Risk Factors Comparison 2024-03-07 to 2023-03-09 Form: 10-K

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The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10- K. As previously discussed, our actual results could differ materially from our forward- looking statements. Our business faces a variety of risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance and financial condition could be adversely affected, and the trading price of our common stock could decline. Risks Related to Our Industry The life sciences industry is very competitive. We expect to encounter increased competition from both established and development- stage companies that continually enter the market. These include companies developing and marketing life science instruments, systems and lab consumables, health care companies that manufacture laboratory- based tests and analyzers, diagnostic and pharmaceutical companies, analytical instrument companies, and companies developing life science or drug discovery technologies. Currently, our principal competition comes from established companies that provide products that perform many of the same functions for which we market our products. Many of our competitors have substantially greater financial, operational, marketing and technical resources than we do. Moreover, these competitors may offer broader product lines and tactical discounts and may have greater name recognition. In addition, we may face competition from new entrants into the field. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. In addition, we face changing customer preferences and requirements, including increased customer demand for more environmentally friendly products. The life sciences industry is also subject to rapid technological change and discovery. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive. In some instances, our competitors may develop or market products that are more effective or commercially attractive than our current or future products. To meet the evolving needs of customers, we must continually enhance our current products and develop and introduce new products. However, we may experience difficulties that may delay or prevent the successful development, introduction and marketing of new products or product enhancements. In addition, our product lines are based on complex technologies that are subject to change as new technologies are developed and introduced in the marketplace. We may have difficulty in keeping abreast of the changes affecting each of the different markets we serve or intend to serve **, and our new products may not be accepted by the marketplace or may generate lower than anticipated revenues**. Our failure to develop and introduce products in a timely manner in response to changing technology, market demands, or the requirements of our customers could cause our product sales to decline, and we could experience significant losses. We offer, and plan to continue to offer, a broad range of products and have incurred, and expect to continue to incur, substantial expenses for the development of new products and enhancements to our existing products. The speed of technological change in our market may prevent us from being able to successfully market some or all of our products for the length of time required to recover development costs. Failure to recover the development costs of one or more products or product lines could decrease our profitability or cause us to experience significant losses. ~~7A~~ **A** portion of our revenues ~~are~~ **is** derived from customers ~~from~~ **in** the pharmaceutical and biotechnology industries and ~~are~~ **is** subject to the risks faced by those industries. Such risks may adversely affect our financial results. We derive a significant portion of our revenues from pharmaceutical ~~and~~ **companies,** biotechnology **companies, and CROs serving these** companies. We expect that pharmaceutical ~~and~~ **companies,** biotechnology companies **and CROs** will continue to be a significant source of our revenues for the foreseeable future, including in our **CMT** ~~Cellular and Molecular Technologies~~ and Preclinical product families. As a result, we are subject to risks and uncertainties that affect the pharmaceutical and biotechnology industries, such as government regulation, ongoing consolidation, uncertainty of technological change, and reductions and delays in research and development expenditures by companies in these industries. In particular, the biotechnology industry is largely dependent on raising capital to fund its operations. If biotechnology companies that are our customers are unable to obtain the financing necessary to purchase our products, our business and results of operations could be adversely affected. In addition, we are dependent, both directly and indirectly, upon general health care spending patterns, particularly in the research and development budgets of the pharmaceutical and biotechnology industries, as well as upon the financial condition and purchasing patterns of various governments and government agencies. As it relates to both the biotechnology and pharmaceutical industries, many companies have significant patents that have expired or are about to expire, which could result in reduced revenues for those companies. If pharmaceutical or biotechnology companies that are our customers suffer reduced revenues as a result of these patent expirations, they may be unable to purchase our products, and our business and results of operations could be adversely affected. ~~Changes~~ **7Changes** in governmental regulations may reduce demand for our products, adversely impact our revenues, or increase our expenses. We operate in many markets in which we and our customers must comply with federal, state, local and international regulations. We develop, configure and market our products to meet customer needs created by, and in compliance with, those regulations. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, and advertising and post marketing reporting. We must incur expense and spend time and effort to ensure compliance with these complex regulations. Possible regulatory actions for non- compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of our products, and criminal prosecution. These actions could result in, among other things, substantial modifications to our business practices and operations; refunds, recalls, or seizures of our products; a total or partial shutdown of production in one or more of our facilities while we or our suppliers remedy the alleged violation;

