertain. ● We may be unable to adequately prevent disclosure of trade secrets and other proprietary information. ● We may be forced to litigate to enforce or defend our intellectual property rights, and / or the intellectual property rights of our licensors. ● Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities. ● Patent reform legislation and recent court decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. ● If third parties claim that our therapeutic candidates or other products infringe upon their intellectual property, commercialization of our therapeutic candidates or products and our operating profits could be adversely affected. ● If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of our therapeutic candidates or products, our business may be materially harmed. Risks Related to Our Securities ● The market price and trading volume of our securities may be volatile and may be affected by economic conditions beyond our control. ● We may be exposed to additional risks as a result of our reverse merger transaction. ● Our annual and quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. ● Raising additional funds through debt or equity financing could be dilutive and may cause the market price of our common stock to decline. ● The sale or issuance of our common stock to Lincoln Park, Cantor and through private placements may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, Cantor and through private placements, or the perception that such sales may occur, could cause the price of our common stock to fall. ● Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. General Risks ● We are at risk of securities class action litigation. RISK FACTORS~~ Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and related notes, before investing in our securities. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, market prices of our securities could decline, and you could lose part or all of your investment. Risks Relating to Our Business, Financial Condition and Capital Requirements We have a history of operating losses, and we may not be able to achieve or sustain profitability. We are a clinical- stage regenerative medicine company and we have not yet generated a profit. We have incurred net losses during each of our fiscal years since our inception. Our net loss for the year ended December 31, ~~2022~~ **2023** was $ 11. ~~9~~ **6** million and our accumulated deficit totaled $ ~~140~~ **152** . ~~6~~ **2** million as of December 31, ~~2022~~ **2023** . We do not know whether or when we will become profitable, if ever. We currently expect operating losses and negative cash flows to continue for at least the next several years. To date, our only approved or cleared products are our Morph universal deflectable guide catheters and Morph AccessPro sheaths, in the United States and Europe; our AVANCE ™ steerable introducer and our Morph DNA deflectable guides in the United States only; and our Helix biotherapeutic delivery system in Europe. Our limited commercialization experience and number of approved products makes it difficult to evaluate our current business and predict our future prospects. Our short commercialization experience and limited number of approved products also makes it difficult for us to forecast our future financial performance and growth and such forecasts are limited and subject to a number of uncertainties, including our ability to successfully complete our Phase III pivotal trials in heart failure and chronic myocardial ischemia and obtain FDA approval for, and then successfully commercialize, the CardiAMP Cell Therapy System. Our ability to generate sufficient revenue to achieve profitability depends on our ability, either alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our therapeutic candidates. We do not anticipate generating revenues from sales of our cell therapy systems or any other biotherapeutic candidates within the next few years, and we may never generate sales of these products. We anticipate that our expenses will increase in the future as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our therapeutic candidates, scale- up manufacturing capabilities and hire additional personnel to support the development of our therapeutic candidates and commercialization efforts. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To achieve and maintain profitability, we must successfully develop our therapeutic candidates, obtain regulatory approvals and manufacture, market and sell those products for which we obtain regulatory approvals. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our therapeutic candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third- party payors and adequate market share for our therapeutic candidates in those markets. We may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our company could cause you to lose part or all of

your investment. Our audited consolidated financial statements as of and for the year ended December 31, ~~2022~~ **2023** have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred significant losses since our inception and we expect that we will continue to incur losses as we aim to successfully execute our business plan and will be dependent on additional public or private financings, collaborations or licensing arrangements with strategic partners, or additional credit lines or other debt financing sources to fund continuing operations. Based on our cash balances, recurring losses since inception and our existing capital resources to fund our planned operations for a twelve- month period, there is substantial doubt about our ability to continue as a going concern. As noted below, we may need to obtain additional funding from equity or debt financings, which **may be highly dilutive to our existing stockholders and** may require us to agree to burdensome covenants, grant security interests in our assets, enter into collaboration and licensing arrangements that require us to relinquish commercial rights, or grant licenses on terms that are not favorable. No assurance can be given at this time as to whether we will be able to achieve our fundraising objectives, regardless of the terms. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations. We will require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts. Our operations have consumed substantial amounts of cash since inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts, including our planned clinical trials for our cell therapy candidates. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. We anticipate that our expenses will increase substantially if and as we: • continue the research and clinical development of our therapeutic candidates; • initiate and advance our therapeutic candidates in expensive clinical studies, including the ongoing Phase III pivotal trial for our CardiAMP Cell Therapy System therapeutic candidate in heart failure, our approved Phase III pivotal trial for our CardiAMP Cell Therapy System therapeutic candidate in chronic myocardial ischemia and our two approved Phase I / II clinical trials for our **allogeneic** ~~Neurokinin- 1 Receptor Positive mesenchymal stem cells (NK1R~~ MSC ~~)~~ therapy in for the treatment of cardiac and pulmonary disease; • seek to identify, assess, acquire, and / or develop other product candidates and technologies; • seek regulatory and marketing approvals in multiple jurisdictions for our therapeutic candidates that successfully complete clinical studies; • build and maintain a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, or otherwise establish collaborations with third parties for the development and commercialization of our therapeutic candidates; • further develop and implement our manufacturing processes and expand our manufacturing capabilities and resources for commercial production; • seek coverage and reimbursement from third- party payors, including government and private payors for future products; • seek to maintain, protect and expand our intellectual property portfolio; and • seek to attract and retain skilled personnel. We have experienced delays, and if we were to experience any future delays or encounter issues with any of the above, including clinical holds, failed studies, inconclusive or complex results, safety or efficacy issues, or other regulatory challenges that require longer follow- up of existing studies, additional major studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above. Further, the net operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. Our existing and any future contractual arrangement that we expect will provide us access to capital may provide less capital than expected and on a delayed basis. We have, and may in the future enter into, contractual arrangements that are designed to facilitate our access to capital. **In December** ~~We entered into a purchase agreement with Lincoln Park Capital Fund, LLC (LPC Purchase Agreement) in March 2021~~ **2023** ~~, pursuant to which Lincoln Park committed to purchase up to $ 20 million of shares our common stock (LPC Facility), and in March 2022~~ , we entered into a sales agreement (**HCW** Sales Agreement) with ~~Cantor Fitzgerald~~ **H. C. Wainwright** & Co. **, LLC** (~~Cantor~~ **HCW**) pursuant to which we may sell shares of our common stock through ~~Cantor~~ **HCW** as the ~~Sales~~ **sales** ~~Agent~~ **agent** at current market prices (**HCW** ATM Offering). However, there are limitations to the **HCW** ~~LPC Facility and the~~ ATM Offering. Specifically, ~~our ability to sell shares under~~ the **HCW** ~~LPC Facility is limited by the terms and conditions in the LPC Purchase Agreement, including restrictions on the amounts we may sell to Lincoln Park at any one time, and a limitation on our ability to sell shares to Lincoln Park to the extent that it would cause Lincoln Park to beneficially own more than 9. 99 % of our outstanding shares of common stock. Additionally, under the LPC Purchase Agreement, we will only be able to sell or issue to Lincoln Park a maximum aggregate number of shares equal to 19. 99 % of the shares of common stock outstanding on the date of the LPC Purchase Agreement (Exchange Cap), unless we obtain shareholder approval to issue shares in excess of the Exchange Cap, or the average price of all applicable sales of our common stock to Lincoln Park under the LPC Purchase Agreement is equal to or greater than the base price of $ 4. 2736, such that the Exchange Cap would not apply to issuances and sales of common stock to Lincoln Park under the LPC Purchase Agreement. Furthermore, the~~ ATM Offering is limited by the terms and conditions in the **HCW** Sales Agreement ~~with Cantor~~ . Under the terms of the **HCW** Sales Agreement, the obligations of ~~Cantor~~ **HCW** are only to use reasonable efforts to sell shares **of** our common stock, but there is no actual obligation to sell or guarantee that we will be able to place any shares. We are also limited in the amount we may sell under the **HCW** Sales Agreement to the amount that is covered by an effective registration statement with the Securities and Exchange Commission **(SEC)** , the current amount of which is approximately $ ~~8~~ **2** . ~~5~~ **2** million. Therefore, we currently do not, and may not in the future, have access to the full amount otherwise available to us under the **HCW** ~~LPC Facility,~~ ATM Offering or any similar contractual arrangement we may enter into in the future. In addition, any amounts we sell under the **HCW** ~~LPC Facility and~~ ATM Offering ~~may~~ **will** not satisfy all of our funding needs or may not fund them on a timely basis, even if we are able and

