**Risk Factors Comparison 2024-04-16 to 2023-03-30 Form: 10-K**

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

An investment in our common stock is subject to risks inherent to our business. The material risks and uncertainties that management believes affect us are described below. Before making an investment decision, you should carefully consider the risks and uncertainties described below together with all of the other information included or incorporated by reference in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are not aware of or focused on or that we currently deem immaterial may also impair our business operations. This Annual Report is qualified in its entirety by these risk factors. If any of the following risks actually occur, our financial condition and results of operations could be materially and adversely affected. If this were to happen, the value of our common stock could decline significantly, and you could lose all or part of your investment. Risks Related to Our Structure and Business A third party owns 20 % of our subsidiary, CARTXpress Bio, Inc. (" CARTXpress Bio "), and holds certain minority investor rights therein. These rights could limit or delay our ability to take certain major actions relating to CARTXpress Bio. In January 2019, ThermoGenesis Corp. contributed its X- Series business into a newly formed subsidiary of ThermoGenesis Corp., CARTXpress Bio. Pursuant to the terms of a reorganization and share exchange agreement, ThermoGenesis Holdings acquired a 20 % equity ownership in ThermoGenesis Corp. from Bay City Capital Fund V, L. P. and certain of its affiliates (" Bay City "). In exchange, Bay City acquired a 20 % ownership in CARTXpress Bio. As a result of these transactions, ThermoGenesis Corp. became a wholly- owned subsidiary of ThermoGenesis Holdings, and ThermoGenesis Corp. owns 80 % of the outstanding equity of CARTXpress Bio, while Bay City owns the remaining 20 % of the outstanding equity of CARTXpress Bio. While we continue to indirectly own 80 % of the outstanding capital stock of CARTXpress Bio, Bay City was granted certain minority investor rights in CARTXpress Bio. These rights include board representation rights, a right of first refusal over sales of CARTXpress Bio. stock by us, co- sale rights with respect to any sale of CARTXpress Bio stock by us, certain piggyback and Form S- 3 registration rights in the event that CARTXpress Bio becomes a publicly traded company at any time in the future and other rights as detailed in the Investors' Rights Agreement. In addition, the board of directors of CARTXpress Bio is comprised of three persons, two of whom are designated by us and one of whom is designated by Bay City. The foregoing minority investor rights in CARTXpress Bio could limit or delay our ability or flexibility to take certain major actions or make major decisions relating to CARTXpress Bio that might be beneficial to our stockholders, unless such actions or decisions have the consent or support of Bay City. Accordingly, the minority investor rights in CARTXpress Bio could have a negative impact on the market price of our common stock. Our largest stockholder has significant influence over us which could limit your ability to influence the outcome of key transactions, including a change of control, and could negatively impact the market price of our common stock by discouraging third party investors. As of December 31, ~~2022~~ **2023**, approximately ~~26~~ **9** % of our outstanding common stock is owned by Boyalife Group USA (" Boyalife "). In addition, pursuant to the terms of the Amended Nomination Agreement we entered into with Boyalife in April 2018, Boyalife has the right to designate a number of members of our board of directors that is in proportion to the " Boyalife Ownership Percentage ", which is Boyalife and its affiliates' combined percentage ownership of outstanding common stock, treating as outstanding any shares of common stock underlying convertible securities that are immediately exercisable by Boyalife and its affiliates' (including under the debt facility) without any further payment. The Amended Nomination Agreement will terminate according to its terms when and if the Boyalife Ownership Percentage falls below 20 %. Boyalife is 100 % owned by Dr. Xiaochun Xu, our Chief Executive Officer and Chairman of our Board of Directors. As a result of their ownership and ability to designate members of our Board of Directors, Boyalife (including Dr. Xu) is able to exercise significant influence over all matters affecting us, including the election of directors, formation and execution of business strategy and approval of mergers, acquisitions and other significant corporate transactions, which may have an adverse effect on our stock price and ability to execute our strategic initiatives. Boyalife and / or Dr. Xu may have conflicts of interest and interests that are not aligned with those of other investors in all respects. As a result of the concentrated ownership of our common stock, Dr. Xu may be able to control matters requiring stockholder approval, including the election of directors, the adoption of amendments to our certificate of incorporation and bylaws, and approval of a sale of our Company, and other significant corporate transactions. This concentration of ownership may delay or prevent a change in control and may have a negative impact on the market price of our common stock by discouraging third party investors from investing or making tender offers for our shares. Boyalife is also a material creditor of our Company. We are a party to a revolving debt facility with Boyalife which has a maximum borrowing availability of $ 10, 000, 000 and an outstanding balance as of December 31, ~~2022~~ **2023** of $ 7, **278,** 000 ~~, 000~~ in principal and $ **634** ~~1, 492~~, 000 in accrued interest. The debt facility, as amended, matures on December 31, ~~2023~~ **2024**, with accrued interest due annually on the last day of each calendar year. Because this debt facility is secured by all of our shares in our ThermoGenesis Corp. subsidiary, an event of default under the debt facility would have a material adverse impact on our interest in ThermoGenesis Corp. if the lender under the debt facility elected to foreclose on such security interest. ~~In addition, we are also a party to a License and Technology Access Agreement and facility lease with affiliates of Dr. Xu and Boyalife upon which our planned CDMO business will be dependent.