and withdrawals or suspensions of current products from the market. Any of these events could disrupt our business and have a material adverse effect on our revenues, profitability and financial condition. Risks Related to Our Business Reductions in customers' research budgets or government funding may adversely affect our business. Many of our customers are universities, government research laboratories, private foundations and other institutions ~~who~~ **that** are dependent on grants from government agencies, such as the NIH, for funding. These customers represent a significant source of our revenue. Research and development spending by our customers may fluctuate based on spending priorities and general economic conditions. The level of government funding for research and development is unpredictable. In the past, NIH grants have been frozen or otherwise made unavailable for extended periods or directed to certain products. Reductions or delays in governmental spending could cause customers to delay or forego purchases of our products. If government funding necessary for the purchase of our products were to decrease, our business and results of operations could be materially, adversely affected. Spending by some of these customers fluctuates based on budget allocations and the timely passage of the annual federal budget. An impasse in federal government budget decisions could lead to substantial delays or reductions in federal spending. ~~8Our~~ - **Our** business is subject to economic, political and other risks associated with international revenues and operations. We manufacture and sell our products worldwide and as a result, our business is subject to risks associated with doing business internationally. A substantial amount of our revenues is derived from international operations, and we anticipate that a significant portion of our sales will continue to come from outside the United States in the future. We anticipate that revenues from international operations will likely continue to increase as a result of our efforts to expand our business in markets abroad. In addition, a number of our manufacturing facilities and suppliers are located outside the United States. Our foreign operations subject us to certain risks, including: effects of fluctuations in foreign currency exchange rates; the impact of local economic conditions **; fluctuations or reductions in economic growth in overseas markets including Asia and Europe** ; local product preferences and seasonality and product requirements; local difficulty to effectively establish and expand our business and operations in international markets; disruptions of capital and trading markets; restrictions and potentially negative tax implications of transfer of capital across borders; differing labor regulations; other factors beyond our control, including potential political instability, terrorism, acts of war, natural disasters and diseases, including COVID- 19 discussed below; unexpected changes and increased enforcement of regulatory requirements and various state, federal and international, intellectual property, environmental, antitrust, anti- corruption, fraud and abuse (including anti- kickback and false claims laws) and employment laws; interruption to transportation flows for delivery of parts to us and finished goods to our customers; and laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States, or CFIUS, and other agencies, including the Foreign Investment Risk Review Modernization Act, or FIRRMA, adopted in August 2018. A small percentage of our products are subject to export control regulations administered by the U. S. Department of the Treasury' s Office of Foreign Assets Control (" OFAC ") and by the Export Administration Regulations administered by the U. S. Department of Commerce' s Bureau of Industry and Security (" BIS "). Based on the nature of the product, its ultimate end use and country of destination, we are sometimes subject to foreign assets control and economic sanctions regulations administered by OFAC, which restrict or prohibit our ability to transact with certain foreign countries, certain individuals and entities identified on the Treasury Department' s " Denied Parties List. " Under the OFAC regulations, the sale or transfer of certain equipment to a location outside the United States may require prior approval in the form of an export license issued by the BIS or the U. S. Department of State' s Directorate of Defense Trade Controls. Some potential international transactions may also be restricted or prohibited based on the location, nationality or identity of the potential end user, customer or other parties to the transaction or may require prior authorization in the form of an OFAC license. **These risks may be exacerbated by geopolitical tensions in various regions of the world such as China, the Asia- Pacific region and the Middle East.** Any delay in obtaining required governmental approvals could affect our ability to conclude a sale or timely commence a project, and the failure to comply with all such controls could result in criminal and / or civil penalties. These international transactions may otherwise be subject to tariffs and import / export restrictions from the United States or other governments. Our overall success as a global business depends, in part, upon our ability to succeed in differing economic, social and political conditions. In order to continue to succeed in our international sales strategy, we must continue developing and implementing policies and strategies that are effective in each location where we do business, which could negatively affect our profitability. ~~Rising~~ **8Rising** inflation and interest rates could negatively impact our revenues, profitability and borrowing costs. In addition, if our costs increase and we are not able to correspondingly adjust our commercial relationships to account for this increase, our net income would be adversely affected, and the adverse impact may be material. Inflation rates, particularly in the U. S., have increased recently to levels not seen in years. **Sustained or** ~~Increased~~ **increased** inflation may result in decreased demand for our products, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised ~~, and may again raise,~~ interest rates in response to concerns about inflation. Increases in interest rates have had, and could continue to have, a material impact on our borrowing costs. In an inflationary environment, we may be unable to raise the sales prices of our products at or above the rate at which our costs increase, which could reduce our profit margins and have a material adverse effect on our financial results and net income. We also may experience lower than expected sales if there is a decrease in spending on products in our industry in general or a negative reaction to our pricing. A reduction in our revenue would be detrimental to our profitability and financial condition and could also have an adverse impact on our future growth. ~~9We~~ - **We** have substantial debt and other financial obligations, and we may incur even more debt. Any failure to meet our debt and other financial obligations or maintain compliance with related covenants could harm our business, financial condition and results of operations. Our credit agreement provides for a term loan of $ 40. 