choose to sell and issue all of our common stock otherwise issuable pursuant to the **HCW** ~~LPC Purchase Agreement and~~ Sales Agreement ~~, respectively~~ . Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. We regularly maintain cash balances at third- party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. A failure of a depository institution to return these deposits, or if a depository institution is subject to other adverse conditions in the financial or credit markets, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history and do not expect to become profitable in the near future and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Losses generated after 2017 do not have an expiration date. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards, or NOLs, and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. None of our pre- Merger tax attributes remain available after the Merger as a result of limitations under Section 382 of the Code. Further, our prior equity offerings and other changes in our stock ownership may have resulted in ownership changes. We have not performed an analysis to assess whether an ownership change has occurred. If we have experienced an ownership change at any time since our formation, utilization of our net operating loss carryforwards would be subject to an annual limitation under Section 382 and 383 of the Code. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carryforwards to offset U. S. federal taxable income and tax credits may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Use of these NOLs will depend on future income in relationship to expiration dates of these carryforwards. Recent U. S. tax legislation and future changes to applicable U. S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations. We are subject to income and other taxes in the U. S. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U. S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. For example, beginning in 2022, the legislation commonly known as the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Code. If the requirement to capitalize Section 174 expenditures is not modified, it may impact our effective tax rate and our cash tax liability in future years. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U. S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U. S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations. Changes with respect to the transition to a territorial tax system are generally expected to have little impact given our lack of foreign operations. Risks Relating to Development and Commercialization Our success depends in large part on our ability to obtain approval for, and successfully commercialize, the CardiAMP Cell Therapy System. The long- term viability of our company is largely dependent on the successful development and commercialization of the CardiAMP Cell Therapy System. We are currently enrolling patients in a Phase III pivotal trial that will be used to support regulatory approval, and we do not have significant long- term data on the CardiAMP Cell Therapy System' s safety and efficacy in either heart failure or chronic myocardial ischemia. While we expect to successfully complete our ongoing Phase III pivotal ~~trial~~ **trials** of the CardiAMP Cell Therapy System in heart failure, there can be no guarantee that the ~~study~~ **studies** will be completed, that the primary endpoints will be achieved **, as they were not in the CardiAMP HF Trial** , or that we will receive regulatory approval for the sale and marketing in the United States. Additionally, while we monitor and audit our and our CROs' activities and data during clinical development, there can be no guarantee that the data we obtain in such activities will be accurate and complete. Our success depends on the accuracy and completeness of such data, and our prospects may be adversely affected if we apply inaccurate or incomplete data in making future decisions. A number of companies in similar fields have suffered significant setbacks during clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Because we are depending heavily on sales of the CardiAMP Cell Therapy System to achieve our revenue goals, failure to successfully complete the study and receive FDA approval, in a timely manner or at all, will harm our financial results and ability to become profitable. Even if we obtain regulatory approval, our ability to successfully market this product will be limited due to a number of factors, including regulatory restrictions in our labeling or requirements to obtain additional post- approval data, if any. In addition, there can be no guarantee that the CardiAMP Cell Therapy System will be accepted by the medical community as a valid alternative to currently available products. If we cannot sell the CardiAMP Cell Therapy System as planned, our financial results will be harmed. FDA acceptance of a Phase III pivotal trial is not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. Failure to successfully complete our ongoing Phase III trial of CardiAMP in heart failure would significantly impair our financial results. Such a failure could (i) delay or prevent the CardiAMP Cell Therapy System from obtaining regulatory approval, (ii) require us to perform another clinical trial, which will be expensive, may not be successful and will significantly delay our ability to commercialize the CardiAMP Cell Therapy System and (iii) impair our ability to convince hospitals and physicians of the benefits of our CardiAMP Cell Therapy System product. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the

indicated uses for CardiAMP, which may limit the market for this product. Because the CardiAMP Cell Therapy System is, to our knowledge, the first cardiac cell- based therapy with an accepted pivotal trial that is to be regulated by the FDA via the premarket approval pathway, the approval process for the CardiAMP Cell Therapy System is uncertain. Although we have obtained FDA acceptance of Phase III pivotal trials of the CardiAMP Cell Therapy System for the treatment of HFrEF and chronic myocardial ischemia, this does not guarantee any particular outcome from regulatory review. To the best of our knowledge, the CardiAMP Cell Therapy System for the treatment of HFrEF is the first cardiac cell- based therapy with an accepted pivotal trial that is to be regulated by the FDA Center for Biologics Evaluation and Research, or CBER, via the premarket approval, or PMA, pathway requiring a single trial. The CardiAMP Cell Therapy System for the treatment of chronic myocardial ischemia is also to be regulated under the same IDE / PMA pathway. All other cardiac cell- based therapies in clinical trials are believed to be regulated by the same agency, but as biologics which generally require two separate pivotal trials. There is no guarantee that the FDA will grant us regulatory clearance or approval to market the CardiAMP Cell Therapy System on the basis of ~~a~~ **the two clinical trials in heart failure or the** single pivotal trial **in chronic myocardial ischemia** , or that the FDA will continue to allow us to develop the CardiAMP Cell Therapy System via the PMA pathway. Two well-controlled pivotal studies could be necessary to provide FDA assurance of safety or effectiveness. If the FDA approval process does not occur as we anticipate **, including,** ~~or~~ **for example, if** we are required to conduct more than ~~one~~ **the currently anticipated number of** pivotal ~~study~~ **studies** to obtain approval, we may incur substantial additional costs and delays to obtain approval, if at all, which would have a material adverse impact on our business, financial condition and prospects. Our autologous and allogeneic therapies, delivery systems and other therapeutic candidates are based on novel technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. At the moment, no cell- based therapies have been approved in the United States for a cardiac indication. The success of our business depends on our ability to develop and commercialize our therapeutic candidates, including CardiAMP. We have concentrated our product research and development efforts on our CardiAMP therapeutic candidate, a novel type of cell- based therapy. Our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience related to our therapeutic candidates and products, that we have experienced or that we may experience in the future, will not cause significant delays or unanticipated costs, or that such development problems can be solved. For example, in 2020, our ~~efforts~~ **effort** to lift a clinical hold on our allogeneic cell therapy product candidate was not successful when reviewed by the FDA due to issues they identified with respect to our chemistry, manufacturing and controls for the approach we had taken. Each element of an IND submission has technical, regulatory, commercial, and other risks and there is no guarantee we will be successful in advancing our therapeutic programs. Also, we may be unable to maintain and further develop sustainable, reproducible and scalable manufacturing processes, or transfer these processes to collaborators, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, the clinical study requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, intended use and market of the potential product candidates. The regulatory approval process for novel product candidates such as our CardiAMP Cell Therapy System and allogeneic cell therapies may be more expensive and take longer than other, better known or extensively studied pharmaceutical or other product candidates to develop. In addition, adverse developments in clinical trials of cell- based products or therapies conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our therapeutic candidates. At the moment, no other cell- based therapies have been approved in the United States for a cardiac indication, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our therapeutic candidates in either the United States or elsewhere. Regulatory requirements governing cell- based therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Cellular, Tissue and Gene Therapies within CBER to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These regulatory authorities and advisory groups and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our products could be reviewed by the FDA' s advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. We have encountered, and may in the future encounter, substantial delays in our clinical studies. We have encountered, and may in the future encounter, substantial delays in our clinical studies. We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve our expected clinical milestones. A failure can occur at any stage of testing. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include: • delays in raising, or inability to raise, sufficient capital to fund the planned trials; • delays in reaching a consensus with regulatory agencies on trial design; • changes in trial design; • inability to identify, recruit and train suitable clinical investigators; • inability to add new clinical trial sites; • delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations, or CROs, and clinical trial sites; • delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site; • delays in recruiting suitable clinical sites and patients (i. e., subjects) to participate in clinical trials; • imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites; • failure by us, CROs or other third parties to adhere to clinical trial requirements; • failure to perform in accordance with the FDA' s current Good Clinical Practices, or GCP, or applicable