~~ We may seek to enter into collaborative arrangements to develop and commercialize products which may not be successful. We may seek to enter into collaborative arrangements to develop and commercialize some of our potential products and product candidates both in North America and international markets. There can be no assurance that we will be able to negotiate collaborative arrangements on favorable terms or at all or that current or future collaborative arrangements will be successful. A significant portion of revenue is derived from customers outside the United States. We may lose revenues, market

share, and profits due to exchange rate fluctuations and political and economic changes related to its foreign business. For the year ended December 31, ~~2022~~ **2023** , sales to customers outside the U. S. comprised approximately ~~37~~ **33** % of revenues. This compares to ~~43~~ **37** % for the year ended December 31, ~~2021~~ **2022** . Our foreign business is subject to economic, political and regulatory uncertainties and risks that are unique to each area of the world. Fluctuations in exchange rates may also affect the prices that foreign customers are willing to pay and may put us at a price disadvantage compared to other competitors. Potentially volatile shifts in exchange rates may negatively affect our financial position and results. The loss of a significant customer may adversely affect our financial condition and results of operations. The percentage of revenues from our largest customer were **30 % and** 33 ~~% and 23~~ % for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. The loss of a large customer may significantly decrease revenues. We may be exposed to liabilities under the foreign corrupt practices act and any determination that we violated these laws could have a material adverse effect on our business. We are subject to the Foreign Corrupt Practices Act (" FCPA "), and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U. S. persons and issuers as defined by the statute, for the purpose of obtaining or retaining business. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. Adverse results of legal proceedings could have a material adverse effect on us. We are subject to, and may in the future be subject to, a variety of legal proceedings and claims that arise out of the ordinary conduct of our business. Results of legal proceedings cannot be predicted with certainty. Irrespective of their merits, legal proceedings may be both lengthy and disruptive to our operations and may cause significant expenditure and diversion of management attention. We may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on a portion of our business operations or a material adverse effect on our financial condition and results of operations. Risks Related to Our Operations We do not have commercial- scale manufacturing capability and have minimal commercial manufacturing experience. We operate GMP manufacturing facilities for device production; however, they are not of sufficient size for large commercial production. We do not have experience in large scale manufacturing, and currently rely on third- party contract manufacturers for a significant portion of our device production. We expect to depend on these contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay production of our current or future products, depriving us of potential product revenues and resulting in additional losses. We have limited sales, marketing and distribution capabilities which may limit our ability to significantly increase sales quickly. We have limited internal capabilities in the sales, marketing, and distribution areas. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities internally or make arrangements with current collaborators or others to perform such activities or that such effort will be successful. If we decide to market any of our new products directly, we must either partner, acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, divert the attention of our management and key personnel, and have a negative impact on further product development efforts. Our inability to protect our patents, trademarks, trade secrets and other proprietary rights could adversely impact our competitive position. We believe that our patents, trademarks, trade secrets and other proprietary rights are important to our success and our competitive position. Accordingly, we commit substantial resources to the establishment and protection of our patents, trademarks, trade secrets and proprietary rights. We use various methods, including confidentiality agreements with employees, vendors, and customers, to protect our trade secrets and proprietary know- how for our products. We currently hold patents for products and have patents pending in certain countries for additional products that we market or intend to market. However, our actions to establish and protect our patents, trademarks, and other proprietary rights may be inadequate to prevent imitation of our products by others or to prevent others from claiming violations of their trademarks and proprietary rights by us. If our products are challenged as infringing upon patents of other parties, we may be required to modify the design of the product, obtain a license, or litigate the issues, all of which may have an adverse business effect on us. We may be subject to claims that our products or processes infringe the intellectual property rights of others, which may cause us to pay unexpected litigation costs or damages, modify our products or processes or prevent us from selling