0 million and a $ 25. 0 million senior revolving credit facility (collectively, the " Credit Agreement ") and will mature on December 22, 2025. As of December 31, ~~2022~~ **2023** , we had outstanding borrowings of $ ~~47~~ **37** . ~~7~~ **1** million under the Credit Agreement. Pursuant to the terms of the Credit Agreement, we are subject to various covenants, including negative covenants that restrict our ability to engage in certain transactions, which may limit our ability to respond to changing business and economic conditions. Such negative covenants include, among other things, limitations on our ability and the ability of our subsidiaries to ~~: •~~ incur debt **or** ~~, • incur~~ liens, ~~•~~ make investments (including acquisitions), ~~•~~ sell assets, and ~~•~~ pay dividends on our capital stock. In addition, the Credit Agreement contains certain financial covenants, including a maximum consolidated net leverage ratio and a minimum consolidated fixed charge coverage ratio, each of which will be tested at the end of each fiscal quarter of the Company ~~. We were not in compliance with certain financial covenants under the Credit Agreement as of September 30, 2022 but we were able to cure such noncompliance by entering into an amendment to the Credit Agreement, dated November 8, 2022~~ . If we are not able to maintain compliance with the covenants under the Credit Agreement, as amended, or are unsuccessful in obtaining waivers or amendments for any covenant defaults in the future, in addition to other actions our lenders may require, the amounts outstanding under the Credit Agreement may become immediately due and payable. This immediate payment may negatively impact our financial condition. In addition, any failure to make scheduled payments of interest and principal on our outstanding indebtedness would likely harm our ability to incur additional indebtedness on acceptable terms. Our cash flow and capital resources may be insufficient to pay interest and principal on our debt in the future. If that should occur, our capital raising or debt restructuring measures may be unsuccessful or inadequate to meet our scheduled debt service obligations, which could cause us to default on our obligations and further impair our liquidity. Further, based upon our actual performance levels, our covenants relating to leverage and fixed charges could limit our ability to incur additional debt, which could hinder our ability to execute our current business strategy. Our ability to make scheduled payments on our debt and other financial obligations and comply with financial covenants depends on our financial and operating performance. Our financial and operating performance will continue to be subject to prevailing economic conditions and to financial, business and other factors, some of which are beyond our control. Failure within any applicable grace or cure periods to make such payments, comply with the financial covenants, or any other non- financial or restrictive covenant, would create a default under our Credit Agreement. Our cash flow and existing capital resources may be insufficient to repay our debt at maturity, in which such case prior thereto we would have to extend such maturity date, or otherwise repay, refinance and or restructure the obligations under the Credit Agreement, including with proceeds from the sale of assets, and additional equity or debt capital. If we are unsuccessful in obtaining such extension, or entering into such repayment, refinance or restructure prior to maturity, or any other default existed under the Credit Agreement, our lenders could accelerate the indebtedness under the Credit Agreement, foreclose against their collateral or seek other remedies, which would jeopardize our ability to continue our current operations. Ethical concerns surrounding the use of our products and misunderstanding of the nature of our business could adversely affect our ability to develop and sell our existing products and new products. Some of our products may be used in areas of research involving animal research and other techniques presently being explored in the life science industry. These techniques have drawn negative attention in the public forum. Government authorities may regulate or prohibit any of these activities. Additionally, the public may disfavor or reject these activities. ~~10Foreign~~ **9Foreign** currency exchange rate fluctuations may have a negative impact on our reported earnings. We are subject to the risks of fluctuating foreign currency exchange rates, which could have an adverse effect on the sales price of our products in foreign markets, as well as the costs and expenses of our foreign subsidiaries. A substantial amount of our revenues is derived from international operations, and we anticipate that a significant portion of revenues will continue to come from outside the United States in the future. As a result, currency fluctuations among the United States dollar, British pound, euro and the other currencies in which we do business have caused and will continue to cause foreign currency translation and transaction gains and losses. We have not used forward exchange contracts to hedge our foreign currency exposures. We attempt to manage foreign currency risk through the matching of assets and liabilities. In the future, we may undertake to manage foreign currency risk through hedging methods, including foreign currency contracts. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can address these risks. Failure or inadequacy of our information technology infrastructure or software could adversely affect our day- to- day operations and decision- making processes and have an adverse effect on our performance. We depend on accurate and timely information and numerical data from key software applications to aid our day- to- day business, financial reporting and decision- making and, in many cases, proprietary and custom- designed software is necessary to operate our business. Disruption caused by the failure of these systems, the underlying equipment, or communication networks could delay or otherwise adversely impact day- to- day business and decision making, could make it impossible for us to operate critical equipment, and could have an adverse effect on our performance. **Our** ~~Although we maintain disaster recovery procedures for our critical systems, our~~ disaster recovery plans may not fully mitigate the effect of any such disruption. Disruptions could be caused by a variety of factors, such