regulatory guidelines in other countries; • delays in the testing, validation, manufacturing and delivery to the clinical sites; • delays caused by patients not completing participation in a trial or not returning for post- treatment follow- up; • delays caused by clinical trial sites not completing a trial; • failure to demonstrate adequate efficacy; • occurrence of serious adverse events in clinical trials that are associated with the therapeutic candidates or products that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or • disagreements between us and the FDA or other regulatory agencies interpreting the data from our clinical trials **, including the determination from the DSMB to recommend pausing our Phase III pivotal CardiAMP Cell Therapy Trial pending the one- year follow- up outcomes analysis** . Delays, including those caused by the above factors, can be costly and could negatively affect our ability to complete clinical trials for our therapeutic candidates. If we are not able to successfully complete clinical trials or are not able to do so in a timely and cost- effective manner, we will not be able to obtain regulatory approval and / or will not be able to commercialize our therapeutic candidates or products, which would have an adverse effect on our business. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates or products or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates or products and may harm our business and results of operations. We may find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our therapeutic candidates. Identifying and qualifying patients to participate in clinical trials of our therapeutic candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our therapeutic candidates as well as completion of required follow- up periods. In general, if patients are unwilling to participate in our cell- based therapy trials because of negative publicity from adverse events in the biotechnology or cell- based industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval for our therapeutic candidates may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our therapeutic candidates or termination of the clinical trials altogether. Patient enrollment and completion of clinical trials are affected by factors including: • size of the patient population; • severity of the disease under investigation; • design of the trial protocol; • eligibility criteria for the particular trial; • perceived risks and benefits of the product candidate being tested; • proximity and availability of clinical trial sites for prospective patients; • availability of competing therapies and clinical trials; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • ability to monitor patients adequately during and after treatment; and • the degree of treatment effect in event- driven trials. Once enrolled, patients may choose to discontinue their participation at any time during the trial, for any reason. Participants also may be terminated from the study at the initiative of the investigator, for example if they experience serious adverse clinical events or do not follow the study directions. If we are unable to maintain an adequate number of patients in our clinical trials, we may be required to delay or terminate an ongoing clinical trial, which would have an adverse effect on our business. We depend on our license and distribution agreement with Biomet Biologics, LLC, and if we fail to comply with our obligations under this agreement, or if our rights under this agreement are otherwise reduced or terminated, we could lose intellectual property rights that are important to our business. We are a party to a license and distribution agreement with Biomet Biologics, LLC under which we obtained an exclusive, nontransferable, worldwide distribution right, patent license and trademark license to Biomet Biologic, LLC' s point of care cell processing platform. Under the terms of the agreement, we are obligated to pay Biomet Biologics, LLC a royalty based on the price of the disposables in the CardiAMP cell processing platform. A breach or termination of this agreement would materially adversely affect the clinical development or commercialization strategy of our CardiAMP therapeutic candidate as currently planned. A reduction or elimination of our rights under this agreement may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business as currently planned. The occurrence of such events could materially harm our business and financial condition. We rely on third parties to conduct some or all aspects of our product manufacturing, diagnostic protocol development, research, and preclinical and clinical testing, and these third parties may not perform satisfactorily. We do not currently, and do not expect to in the future, independently conduct all aspects of our product manufacturing, anticipated companion diagnostic testing, protocol development, research and monitoring and management of our ongoing preclinical and clinical programs. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, our commercialization activities or our therapeutic candidate or companion diagnostic development activities may be delayed or suspended. Our reliance on these third parties for research and development activities, including the conduct of any IDE and IND- enabling studies, reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. For example, for therapeutic candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IDE and IND- enabling studies and clinical trials are conducted in accordance with the trial plan and protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may be delayed in completing, or unable to complete, the preclinical studies and clinical trials required to support future IDE and IND submissions and approval of our therapeutic candidates. Reliance on third- party manufacturers entails exposure to risks to which we would not be subject if we manufactured the therapeutic candidates or companion diagnostic ourselves, including: • we may be unable to negotiate manufacturing agreements with third parties under commercially reasonable terms; • reduced control over the manufacturing process for our therapeutic candidates and companion diagnostic as a result of using third- party manufacturers for many aspects of manufacturing activities; • termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our therapeutic candidates or companion diagnostic; and •

disruptions to the operations of our third- party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier. Any of these events could lead to delays in the development of our therapeutic candidates, including delays in our clinical trials, or failure to obtain regulatory approval for our therapeutic candidates, or it could impact our ability to successfully commercialize our current therapeutic candidates, companion diagnostic or any future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure or total or partial suspension of production. We rely on third parties to conduct, supervise and monitor 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 for or commercialize our product candidates and our business could be substantially harmed. We rely on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with the FDA' s GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA, the EMA, or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our therapeutic candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our therapeutic candidates. If any such event were to occur, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We may also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our therapeutic candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue. We depend on third- party vendors to manufacture some of our components and sub- assemblies, which could make us vulnerable to supply shortages and price fluctuations that could harm our business. We currently manufacture some of our components and sub- assemblies internally and rely on third- party vendors for other components and sub- assemblies used in our products and therapeutic candidates. Our reliance on third- party vendors subjects us to a number of risks that could impact our ability to manufacture our products and therapeutic candidates and harm our business, including: • interruption of supply resulting from modifications to, or discontinuation of, a supplier' s operations; • delays in product shipments resulting from uncorrected defects, reliability issues or a supplier' s failure to consistently produce quality components; • price fluctuations due to a lack of long- term supply arrangements with our suppliers for key components; • inability to obtain adequate supply in a timely manner or on commercially reasonable terms; • difficulty identifying and qualifying alternative suppliers for components in a timely manner; • inability of the manufacturer or supplier to comply with Quality System Regulations, or QSRs, enforced by the FDA and state regulatory authorities; • inability to control the quality of products manufactured by third parties; • production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and • delays in delivery by our suppliers due to changes in demand from us or their other customers. Any significant delay or interruption in the supply of components or sub- assemblies, or our inability to obtain substitute components, sub- assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business. Our future commercial success depends upon attaining significant market acceptance of our therapeutic candidates, if approved, among physicians, patients and healthcare payors. Even when product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians, payors and patients. Many potential market participants have limited knowledge of, or experience with, cell- based products and therapies, so gaining market acceptance and overcoming any safety or efficacy concerns may be more challenging than for more traditional therapies. Our efforts to educate the medical community and third- party payors on the benefits of our therapeutic candidates may require significant resources and may never be successful. Such efforts to educate the marketplace