our products. Although it is our intention to avoid infringing or otherwise violating the intellectual property rights of others, third parties may nevertheless claim that our processes and products infringe their intellectual property and other rights. Our strategies of capitalizing on growing international demand as well as developing new innovative products across multiple business lines present similar infringement claim risks both internationally and in the U. S. as we expand the scope of our product offerings and markets. We compete with other companies for contracts in some small or specialized industries, which increases the risk that the other companies will develop overlapping technologies leading to an increased possibility that infringement claims will arise. Whether or not these claims have merit, we may be subject to costly and time- consuming legal proceedings, and this could divert management' s attention from operating our business. In order to resolve such proceedings, we may need to obtain licenses from these third parties or substantially re- engineer or rename our products in order to avoid infringement. In addition, we might not be able to obtain the necessary licenses on acceptable terms, or at all, or be able to re-engineer or rename our products successfully. We may not be able to protect our intellectual property in countries outside the United States. Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. This is particularly relevant to us as a significant amount of our current and projected future sales are outside of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an

adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the U. S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. Any failure to achieve and maintain the high design and manufacturing standards that our products require may seriously harm our business. Our products require precise, high- quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel as well as our vendors. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. Additionally, the large amount of AXP disposable inventory certain distributors and end- users maintain may delay the identification of a manufacturing error and expand the financial impact. A manufacturing error or defect, or previously undetected design defect, or uncorrected impurity or variation in a raw material component, either unknown or undetected, could affect the product. Despite our high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we or our vendors are unable to manufacture our products in accordance with necessary quality standards, our business and results of operations may be negatively affected. Our products may be subject to product recalls which may harm our reputation and divert our managerial and financial resources. The FDA and similar governmental authorities in other countries have the authority to order the mandatory recall of our products or order their removal from the market if the governmental entity finds our products might cause adverse health consequences or death. The FDA may also seize product or prevent further distribution. A government- mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects (including labeling defects). In the past, we have initiated voluntary recalls of some of our products and we could do so in the future. Any recall of our products may harm our reputation with customers, divert managerial and financial resources and negatively impact our profitability. We are dependent on our suppliers and manufacturers to meet existing regulations. Certain of our suppliers and manufacturers are subject to heavy government regulations, including FDA QSR compliance, in the operation of their facilities, products and manufacturing processes. Any adverse action by the FDA against our suppliers or manufacturers could delay supply or manufacture of component products required to be integrated or sold with our products. Although we attempt to mitigate this risk through inventory held directly or through distributors, and audit our suppliers, there are no assurances we will be successful in identifying issues early enough to allow for corrective action or transition to an alternative supplier, or in locating an alternative supplier or manufacturer to meet product shipment or launch deadlines. As a result, our sales, contractual commitments and financial forecasts may be significantly affected by any such delays. Dependence on suppliers for custom components may impact the production schedule. We obtain products and custom components from a limited number of suppliers. If the supplier raises the price or discontinues production, we may have to find another qualified supplier to provide the item or re- engineer the item. In the event that it becomes necessary for us to find another supplier, we would first be required to qualify the quality assurance systems and product quality of that alternative supplier. Any operational issues with re- engineering or the alternative qualified supplier may impact the production schedule, therefore delaying revenues, and this may cause the cost of disposables or key components to increase. Dependence on contract manufacturers for disposable products. We obtain the majority of our disposable products from contract manufacturers. Production halts or delays by these manufacturers could have a significant impact on our business. Our safety stock levels are generally not sufficient to handle an unexpected shut- down or delay in production by these contract manufacturers. In the event of a significant unplanned delay in production, we may need to find a new contract manufacturer, which could be a lengthy process and require a significant financial commitment, impacting our ability to fulfill customer orders and maintain current sales levels for a period of time until the new contract manufacturer can start production of our disposable products. Failure to meet the financial covenant in our Technology License and Escrow Agreement could decrease our AXP revenues. Under our Sixth Amended and Restated Technology License and Escrow Agreement with CBR if our cash balance and short- term investments net of non- convertible debt and borrowed funds that are payable within one year are not greater than $ 1, 000, 000 at any month end, CBR may take possession of the escrowed intellectual property and initiate manufacturing of the applicable device and disposables. If this were to occur, our revenues would be negatively impacted. In order to remain compliant, we may have to complete additional financings or provide consideration to the counter party to modify the obligations. Failure to retain or hire key personnel may adversely affect our ability to sustain or grow our business. Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, clinical, regulatory, sales, marketing and managerial personnel. Our future success partially depends upon the continued services of key technical and senior management personnel. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial and technical personnel. The inability to retain or attract qualified personnel could have a significant negative effect upon our efforts and thereby materially harm our business and future financial condition. Most of our operations are conducted at a single location. Any disruption at our facilities could delay revenues or increase our expenses. Our U. S. device operations are conducted at a single location although we contract the manufacturing of certain devices, disposables and components. We take precautions to safeguard our facilities, through insurance, health and safety protocols, and off- site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, and other natural disasters may not be adequate to cover our losses in any particular case. Failure to maintain and / or upgrade our information technology systems may have an adverse effect on our operations. We rely on various information technology systems to manage our operations, and we evaluate these systems against our current and expected requirements. Although we have no current plans to implement modifications or upgrades to our systems, we will eventually be required to make changes to legacy systems and acquire new systems with new

functionality. Any information technology system disruptions, if not anticipated and appropriately mitigated, could have an adverse effect on our business and operations. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us. We are required to establish and maintain adequate internal control over financial reporting, which are processes designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. We are also required to comply with Section 404 of the Sarbanes- Oxley Act of 2002, which (among other things) requires public companies to conduct an annual review and evaluation of their internal control over financial reporting. However, as a " smaller reporting company, " we are not required to obtain an auditor attestation regarding our internal control over financial reporting. If, in the future, we require an attestation report from our independent registered public accounting firm and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected. Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer. In the ordinary course of the Company' s business, the Company collects and stores sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners and personally identifiable information of the Company' s employees on its networks. The secure processing, maintenance and transmission of this information is critical to the Company' s operations and business strategy. Despite the Company' s security measures, its information, technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise the Company' s networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings or regulatory penalties and could disrupt the Company' s operations and the services it provides to customers, damage the Company' s reputation, and cause a loss of confidence in the Company' s products and services, which could adversely affect the Company' s business. **The** ~~Our business has been adversely affected by the Coronavirus (COVID- 19) pandemic and may continue to be adversely affected by the pandemic. We believe that the~~ COVID- 19 pandemic **created** ~~has had~~ a ~~material negative~~ **global health crisis and an unprecedented disruption of commercial activity around the world. The future consequences of COVID- 19 or other pandemics, wars or other hostilities, geopolitical instability, widespread cyberattacks, climate events or other national or global crises are uncertain and we cannot predict how such events may affect our future financial condition and results of operations. Disruptions in commercial activity and changes in consumer spending resulting from the COVID- 19 pandemic significantly affected worldwide commerce and the global economy. Although we operated continuously throughout the pandemic, and while conditions in the U. S. and around the world have significantly improved, we cannot predict how new variants of coronavirus could** impact ~~on~~ our ~~business and results of~~ operations **in the future** . ~~The pandemic had a~~ **In addition, we could be affected by other** significant **events** ~~impact on the cord blood industry, with fewer cord blood units being stored globally after the start of the pandemic. Internationally, customs delays have led some customers to temporarily switch to manual processing due to the long wait to clear products through customs departments with reduced staffing. As a result, the pandemic resulted~~ in **the United States or abroad that could cause similar** ~~disruption~~ **disruptions** ~~to our supply chain and~~ in **commerce, like future** ~~customer demand during fiscal 2021. The continued impact of the pandemic~~ **pandemics** ~~on~~ **, the outbreak of war** ~~our~~ **or** ~~business and results of operations will~~ **other hostilities, geopolitical conflicts, cyberattacks affecting infrastructure we** depend on **, and climate emergencies. The direct and indirect effects of the COVID- 