may require more resources than are required by conventional therapies marketed by our competitors. We cannot assure you that our products will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The market acceptance of each of our therapeutic candidates will depend on a number of factors, including: • the efficacy and safety of the therapeutic candidate, as demonstrated in clinical trials; • the clinical indications for which the product is approved, and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label; • acceptance by physicians and patients of the product as a safe and effective treatment; • the cost, safety and efficacy of treatment in relation to alternative treatments; • the continued projected growth of markets for our various indications; • relative convenience and ease of administration; • the prevalence and severity of adverse side effects; and • the effectiveness of our sales and marketing efforts. Market acceptance is critical to our ability to generate significant revenue. Any therapeutic candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer. Our ability to compete is highly dependent on demonstrating the benefits of CardiAMP to physicians, hospitals and patients. In order to generate sales, we must be able to clearly demonstrate that CardiAMP is both a more effective treatment system and less costly than alternative products and treatments offered by our competitors. If we are unable to convince physicians that CardiAMP leads to significant improvement in functional capacity, improved quality of life and reduced hospitalization, our business will suffer. We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do. Our industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market, including AstraZeneca, Bayer, Blue Rock Therapeutics, Bristol- Myers Squibb, Lisata Therapeutics, Capricor Therapeutics, Celixir, Celyad, Daiichi Sankyo, Fuji Film, Mesoblast, Moderna, Orizuru Therapeutics, Sana Biotechnology, Takeda Pharmaceuticals, Tenaya Therapeutics, Terumo, Vericel Corp, and uniQure, among others. Many of our competitors, potentially including the aforementioned, have significantly greater development, financial, manufacturing, marketing, technical and human resources than we do. Large pharmaceutical and medical device companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical and medical device products. Recent and potential future merger and acquisition activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Established companies may also invest heavily to accelerate discovery and development of novel products that could make our therapeutic candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and / or FDA approval or discovering, developing and commercializing our therapeutic candidates or competitors to our therapeutic candidates before we do. Specialized, smaller or early- stage companies may also prove to be significant competitors, particularly those with a focus and expertise in the stem cell industry and / or those with collaboration arrangements and other third- party payors. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and results of operations will suffer. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our therapeutic candidates, if approved, we may be unable to generate any revenues. We currently have a limited organization for the sales, marketing and distribution of products and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market any products that may be approved, including the **autologous** CardiAMP Cell Therapy System and our ~~Neurokinin- 1 Receptor Positive~~ allogeneic **MSC** therapies, we must build our sales, distribution, marketing, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. We have limited prior experience in the marketing, sale or distribution of approved products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our therapeutic candidates. Our strategy is to obtain FDA approval and market the CardiAMP Cell Therapy System for potential heart failure and chronic myocardial ischemia indications using a dedicated direct sales model focused on selected cardiologists and interventional cardiologists. We may in the future, choose to align ourselves with collaborators as part of our commercialization strategy, particularly outside of the United States, and our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our therapeutic candidates or companion diagnostic or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our therapeutic candidates and companion diagnostic to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our therapeutic candidates or companion diagnostic, our ability to generate revenues from product sales, including sales of the CardiAMP Cell Therapy System and other therapies, will be adversely affected. Building an internal sales force involves many challenges, including: • recruiting and retaining talented people; • training employees that we recruit; • setting the appropriate system of incentives; • managing additional headcount; and • integrating a new business unit into an existing corporate architecture. If we are unable to build our own sales force or negotiate a strategic partnership for the commercialization of our autologous or allogeneic cell therapies in the United States, we may be forced to delay the potential commercialization of these therapies or reduce the scope of our sales and marketing. To fund commercialization activities, we will need to obtain additional capital, which may not be available to us on

acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our therapies to market or generate product revenue. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third- party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time- consuming and could delay any launch. If the commercial launch of a therapeutic candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We have limited experience manufacturing our therapeutic candidates or products in commercial quantities, which could harm our business. Because we have only limited experience in manufacturing therapeutic candidates or products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following: • we intend to significantly expand our manufacturing capacity, and our production processes may have to change to accommodate this growth; • key components and sub- assemblies of our products and therapeutic candidates are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub- assemblies; if we experience a shortage in any of these components or sub- assemblies, we will need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays; • we may experience a delay in completing validation and verification testing for new controlled- environment rooms at our manufacturing facilities; • we have limited experience in complying with FDA' s QSRs, which applies to the manufacture of our products and therapeutic candidates; and • to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for our manufacturing operations. If we fail to obtain and sustain an adequate level of reimbursement for our products by third- party payors, sales and profitability would be adversely affected. Our ability to commercialize any therapeutic candidates or products successfully will depend, in part, on the extent to which coverage and reimbursement for our therapeutic candidates or products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, our revenue and profitability could be materially and adversely affected. Third-party payors, such as government programs, including Medicare in the United States, or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for medical products and services, and many third- party payors limit coverage of or reimbursement for newly approved therapies or products. Reimbursement rates and coverage from private health insurance companies vary depending on the company, the insurance plan and other factors. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our therapeutic candidates to each private health insurance company separately, with no assurance that adequate coverage and reimbursement will be obtained. A current trend in the U. S. healthcare industry as well as in other countries around the world is toward cost containment, including a number of legislative and regulatory changes to the health care system that could impact our ability to sell our approved therapies or products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States, which has resulted in lower rates of reimbursement. In 2010, the Affordable Care Act was enacted. This expansion in the government' s role in the U. S. healthcare industry may further lower rates of reimbursement. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through ~~2027~~ **2032** unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, on our financial operations. In 2017, the European Union released new regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in- vitro diagnostics that were to go into effect over a three- year period from 2020 to 2022. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated. Adjusting to the new Medical Device Regulation may prove to be costly and disruptive to our business. In February 2023, the European Parliament voted to extend the Medical Devices Regulation transition periods to avoid a shortage of life- saving products in the economic region. It is expected that conformity assessment process for MDR needs to be completed by the end of 2027 for high- risk devices and the end of 2028 for lower- risk devices **. For business reasons, we may forgo our CE Mark in the future to focus our resources in the U. S. market** . Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. In particular, third- party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish, which could result in revenue and profitability being lower than anticipated. There may be significant delays in obtaining coverage and reimbursement for newly approved therapies or products, and coverage may be more limited than the purposes for which the therapy or product is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a therapy or product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution

expenses. Interim reimbursement levels, if applicable, may also be insufficient to cover our and any partner' s costs and may not be made permanent. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved therapies or products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize therapies or products and our overall financial condition. Furthermore, reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country- by- country basis. In many countries, therapies or products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and / or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices which are not sufficient to allow us to generate a profit, this would adversely affect sales and profitability. We work with outside scientists and their institutions in developing therapeutic candidates and products. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise. We work with scientific advisors and collaborators at academic research institutions in connection with our development programs. These scientific advisors serve as our link to the specific pools of trial participants we are targeting in that these advisors may: • identify individuals as potential candidates for study; • obtain their consent to participate in our research; • perform medical examinations and gather medical histories; • conduct the initial analysis of suitability of the individuals to participate in our research based on the foregoing; and • collect data and biological samples from trial participants periodically in accordance with our study protocols. These scientists and collaborators are not our employees, rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business. If the market opportunities for our therapeutic candidates or products are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer. It is very difficult to estimate the future commercial potential of the CardiAMP Cell Therapy System, the ~~Neurokinin- 1 Receptor Positive~~ allogeneic **MSC** therapies and our commercialized products due to factors such as safety and efficacy compared to other available treatments, changing standards of care, third- party payor reimbursement standards, patient and physician preferences, and the availability of competitive alternatives that may emerge. We believe that approximately 70 % of the NYHA Class II and Class III HFrEF patients in the United States will be eligible for CardiAMP due to a sufficient CardiAMP cell population **score and a sufficient NTproBNP** score. However, if considerably less than approximately 70 % of NYHA Class II and Class III ischemic heart failure patients are eligible for CardiAMP due to an insufficient CardiAMP cell population analysis **or due to lower NTproBNP levels** , it ~~would~~ **could** significantly and negatively impact our business, financial condition and results of operations. Risks Relating to Government Regulation, Compliance and Litigation Even if we obtain regulatory approval for a product candidate, including our **autologous** CardiAMP Cell Therapy System, **CardiALLO** ~~Neurokinin- 1 Receptor Positive~~ allogeneic **MSC** therapy and other therapeutic candidates, these products or therapies, along with our other regulated products, will be subject to ongoing regulatory scrutiny. Even if we obtain regulatory approval or clearance in a jurisdiction, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of our therapeutic candidates or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. For example, once a product receives regulatory approval or clearance for sale, we are obligated to monitor and report adverse events and any failure of a product to meet the specifications in the applicable regulatory approval or clearance. We must also submit new or supplemental applications and obtain FDA approval or clearance for certain changes to the approved or cleared product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices or QSRs and adherence to commitments made in the applicable regulatory approval. If we or 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 relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of any of our therapeutic candidates, a regulatory agency may impose the following: • restrictions on the marketing or manufacturing of our products, withdrawal of our products from the market, or voluntary or mandatory product recalls; • costly regulatory inspections; • fines, warning letters, or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of applicable regulatory approvals; • product seizure or detention, or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties by FDA or other regulatory bodies. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our therapeutic candidates and generate revenues. We may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies. We have not obtained regulatory approval for either our CardiAMP Cell Therapy System, **CardiALLO** ~~Neurokinin- 1 Receptor Positive~~ allogeneic **MSC** therapies or other therapeutic candidates. We must conduct extensive testing of our therapeutic candidates to demonstrate their safety and efficacy, including human clinical trials and, if applicable, preclinical animal testing, before we can obtain regulatory approval to market and sell them. Conducting such

testing is a lengthy, time- consuming, and expensive process and there is a high rate of failure. Our current and completed preclinical and clinical results for our therapeutic candidates are not necessarily predictive of the results of our ongoing or future clinical trials. Promising results in preclinical studies of a therapeutic candidate may not be predictive of similar results in humans during clinical trials, and successful results from early human clinical trials of a therapeutic candidate may not be replicated in later and larger human clinical trials or in clinical trials for different indications. If the results of our ongoing or future clinical trials are negative or inconclusive with respect to the efficacy of our therapeutic candidates or if we or they do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our therapeutic candidates, we may be prevented or delayed in obtaining marketing approval for our therapeutic candidates. If we fail to obtain and maintain necessary regulatory clearances or approvals for our therapeutic candidates or products, or if clearances or approvals for our therapeutic candidates or products in additional indications are delayed or not issued, our commercial operations would be harmed. We are required to timely file various reports with the FDA, require that we report to the regulatory authorities if our therapeutic candidates or products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. If we initiate a correction or removal to reduce a risk to health posed, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a product recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our therapeutic candidates or products. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our therapeutic candidates or products to ensure that the claims we make are consistent with our regulatory approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions: • adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recall or seizure of our products; • operating restrictions, partial suspension or total shutdown of production; • refusing our requests for premarket approval of new products, new intended uses or modifications to existing products; • withdrawing premarket approvals that have already been granted; and • criminal prosecution. If any of these events were to occur, our business and financial condition would be harmed. Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our therapeutic candidates or products or limit the scope of any approved indication or market acceptance. Participants in clinical trials of our investigational cell- based therapies and products may experience adverse reactions or other undesirable side effects. While some of these can be anticipated, others may be unexpected. We cannot predict the frequency, duration, or severity of adverse reactions or undesirable side effects that may occur during clinical investigation. If any of our therapeutic candidates or products, prior to or after any approval for commercial sale, cause adverse events or are associated with other safety risks, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend (e. g., through a clinical hold) or terminate clinical trials; • regulatory authorities may deny regulatory approval of our therapeutic candidates or products; • regulatory authorities may restrict the indications or patient populations for which a therapeutic candidate or products is approved; • regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and / or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy, or REMS, in connection with approval, if any; • regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS than any therapeutic candidate or product that is approved; • we may be required to change the way the therapy or therapeutic candidate or product is administered or conduct additional clinical trials; • patient recruitment into our clinical trials may suffer; • we could be required to provide compensation to subjects for their injuries, e. g., if we are sued and found to be liable or if required by the laws of the relevant jurisdiction or by the policies of the clinical site; or • our reputation may suffer. There can be no assurance that adverse events associated with our therapeutic candidates or products will not be observed, even where no prior adverse events have occurred. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our therapeutic candidates or products are unlikely to receive regulatory approval or are unlikely to be successfully commercialized. Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial for any reason this would have an adverse effect on our business. Our therapeutic candidates are intended to treat patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to our therapeutic candidates. Generally, patients remain at high risk following their treatment with our autologous and allogeneic therapeutic candidates. As a result, it is likely that we will observe severe adverse outcomes during our clinical trials for these therapeutic candidates, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to our therapeutic candidates, our ability to obtain regulatory approval for the applicable therapeutic candidate may be adversely impacted and our business

could be materially harmed. If we or our suppliers fail to comply with the FDA' s QSRs, our manufacturing operations could be delayed or shut down and product sales could suffer. Our manufacturing processes and those of our third- party suppliers are required to comply with the FDA' s QSRs, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. **Further, the FDA recently issued a final rule replacing the QSR with QMSR, which goes into effect in February 2026.** Failure to take adequate corrective action in response to an adverse Quality System inspection **or failure to comply with applicable regulatory requirements** could result in, among other things, a shut- down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays and cause our revenues to decline. We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. The FDA has broad post- market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. If the FDA or CDHS inspect our facility and discover compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility, we may be unable to produce our products, which may have an adverse impact on our business. The requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time- consuming, and unpredictable. If we are unable to obtain timely regulatory approval for our therapeutic candidates, our business may be substantially harmed. The regulatory approval process is expensive, and the time and resources required to obtain approval from the FDA or other regulatory authorities in other jurisdictions to sell any therapeutic candidate or product is uncertain and approval may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the discretion of the regulatory authorities. For example, governing legislation, approval policies, regulations, regulatory policies, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a therapeutic candidate' s clinical development and may vary among jurisdictions. It is possible that none of our existing or future therapeutic candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. Further, regulatory requirements governing cell- based therapy products in particular have changed frequently and may continue to change in the future. For example, in November 2014, Japan' s parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or PMD Act, establishes a framework for expedited approval in Japan for regenerative medical products. As this is a new regulation, it is not clear yet what impact it will have on the operation of our business. Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our therapeutic candidates or products or lead to significant post- approval limitations or restrictions. As we advance our therapeutic candidates or products, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our therapeutic candidates or products. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a therapeutic candidate or product to market could decrease our ability to generate sufficient revenue to maintain our business. Our therapeutic candidates could fail to receive regulatory approval for many reasons, including the following: • we may be unable to successfully complete our ongoing and future clinical trials of therapeutic candidates; • we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a therapeutic candidate is safe, pure, and potent for any or all of a therapeutic candidate' s proposed indications; • we may be unable to demonstrate that a therapeutic candidate' s benefits outweigh the risk associated with the therapeutic candidate; • the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials; • the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval; • the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • a decision by the FDA, other regulatory authorities or us to suspend or terminate a clinical trial at any time; • the data collected from clinical trials of our therapeutic candidates may be inconclusive or may not be sufficient to obtain regulatory approval in the United States or elsewhere; • the inability to obtain sufficient quantities of the therapeutic candidates for use in clinical trials; • our third- party manufacturers of supplies needed for manufacturing therapeutic candidates may fail to satisfy FDA or other regulatory requirements and may not pass inspections that may be required by FDA or other regulatory authorities; • the failure to comply with applicable regulatory requirements following approval of any of our therapeutic candidates may result in the refusal by the FDA or similar foreign regulatory agency to approve a pending PMA or BLA, or supplement to a PMA or BLA submitted by us for other indications or new therapeutic candidates or products; and • the approval policies or regulations of the FDA or other regulatory authorities outside of the United States may significantly change in a manner rendering our clinical data insufficient for approval. We may gain regulatory approval for any of our therapeutic candidates in some but not all of the territories available and any future approvals may be for some but not all of the target indications, limiting their commercial potential. Regulatory requirements and timing of product approvals vary from country to country and some jurisdictions may require additional testing beyond what is required to obtain FDA approval.

Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. In addition, regulatory approval does not specify pricing or reimbursement which may not match our expectations based on the results of our clinical data. Even if we obtain and maintain approval for our therapeutic candidates or products from the FDA, we may never obtain approval for our therapeutic candidates or products outside of the United States, which would limit our market opportunities and adversely affect our business. Approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our therapeutic candidates or products, if approved, outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a therapeutic candidate or product must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge, if approved, is also subject to approval. While we may decide to submit a request to the EMA for approval of our therapeutic candidates, including CardiAMP, as Advanced Therapeutic Medicinal Products, or ATMPs, in Europe, obtaining such approval is a lengthy and expensive process and the EMA has its own procedures for approval. Even if a therapeutic candidate or product is approved, the FDA or the EMA, as the case may be, may limit the indications for which it may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of therapeutic candidates or products with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval may be withdrawn. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our therapeutic candidates or products will be harmed and our business will be adversely affected. We may face competition from biosimilars due to changes in the regulatory environment. We may face competition for ~~the~~ **our** allogeneic ~~Neurokinin- 1 Receptor Positive~~ therapies from biosimilars due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be " highly similar, " or biosimilar to, or " interchangeable " with an FDA- approved innovator (original) biological product. This new pathway could allow competitors to reference data from innovator biological products already approved after 12 years from the time of approval. In Europe, a competitor may reference data from biological products already approved but will not be able to get on the market until 10 years after the time of approval. This 10- year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our allogeneic ~~Neurokinin- 1 Receptor Positive~~ therapies, if approved. Additionally, the FDA may approve our competitors' products through a PMA pathway, similar to CardiAMP. If competitors are able to obtain marketing approval for biosimilars referencing **our CardiALLO** ~~Neurokinin- 1 Receptor Positive~~ allogeneic cell therapy, if approved, it may become subject to competition from such biosimilars with the attendant competitive pressure and consequences. We are subject to significant regulation and oversight in the United States. Our failure to comply with these laws could harm our results of operations and financial condition. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse will be applicable to our business. Healthcare fraud and abuse regulations are complex and can be subject to varying interpretations as to whether or not a statute has been violated. The laws that may affect our ability to operate include: • the federal Anti- Kickback Statute which prohibits, among other things, the knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service which may be payable by the federal health care programs (e. g., drugs, supplies, or health care services for Medicare or Medicaid patients); • the federal False Claims Act which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment for government funds (e. g., payment from Medicare or Medicaid) or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim for government funds; • HIPAA, as amended by HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HIPAA imposes civil and criminal liability for the wrongful access or disclosure of protected health information; • the federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended, the ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, those physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; • the federal Food, Drug and Cosmetic Act which prohibits, among other things, the adulteration or misbranding of drugs and devices; • the U. S. Foreign Corrupt Practices Act which

prohibits corrupt payments, gifts or transfers of value to non- U. S. officials; and • non- U. S. and U. S. state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers. The federal fraud and abuse laws have been interpreted to apply to arrangements between medical device and pharmaceutical manufacturers and a variety of health care professional. Although the federal Anti- Kickback Statute has several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, all elements of the potentially applicable exemption or safe harbor must be met in order for the arrangement to be protected, and prosecutors have interpreted the federal healthcare fraud statutes to attack a wide range of conduct by medical device and pharmaceutical companies. In addition, most states have statutes or regulations similar to the federal anti- kickback and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. Further, the ACA, among other things, amended the intent standard under the Anti- Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA makes clear that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim under the federal False Claims Act. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business. Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, Congress amended the privacy and security provisions of HIPAA. HIPAA imposes limitations on the use and disclosure of an individual' s healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non- compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual' s health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U. S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for noncompliance. The European Union' s Data Protection Directive, Canada' s Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state / provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches. A recall of any of our commercialized products, or the discovery of serious safety issues, could have a significant negative impact on us. The FDA and other relevant regulatory agencies have the authority to require or request the recall in the event of material deficiencies or defects in design or manufacture or in the event an unacceptable risk to health. Manufacturers may, under their own initiative, also initiate a recall. A government- mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results. Further, under the FDA' s reporting regulations, we are required to report to the FDA any event that reasonably suggests that our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction of the same or similar product marketed by us were to recur, would likely cause or contribute to death or serious injury. The FDA also requires reporting of serious, life- threatening, unexpected and other adverse experiences and the submission of periodic safety reports and other information. Malfunctions or other adverse event reports may result in a voluntary or involuntary recall and other adverse actions, which could divert managerial and financial resources, impair our ability to manufacture in a cost- effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. Similar reporting

requirements exist in Europe and other jurisdictions. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. For example, in 2014 we notified the FDA that we were going to initiate a voluntary recall of our Morph AccessPro product based on a manufacturing observation, which was completed to the FDA' s satisfaction in the same year, and in 2017 we updated our instructions for use for the Helix ™ and Morph catheter products to provide guidance on known potential risks. There can be no guarantee that we will not experience similar product recalls or changes in the future with these products or our other products or therapeutic candidates, if approved. Modifications to our products may require reclassifications, new regulatory approvals or clearances, or may require us to cease marketing or recall the modified products until new CE marking is obtained. Currently there are ~~eight~~ **a number of** Morph product family model numbers that have been approved for commercial use in the United States via a 510 (k) clearance. A modification to these products could lead to a reclassification and could result in further requirements (including additional clinical trials) to maintain each respective clearance or approval. If we fail to comply with such further requirements, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. The use, misuse or off- label use of our products or therapies, if approved, may result in injuries that lead to product liability suits, which could be costly to our business. We are not permitted to make claims about the use of our marketed products and will not be permitted to make claims about the use of our therapeutic candidates, if approved, outside of their approved indications. Further, we are not and will not be able to proactively discuss or provide information on off- label uses of such products, with very specific and limited exceptions. However, we cannot prevent a physician from using our products or therapeutic candidates, if approved, for off- label applications. Off- label use of our products or therapies, if approved, is more likely to result in complications that have serious consequences. Product liability claims are especially prevalent in our industry and could harm our reputation, divert management' s attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that may be made against us. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA' s refusal to approve a product or therapeutic candidate, the suspension or withdrawal of an approved product or therapy from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions. Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of activity relating to pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee misconduct could also 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, or a breach of insider trading laws. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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 significant impact on our business, including the imposition of significant fines or other sanctions. Price controls may be imposed in foreign markets, which may adversely affect our future profitability. In some countries, particularly European Union member states, Japan, Australia and Canada, the pricing of therapies and products is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapy or product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our therapies or products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be adversely affected. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our therapeutic candidates or products. We face an inherent risk of product liability as a result of the human clinical use of our therapeutic candidates and products and will face an even greater risk if we continue to commercialize our therapeutic candidates and products. For example, we may be sued if any therapy or product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of inherent dangers, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities

or be required to limit commercialization. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand, even if such products or therapies are approved; • injury to our reputation; • withdrawal of clinical trial participants; • costs to defend the related litigations; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • recalls, withdrawals, or labeling, marketing or promotional restrictions; • increased cost of liability insurance; • loss of revenue; • the inability to receive regulatory approvals or commercialize our approved products or therapies; and • a decline in our share price. Although we maintain product liability insurance with coverage that we believe is consistent with industry norms for companies at our stage of development, the amount or breadth of our coverage may not be adequate for the claims that may be made against us. Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products or therapies we develop. Additionally, our insurance policies have various exclusions, and we may be subject to a product liability claim for which we have no coverage or reduced coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Risks Related to the Operation of Our Business If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our therapeutic candidates, conduct our clinical trials and commercialize our therapeutic candidates. We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are " at will " employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations. As we mature and expand our research and development and other pre- commercialization activities, we expect to expand our existing full- time employee base and to hire more consultants and contractors. In addition, we currently plan to commercialize the CardiAMP Cell Therapy System, if approved, using an internal sales force to selected cardiologists, interventional cardiologists and third- party payors in the United States. Our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Our business and operations would suffer in the event of system failures. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and potential collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, our systems have been impacted by computer viruses in the past, and while we have not experienced any material system failure, accident or security breach that has resulted in lasting impacts 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 clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for manufacturing our therapeutic candidates and conducting clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 therapeutic candidates could be delayed. Any cybersecurity breaches or our actual or perceived failure to comply with such legal obligations by us, or by our third- party service providers or partners, could harm our business. We collect, store, process and use our customers' personally identifiable information and other data, and we rely on third parties that are not directly under our control to do so as well. While we take measures intended to protect the security, integrity and confidentiality of the personal information and other sensitive information we collect, store or transmit, we cannot guarantee that inadvertent or unauthorized use or disclosure will not occur, or that third parties will not, gain unauthorized access to this information. There have been a number of recent reported incidents where third parties have used software to access the personal data of their partners' customers for marketing and other purposes. If we or our third- party service providers were to experience a breach, disruption or failure of systems compromising our customers' data, or if one of our third- party service providers or partners were to access our customers' personal data without our authorization, our brand and reputation could be adversely affected, use of our products could decrease and we could be exposed to a risk of loss, litigation and regulatory

proceedings. In addition, a breach could require expending significant additional resources related to the security of information systems and disrupt our operations. The use of data by our business and our business associates is highly regulated in all our operating countries. Privacy and information- security laws and regulations change, and compliance with them may result in cost increases due to, among other things, systems changes and the development of new processes. If we or those with whom we share information fail to comply with laws and regulations, such as the General Data Protection Regulation (GDPR) and California Consumer Privacy Act (CCPA), our reputation could be damaged, possibly resulting in lost business, and we could be subjected to additional legal risk or financial losses as a result of non- compliance. Complying with such laws may also require us to modify our data processing practices and policies and incur substantial expenditures. **See Item 1C " Cybersecurity " of this Annual Report on Form 10- K for additional information about our cybersecurity processes.**