19 pandemic are widespread and may evolve, and the effects of similar** future ~~developments relating to~~ **disasters are also uncertain. It is possible that** the pandemic ~~in general~~ and **similar events, and economic conditions resulting from** ~~the~~ **those events** ~~cord blood industry in particular~~ , ~~and such~~ **could affect our business in the** future ~~developments are highly uncertain and~~ **in ways that we do not or** cannot **now anticipate** ~~be predicted. Such developments may include the continued geographic spread of the virus, the severity of the disease, the duration of the outbreak, the actions that may be taken by various governmental authorities in response to the outbreak, and the possible continued impact on the U. S. or global economy. As a result, at the time of this filing, it is impossible to predict the continued impact of the pandemic on our business, liquidity, capital resources and financial results~~ . Risks Related to Our Industry Our business is heavily regulated, resulting in increased costs of operations and delays in product sales. Many of our products require FDA approval or clearance to sell in the U. S. and will require approvals from comparable agencies to sell in foreign countries. These authorizations may limit the U. S. or foreign markets in which our products may be sold. Further, our products must be manufactured under the requirements of our quality system for continued CE- Marking so they can continue to be marketed and sold in Europe. These requirements are similar to the QSR of both the FDA and California Department of Public Health. Failure to comply with or incorrectly interpret these quality system requirements and regulations may subject us to delays in production while we correct deficiencies found by the FDA, the State of California, or our notifying body as a result of any audit of our quality system. If we are found to be out of compliance, we could receive a Warning Letter or an untitled letter from the FDA or even be temporarily shut down in manufacturing and product sales while the non- conformances are rectified. Also, we may have to recall products and temporarily cease their manufacture and distribution, which would increase our costs and reduce our revenues. The FDA may also invalidate our PMA or 510 (k) if appropriate regulations relative to the PMA or 510 (k) products are not met. The notified bodies may elect to not renew CE- Mark certification. Any of these events would negatively impact our revenues and costs of operations. Changes in governmental regulations may reduce demand for our products or increase our expenses. We compete in many markets in which we and our customers must comply with federal, state, local and international regulations, such as environmental, health and safety and food and drug regulations. We develop, configure and market our products to meet customer needs created by those regulations. Any significant change in regulations could reduce demand for our products or increase our expenses. For example, many of our instruments are marketed to the industry for enabling new

regenerative therapies. Changes in the FDA' s regulation of the devices and products directed at regenerative medicine, and development process for new therapeutic applications could have an adverse effect on the demand for these products. To sell in international markets we are subject to regulation in foreign countries. In cooperation with our distribution partners, we market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in certain non- U. S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold. There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition. Operating in foreign jurisdictions subjects us to regulation by non- U. S. authorities. We have operations in India, and as such are subject to Indian regulatory agencies. A number of risks are inherent in conducting business and clinical operations overseas. In order for us to operate as a majority owned foreign corporation in India, we are subject to financial regulations imposed by the Reserve Bank of India. This includes the rules specific to the capital funding, pledging of assets, repatriation of funds and payment of dividends from and to the foreign subsidiaries and from and to us in the U. S. If our competitors develop and market products that are more effective than our product candidates or obtain regulatory and market approval for similar products before we do, our commercial opportunity may be reduced or eliminated. The development and commercialization of new pharmaceutical products is competitive, and we will face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of our competitors have substantially greater financial and technical resources and development, production and marketing capabilities than we do. In addition, many of these companies have more experience than we do in pre- clinical testing, clinical trials and manufacturing of compounds, as well as in obtaining FDA and foreign regulatory approvals. As a result, there is a risk that one of the competitors will develop a more effective product for the same indications for which we are developing a product or, alternatively, bring a similar product to market before we can. With regards to the BioArchive and AXP Systems, numerous larger and better- financed medical device manufacturers may choose to enter this market. Changes in healthcare policy could subject us to additional regulatory requirements that may delay the commercialization of our products and increase our costs. The U. S. government and other governments have shown significant interest in pursuing healthcare reform. Any government- adopted reform measures could adversely impact the pricing of our diagnostic products and tests in the U. S. or internationally and the amount of reimbursement available from governmental agencies or other third- party payors. The continuing efforts of the U. S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products and services that we believe are fair, which may