Interruptions in supply or inventory loss may adversely affect our operating results and financial condition. Our therapeutic candidates and products are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for manufacture and storage, subjects us to production risks. While batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product or therapy launches. Any supply interruption or the loss thereof could hinder our ability to timely distribute our approved products and satisfy demand. Any unforeseen storage failure or loss in supply could delay our clinical trials and, if our therapeutic candidates are approved, result in a loss of our market share and negatively affect our revenues and operations. We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. A majority of our management operates in our principal executive offices located in Sunnyvale, California and we currently manufacture our Helix ™ and Morph products at this facility and use it for storage of our clinical trial materials and biobanking. If our Sunnyvale offices were affected by a natural or man- made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. The ultimate impact of any such events on us, our significant suppliers and our general infrastructure is unknown. Our ~~business, financial condition, results of operations, including our preclinical studies and clinical trials, could continue to be harmed by the effect of the COVID- 19 pandemic or other health epidemics and pandemics. We are subject to risks related to public health crises such as the global pandemic associated with the COVID- 19 pandemic. As a result of the COVID- 19 outbreak, we have experienced and may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including: • Fewer individuals undertaking voluntary treatment, including participation in clinical trials, whether due to contracting COVID- 19, self- isolating or quarantining to lower the risk of contracting COVID- 19 or being unable to access care as a result of healthcare providers tending to COVID- 19 patients, resulting in delays or difficulties in enrolling patients in our clinical trials; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • delays or disruptions in non- clinical experiments due to unforeseen circumstances at contract research organizations and vendors along their supply chain; • increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID- 19, being forced to quarantine, or not accepting home health visits; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; • interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non- essential), which may impact the integrity of subject data and clinical study endpoints; • interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact approval timelines; • interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and • limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions. Numerous state and local jurisdictions have imposed, and others in the future may impose, " shelter- in- place " orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID- 19. Multiple times in 2021, the governor of California, where our facilities are located, issued a " shelter- in- place " order restricting non- essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Such orders and restrictions, have resulted in slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Such orders or restrictions may continue or be re- instated,~~

~~thereby causing additional negative impact on our operations. In addition, the spread of more contagious or deadly variants, such as the Delta and Omicron variants, could cause the COVID- 19 pandemic to last longer or be more severe than expected. In addition, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. The extent to which the COVID- 19 pandemic or other viral pandemics may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence. In addition, a recession, further market correction or depression resulting from the spread of COVID- 19 could materially affect our business and the value of our notes and our common stock. Our~~ financial controls and procedures may not be sufficient to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. The effectiveness of our controls and procedures may in the future be limited by a variety of factors, including: • faulty human judgements and simple errors, omissions or mistakes; • fraudulent actions of an individual or collusion of two or more people; • inappropriate management override of procedures; and • the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information. If we identify material weaknesses in our internal control over financial reporting in the future, if we are unable to comply with the requirements of Section 404 in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources **. Risks Relating to Our Intellectual Property We may not be able to protect our proprietary technology in the marketplace** . Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property of our therapeutic candidates and products. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our current therapeutic candidates or products or any future therapeutic candidates or products, or fail to otherwise provide us with any competitive advantage. As such, we do not know the degree of future protection that we will have on our therapeutic candidates or products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our therapeutic candidates or products could have a material adverse impact on our business. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent technology in jurisdictions with significant or otherwise relevant commercial opportunities or activities. However, patent protection may not be available for some of the therapeutic candidates or products we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed. The patent protection of biotherapeutics is complex and uncertain. The scope and extent of patent protection for our therapeutic candidates and products are particularly uncertain. To date, our principal therapeutic candidates have been based on specific subpopulations of known and naturally occurring adult stem cells. We anticipate that the therapeutic candidates or products we develop in the future will continue to include or be based on the same or other naturally occurring stem cells or derivatives or products thereof. Although we have sought and expect to continue to seek patent protection for our therapeutic candidates and products, their methods of use, methods of manufacture, and methods of delivery, any or all of them may not be subject to effective patent protection. Publication of information related to our therapeutic candidates and products by us or others may prevent us from obtaining or enforcing patents relating to these products and therapeutic candidates. Furthermore, others may independently develop similar therapeutic candidates or products, may duplicate our therapeutic candidates or products, or may design around our patent rights. In addition, any of our issued patents may be declared invalid. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic therapeutic candidate or product to compete with our therapeutic candidates or products. Filing, prosecuting and defending patents on therapeutic candidates or products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own therapeutic candidates or products and further, may export otherwise infringing therapeutic candidates or products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These therapeutic candidates or products may compete with our current or future therapeutic candidates or products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing therapeutic candidates or products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly

and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may be unable to adequately prevent disclosure of trade secrets and other proprietary information. We maintain certain of our proprietary know- how and technological advances as trade secrets, especially where we do not believe patent protection is appropriate or obtainable, including, but not exclusively, with respect to certain aspects of the manufacturing of our therapeutic candidates or products. However, trade secrets are difficult to protect. We take a number of measures to protect our trade secrets including, limiting disclosure, physical security and confidentiality and non- disclosure agreements. We enter into confidentiality agreements with our employees, consultants, outside scientific collaborators, contract manufacturing partners, sponsored researchers and other advisors and third parties to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other therapeutic candidates or products that compete with our therapeutic candidates or products or cause additional, material adverse effects upon our business, results of operations and financial condition. We may be forced to litigate to enforce or defend our intellectual property rights, and / or the intellectual property rights of our licensors. We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope and may no longer be used to prevent the manufacture and sale of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office, or the USPTO, may place pending applications at risk of non-issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post- grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and / or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of litigation proceedings more effectively than we can because of their greater financial resources and personnel. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in- license needed technology or enter into strategic collaborations that would help us bring our therapeutic candidates to market. As a result, uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent reform legislation and recent court decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has and continues to develop and implement regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act. The full effect of these changes is currently unclear as the USPTO has not yet adopted all pertinent final rules and regulations, the courts have yet to address these provisions and the applicability of the Leahy- Smith Act and new regulations on specific patents, including our patents discussed herein, have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. As a result, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition. On June 13, 2013, the U. S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, Inc., held that isolated DNA sequences are not patentable because they constitute a product of nature. The Supreme Court did not address stem cells in particular, and as a result, it is not yet clear what, if any, impact this Supreme Court decision or future decisions will have on the operation of our business. **If third parties claim that our therapeutic candidates or other products infringe upon their intellectual property, commercialization of our therapeutic candidates or products and our operating profits could be adversely affected.** There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third- party proprietary technologies we have licensed. Any such claims

could also be expensive and time consuming to defend and divert management' s attention and resources and could delay or prevent us from commercializing our therapeutic candidates or products. Our competitive position could suffer as a result. Although we have reviewed certain third- party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom- to- operate search or analysis for our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third- party' s intellectual property. From time to time, we have reviewed the claims of specific patents owned by third parties. While we have concluded that no claims of any of these patents would be infringed by our products, that all relevant claims would expire before our products would be commercialized, or both, we cannot guarantee that the patent owners would not disagree and conclude that our products would infringe these claims. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of our therapeutic candidates or products, our business may be materially harmed. Depending on the timing, duration and specifics of FDA marketing approval of our therapeutic candidates or products, if any, one of the U. S. patents covering each of such approved therapeutic candidate or product or the use thereof may be eligible for up to five years of patent term restoration under the Hatch- Waxman Act. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our therapeutic candidates, including by the EMA in the European Union or the Pharmaceutical and Medical Devices Agency in Japan. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, if a patent we wish to extend is owned by another party and licensed to us, we may need to obtain approval and cooperation from our licensor to request the extension. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our therapeutic candidates or products will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties for manufacturing, and because we collaborate with various organizations and academic institutions on the advancement of our clinical trials, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. **Risks Related to Our Securities If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our securities could be delisted from the Nasdaq. The listing of our securities on the Nasdaq Capital Market (Nasdaq) is contingent on our compliance with the Nasdaq' s conditions for continued listing. We are currently not in compliance with Nasdaq listing requirements, specifically those that require us to maintain a minimum market value of listed securities of at least $ 35. 0 million (MVLS Requirements) and a minimum $ 1. 00 per share closing bid price for our common stock (Minimum Bid Price Requirement). On March 6, 2024 and March 12, 2024, we received delisting determination letters from the Nasdaq advising us that we did not regain compliance with the MVLS Requirement and the Minimum Bid Price Requirement, respectively, by the initial compliance dates afforded by the Nasdaq. As a result, trading of our securities on the Nasdaq was subject to suspension at the opening of business on March 15, 2024 and a Form 25- NSE would have been filed with the SEC to remove our securities from listing and registration on the Nasdaq unless we requested an appeal of these determinations to a Nasdaq Hearings Panel (Panel). On March 12, 2024, we submitted a hearing request to the Panel to appeal the delisting determinations. Our request for a hearing has stayed the suspension of our securities and the filing of a Form 25- NSE pending the Panel' s decision. At the hearing, we intend to present a plan to regain compliance with the MVLS Requirement and the Minimum Bid Price Requirement. If the Panel does not grant our request for continued listing, or**

otherwise provide a further extension for us to regain compliance with the MVLS Requirement and the Minimum Bid Price Requirement, our securities will be subject to delisting by the Nasdaq. In the event our securities are no longer listed for trading on Nasdaq, our trading volume and share price may decrease and we may experience further difficulties in raising capital, which could materially affect our operations and financial results. Further, delisting from the Nasdaq could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers and employees and could also trigger various defaults under our financing arrangements and other outstanding agreements. The market price and trading volume of our securities may be volatile and may be affected by economic conditions beyond our control. The market price of our securities is likely to be volatile. Some specific factors that could negatively affect the price of our securities or result in fluctuations in its price and trading volume include: • results of clinical trials of our therapeutic candidates; • results of clinical trials of our competitors' products; • regulatory actions with respect to our therapeutic candidates or products or our competitors' products; • actual or anticipated fluctuations in our quarterly operating results or those of our competitors; • publication of research reports by securities analysts about us or our competitors in the industry; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • our liquidity positions; • issuances by us of debt or equity securities; • litigation involving our company, including stockholder litigation, investigations or audits by regulators into the operations of our company, or proceedings initiated by our competitors or clients; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; • the passage of legislation or other regulatory developments affecting us or our industry, fluctuations in the valuation of companies perceived by investors to be comparable to us; • trading volume of our common stock and warrants; • sales or perceived potential sales of our common stock and / or warrants by us, our directors, senior management or our stockholders in the future; • short selling or other market manipulation activities; • announcement or expectation of additional financing efforts; • terrorist acts, acts of war or periods of widespread civil unrest; • natural disasters **, pandemics, such as COVID- 19,** and other calamities; • changes in market conditions for biopharmaceutical stocks; and • conditions in the U. S. financial markets or changes in general economic conditions, including as a result of inflation and changes in interest rates. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, the price and trading volume of our securities could decline. The trading market for our securities will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our securities would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, the price of our securities would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the price or trading volume of our securities to decline. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of ~~December 31~~ **March 27** , ~~2022~~ **2024** , our executive officers, directors, 5 % stockholders and their affiliates beneficially owned approximately ~~25~~ **20** . 1 % of our voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders. As a smaller reporting company, we are subject to scaled disclosure requirements that may make it more challenging for investors to analyze our results of operations and financial prospects. Currently, we are a " smaller reporting company, " as defined by Rule 12b- 2 of the Exchange Act. As a " smaller reporting company, " we are able to provide simplified executive compensation disclosures in our filings and have certain other decreased disclosure obligations in our filings with the SEC, including being required to provide only two years of audited financial statements in annual reports. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects. Furthermore, we are a non- accelerated filer as defined by Rule 12b- 2 of the Exchange Act, and, as such, are not required to provide an auditor attestation of management' s assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404 (b) of the Sarbanes- Oxley Act. Because we are not required to, and have not, had our auditors provide an attestation of our management' s assessment of internal control over financial reporting, a material weakness in internal controls may remain undetected for a longer period. We may be exposed to additional risks as a result of our reverse merger transaction. We may be exposed to additional risks as a result of our " reverse merger " transaction and rules and regulations relating to shell companies or former shell companies. There has been increased focus in recent years by government agencies on transactions such as the reverse merger transaction, and we may be subject to increased scrutiny and / or restrictions by the SEC and other government agencies and holders of our securities as a result of the completion of that transaction. This may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms. The occurrence of any such event could cause our business or stock price to suffer. Our annual and quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to annual and quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including: • variations in the level of expenses related to our therapeutic candidates, products or future development programs; • if any of our therapeutic candidates receives regulatory approval, the level of underlying demand for these therapeutic candidates and wholesalers' buying patterns; • addition or termination of clinical trials or funding support; • our execution of any collaborative, licensing or similar arrangements, and the

timing of payments we may make or receive under these arrangements; • any intellectual property infringement lawsuit in which we may become involved; • regulatory developments affecting our therapeutic candidates or products or those of our competitors; • the timing and cost of, and level of investment in, research and development activities relating to our therapeutic candidates, which may change from time to time; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to acquire or develop additional therapeutic candidates and technologies; • future accounting pronouncements or changes in our accounting policies; • the timing and success or failure of clinical studies for our therapeutic candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; • the risk / benefit profile, cost and reimbursement policies with respect to our therapeutic candidates, if approved, and existing and potential future therapies or biologics that compete with our products or therapeutic candidates; and • the changing and volatile U. S., European and global economic environments, including inflationary pressures and increased federal interest rates. If our annual or quarterly operating results fall below the expectations of investors or securities analysts, the price of our securities could decline substantially. Furthermore, any annual or quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that annual and quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Raising additional funds through debt or equity financing could be **highly** dilutive and may cause the market price of our common stock to decline. **We will attempt to** ~~To the extent that we~~ raise additional capital through the sale of equity or convertible debt securities, including through the **HCW** ~~LPC Purchase Agreement with Lincoln Park or the~~ Sales Agreement ~~with Cantor~~, **which may be highly dilutive to** ~~your~~ **our existing stockholders** ~~ownership interest may be diluted~~, and the terms of these securities may include liquidation or other preferences that adversely affect ~~your~~ **the** rights ~~as a~~ **of our existing** ~~stockholder~~ **stockholders**. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to limit valuable rights to our intellectual property, technologies, therapeutic candidates or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts ~~may~~ **will** divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our therapeutic candidates. Sales of a substantial number of shares of our common stock **or rights to purchase our common stock** could cause our stock price to fall. Sales of a substantial number of shares of our common stock **or rights to purchase our common stock,** or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to the **HCW** ~~LPC Purchase Agreement or the~~ Sales Agreement or under our equity incentive plans, could result in additional dilution of the percentage ownership of our **existing** stockholders and could cause our stock price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders ~~may~~ **would likely** experience substantial dilution. We may sell our common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell our common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales ~~may~~ **would likely** also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Furthermore, ~~under the LPC Agreement, Lincoln Park committed to purchase up to $ 20 million of shares of our common stock. Sales under the LPC Purchase Agreement, if any, would be at our discretion from time to time through March 29, 2024, subject to certain limitations and conditions. Further,~~ we filed a prospectus supplement related to the offer and sale of up to $ ~~10~~ **2** . ~~5~~ **75** million of our common stock under the **HCW** Sales Agreement. Any such **HCW** Sales Agreement sales would be made by ~~Cantor~~ **HCW** on a reasonable efforts basis. Any sales under the **HCW** ~~LPC Purchase Agreement or the~~ Sales Agreement must be in compliance with the terms of such agreement and applicable law and the purchase price for such sales will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall and any such issuances would be dilutive to our existing stockholders. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. **General Risks** If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and

state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business.