impact our ability to generate revenues and achieve and maintain profitability. New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and judicial decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue or force us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current executive administration in the U. S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U. S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post- marketing authority, including the authority to require post- marketing studies and clinical studies of products, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA' s exercise of this authority could result in delays or increased costs during product development, clinical studies and regulatory review, increased costs to assure compliance with post- approval regulatory requirements, and potential restrictions on the sale and / or distribution of approved products, all of which could materially adversely affect our business, prospects and financial condition. Product liability and uninsured risks may adversely affect the continuing operations. We operate in an industry susceptible to significant product liability claims. We may be liable if any of our products or services cause injury, illness, or death. These claims may be brought by individuals seeking relief or by groups seeking to represent a class. We also may be required to recall certain of our products should they become damaged or if they are defective. We are not aware of any material product liability claims against us. However, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. We maintain a product liability policy and a general liability policy that includes product liability coverage. However, a product liability claim against us could have a material adverse effect on our business or future financial condition. Risks Related to Operating Results and Financial Markets We have incurred net losses and we anticipate that our losses will continue. We have not been profitable for a significant period. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we had a net loss of $ ~~11~~ **18**, ~~812~~ **819**, 000 and $ 11, ~~880~~ **812**, 000 respectively and an accumulated deficit at December 31, ~~2022~~ **2023**, ~~,~~ of $ ~~266~~ **284**, ~~193~~ **168**, 000. The report of our independent auditors on our December 31, ~~2022~~ **2023** financial statements includes an explanatory paragraph indicating there is substantial doubt about our ability to continue as a going concern. We will continue to incur significant costs as we develop and market our current products and related applications. Although we are executing our business plan to develop, market and launch new products, continuing

losses may impair our ability to fully meet our objectives for new product sales or threaten our ability to continue as a going concern in future years. We will need to raise additional capital to fund our operations and the furtherance of our business plan. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will need to raise additional capital. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. In order to raise additional capital, we may seek to sell additional equity and / or debt securities or obtain a credit facility or other loan, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and / or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unfavorable terms. Risks Related to Our Common Stock If our common stock, including the price of our common stock does not meet the requirements of the Nasdaq Capital Market Stock Exchange (" Nasdaq "), our shares may be delisted. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted. The listing standards of Nasdaq provide, among other things, that a company may be delisted if the bid price of its stock drops below $ 1. 00 for a period of 30 consecutive business days. **Nasdaq' s listing standards provide that a company may be delisted if the bid price of its stock drops below $ 1. 00 for a period of 30 consecutive business days. On January 8, 2024, we received written notice from the Nasdaq Listing Qualifications Department notifying the Company that it was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550 (a) (2) for continued listing on the Nasdaq Capital Market, due to the bid price of the Company' s common stock closing below the minimum $ 1. 00 per share for the thirty (30) consecutive business days prior to the date of the Notification Letter. In accordance with listing rules, the Company was afforded 180 days, or until July 8, 2024, to regain compliance. If during this 180- day compliance period the closing bid price of the Company' s common stock is at least $ 1. 00 per share for a minimum of ten consecutive business days, then Nasdaq will provide the Company with written confirmation of compliance and the matter will be closed. If compliance cannot be demonstrated by July 8, 2024, the Company may be eligible for additional time. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards on Nasdaq (except the bid price requirement). In addition, the Company would be required to provide written notice of its intention to cure the minimum bid price deficiency during this second 180- day compliance period by effecting a reverse stock split, if necessary. The Notice states that, if the Company meets these standards, then the Company may be eligible to have an additional 180- calendar day compliance period. If the Company is not granted an additional 180- day compliance period, then Nasdaq will provide written notification that the Company' s securities will be subject to delisting. At that time, the Company may appeal the determination to delist its securities to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement or otherwise maintain compliance with the other listing requirements.** Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Liquidity of our common stock. Although there is a public market for our common stock, trading volume has been historically low, which could impact the stock price and the ability to sell shares of our common stock. We can give no assurance that an active and liquid public market for shares of common stock will continue in the future. In addition, future sales of large amounts of common stock could adversely affect the market price of our common stock and our ability to raise capital. The price of our common stock could also drop as a result of the exercise of options for common stock or the perception that such sales or exercise of options could occur. These factors could also have a negative impact on the liquidity of our common stock and our ability to raise funds through future stock offerings. We do not pay cash dividends. We have never paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. Instead, we intend to apply earnings, if any, to the expansion and development of our business. Thus, the liquidity of your investment is dependent upon your ability to sell stock at an acceptable price. The price can go down as well as up and may limit your ability to realize any value from your investment, including the initial purchase price. Our Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive venue for certain litigation that may be initiated by our stockholders, which may limit a stockholder' s ability to obtain a favorable judicial forum for such disputes with us or our directors, officers or employees. Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative venue, the Court of Chancery of the State of Delaware will be the sole and exclusive venue for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. This choice of venue provision will not apply to actions or proceedings brought to enforce a duty or liability created by the Securities Act or the Exchange Act. This choice of venue provision may limit a stockholder' s ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage the filing of lawsuits with respect to such claims. If a court were to find this choice of venue provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in another jurisdiction, which could adversely affect our business and financial condition. **Sales of substantial amounts of our Common Stock by the selling stockholders named in the Registration Statements on Form S- 3 filed by us in April 2023, or the perception that these sales could occur,**

**could adversely affect the price of our Common Stock. In April 2023, we filed two resale registration statements on Form S- 3 for the selling stockholders named therein, and such registration statements were declared effective in April and May 2023, respectively. The sale by the selling stockholders of a significant number of shares of Common Stock could have a material adverse effect on the market price of our Common Stock. In addition, the perception in the public markets that the selling stockholders may sell all or a portion of their shares as a result of the registration of such shares for resale pursuant to this prospectus could also in and of itself have a material adverse effect on the market price of our Common Stock. We cannot predict the effect, if any, that market sales of those shares of Common Stock or the availability of those shares of Common Stock for sale will have on the market price of our Common Stock.** Risks Related to Our ~~Planned~~ **New** Contract Development and Manufacturing Organization (CDMO) Service **Our CDMO business is a new business line for us, and we have not yet recognized any material revenues from this business, and we are subject to the general risks associated with entering into a new business. We have not yet received material revenues from our new CDMO business, and there is no assurance that we will be able to generate sufficient business to generate material revenues. In addition,** ~~Initiating~~ **initiating** new business activities or strategies **like** ~~or~~ **our new CDMO** ~~significantly expanding existing~~ business ~~activities or strategies~~ may expose us to new ~~risks and may increase our costs associated with doing business. Initiating new business activities or strategies or significantly expanding existing business activities or strategies may expose us to new~~ or increased financial, regulatory, reputational and other risks. **We** ~~Such innovations are important and necessary ways to grow our business and respond to changing circumstances in our industry; however, we~~ cannot be certain that we will be able to manage the associated risks and compliance requirements effectively. Such risks include a lack of experienced management- level personnel, increased administrative burden, increased logistical problems common to large, expansive operations, increased credit and liquidity risk and increased regulatory scrutiny ~~. Will need to raise additional capital in order to execute our planned CDMO business, the failure of which could adversely impact our business transformation. Without adequate funding, we may not be able to establish CDMO facilities in the United States. We expect to continue to finance start- up costs related to our CDMO division, primarily by issuing equity or convertible debt securities, which could significantly dilute the ownership of existing stockholders. Furthermore, any newly issued securities could have rights, preferences and privileges senior to those of our existing common stock; and any issuances of equity securities may be at or below the prevailing market price of our common stock, which could cause the market price of our common stock to decline. We may have difficulty obtaining additional funds, and we may have to accept terms that would adversely affect our stockholders. In addition, any adverse conditions in the credit and equity markets may adversely affect our ability to raise funds when needed. The failure to achieve adequate funding may delay our planned CDMO business program and service launches~~ . Our success may depend on our ability to attract and retain key scientific or professional talents in the CDMO field. The Company currently lacks certain unique personnel for CDMO services. We will need to actively search and recruit the talents that are necessary for our business growth. Our success in transforming into CDMO services depends substantially on the efforts and abilities to recruit and retain key personnel. The competition for qualified CDMO services key personnel, is intense. The inability to hire, train, and retain key personnel could delay the launching of our CDMO services, disrupt our business, and interfere with our ability to execute our CDMO business plan. We will need to increase the size and capabilities of our organization to support our CDMO services, and we may experience difficulties in managing this growth. As our development and commercialization plans develop, we will need to add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth may create significant added responsibilities for Company management. Our future financial performance and our ability to successfully run our CDMO services division will depend, in part, on our ability to effectively manage future growth ~~. Our competitive advantages such as our CAR- TXpress ™ technology being able to compete favorably and profitably in the CDMO cell manufacturing business, are critical to the success of our planned CDMO business. While we believe our proprietary CAR- TXpress ™ technology platform is superior to other existing cell processing technologies, our data is based on very limited sources. CAR- TXpress ™ technology has not been used to manufacture any cell therapy product candidate previously. The ability to accurately calculate total cost for the manufacturing expenses, expected future revenue, and profitability can vary among different product candidates and is difficult to estimate. There is no guarantee that our technology would reduce the manufacturing cost and deliver the competitive advantage that we have anticipated~~ . We are dependent on our ability to predict the CDMO cell manufacturing market and to identify customers. While there is an increasing number of clinical trials for cell therapies, the number of cell and gene therapy products that have reached commercial production is still limited. Cell therapy is an emerging industry and a significant global market for manufacturing services may never emerge. The number of customers who may use cell- based therapies, and the demand for cell manufacturing services, is difficult to estimate. If cell therapies under development are not proven safe and effective, demonstrate unacceptable risks or side effects or fail to receive regulatory approval if required; our manufacturing business may be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U. S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad and profitable global market for cell therapies and services and our ability to capture a share of this market through identifying the proper customers. We may fail to effectively utilize licensed technologies. We have entered into a licensing agreement and in the future, we may seek additional collaborations or strategic alliances or enter into additional licensing arrangements with organizations that we believe will complement or augment our own technologies and services. Licensing and collaborations arrangements are subject to numerous risks, and we may not realize the benefits of such alliances or licensing arrangements as we anticipated. External competition from other CDMO cell manufacturing service providers may be harmful to our ~~planned~~ CDMO business. We face competition from other companies that are large, well- established manufacturers with financial, technical, research and development and sales and marketing resources that are significantly greater than ours. We also face competition from academic and research

institutions that may choose to self- manufacture rather than utilize a contract manufacturer. To be successful, we will need to convince potential customers that our technology and capabilities are more innovative, of higher- efficiency and more cost-effective than could be achieved through internal manufacturing; and demonstrate that our technology and expertise in automated cell processing is unique to the industry. Our ability to achieve this and to successfully compete against other manufacturers will depend, in large part, on our success in developing innovative cell processing technologies that improve the efficiency and reduce the drug cost associated with cell therapy manufacturing. If we are unable to successfully demonstrate our competitive advantages, we may not be able to compete against other manufacturers. While there is an increasing number of product candidates in clinical trials with a smaller number that have reached commercial production, cell therapy is a developing industry and a significant global market for manufacturing services may never emerge. Cell therapy is in its early stages and is still a developing area of research, with few cell therapy products approved for clinical use. Many of the existing cellular therapy candidates are based on novel cell technologies that are inherently risky and may not be understood or accepted by the marketplace, making it difficult for their own funding to enable them to continue their business. The number of people who may use cell or tissue- based therapies, and the demand for cell processing services, is difficult to forecast. If cell therapies under development by third parties are not proven safe and effective, demonstrate unacceptable risks or side effects or, where required, fail to receive regulatory approval, our manufacturing business will be significantly impaired. While the therapeutic application of cells to treat serious diseases is currently being explored by a number of companies, to date there are only a handful of approved cell therapy products in the U. S. Ultimately, our success in deriving revenue from manufacturing depends on the development and growth of a broad and profitable global market for cell, gene and tissue- based therapies and services and our ability to capture a share of this market. ITEM 1B. Unresolved Staff Comments ~~None. ITEM 2. Properties~~