as catastrophic events or weather, power outages, or cyber- attacks on our systems by outside parties. We review our information technology (" IT ") systems regularly to assess and implement opportunities to improve or upgrade our enterprise resource planning (" ERP ") or other information systems required to operate our business effectively. Our ERP systems are critical to our ability to accurately maintain books and records, record transactions, provide important information to our management and prepare our financial statements. The implementation of any IT systems, including ERP systems, has required in the past, and may continue to require, the investment of significant financial and human resources. In addition, we may not be able to successfully complete the implementation of the ERP systems without experiencing difficulties. Any disruptions, delays or deficiencies in the design and implementation of any IT system, including ERP systems could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. An information security incident, including a cybersecurity breach, could have a negative impact ~~to~~ **on** our business or reputation. To meet business objectives, we rely on both internal IT systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third- party providers have the required capabilities and controls ~~,~~ to address this risk. ~~To~~ **While we have been, and may continue to be, subject to cybersecurity risks and incidents related to our business, to** date, we have not experienced any material impact to the business or operations resulting from information or cybersecurity ~~attacks~~ **incidents** ; however, because of the frequently ~~changing attack techniques~~ **evolving tactics adopted by threat actors** , along with the increased volume and sophistication of ~~the~~ attacks **by such threat actors** , there is the potential for us to be **materially** adversely impacted **in the future** . This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. Additionally, the California Consumer Privacy Act of 2018 (the " CCPA "), which became effective on January 1, 2020, provides private rights of action for data breaches and requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices and allow consumers to opt out of certain data sharing with third parties. Compliance with the CCPA and other current and future applicable privacy, cybersecurity and related laws can be costly and time- consuming. Significant capital investments and other expenditures could also be required to remedy cybersecurity problems and prevent future breaches, including costs associated with additional security technologies, personnel, experts and credit monitoring services for those whose data has been breached. These costs, which could be material, could adversely impact our results of operations in the period in which they are incurred and may not meaningfully limit the success of future attempts to breach our information technology systems. **We may be unable to renew leases or enter into new leases on favorable terms. Our facilities are located in leased premises. Several of our leases will expire in 2024 and we may be unable to renew such leases or enter into new leases on favorable terms and conditions or at all. A significant rise in real estate prices or real property taxes could also result in an increase in lease cost, and thereby negatively impacting the Company' s results of operations and cash flow. As a result, we may incur additional costs including increased rent and other costs related to our renegotiation of lease terms for our facilities or for a new lease in a desirable location.** ~~11We~~ **10We** may incur additional restructuring costs or not realize the expected benefits of our initiatives to reduce operating expenses in the future. We may not be able to implement all of the actions that we intend to take in the restructuring of our operations, and we may not be able to fully realize the expected benefits from such realignment and restructuring plans or other similar restructurings in the future. In addition, we may incur additional restructuring costs in implementing such realignment and restructuring plans or other similar future plans in excess of our expectations. The implementation of our restructuring efforts, including the reduction of our workforce, may not improve our operational and cost structure or result in greater efficiency of our organization; and we may not be able to support sustainable revenue growth and profitability following such restructurings. If we are not able to manage our growth, our operating profits may be adversely impacted. Our success will depend on the expansion of our operations through organic growth, and we may execute acquisitions in the future to augment this growth. Effective growth management will place increased demands on our management team, operational and financial resources and expertise. To manage growth, we must optimize our operational, financial and management processes and systems, and information technology infrastructure and hire and train additional qualified personnel. While we are currently in the process of evaluating potential improvements to and consolidation of many of our processes and systems, we may not be able to implement these changes in an efficient or timely manner. Failure to manage our growth effectively, including failure to improve our systems and processes timely or efficiently, could impair our ability to generate revenues or could cause our expenses to increase more rapidly than revenues, resulting in operating losses or reduced profitability. We may incur a variety of costs in connection with acquisitions we may seek to consummate in the future, and we may never realize the anticipated benefits of our acquisitions due in part to difficulties integrating the businesses, operations and product lines. Our business strategy has historically included the acquisition of businesses, technologies, services or products that we believe are a strategic fit with our business. If we were to undertake future acquisitions, the process of integrating the acquired business, technology, service and / or product (s) may result in unforeseen operating difficulties and expenditures and potentially absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may fail to realize the anticipated benefits of an acquisition as rapidly as expected, or at all. Such transactions are inherently risky, and any such recent or future acquisitions could reduce stockholders' ownership, cause us to incur debt, expose us to future liabilities and result in amortization expenses related to intangible assets with definite lives, which may adversely impact our ability to undertake future acquisitions on substantially similar terms. We may also incur significant expenditures in anticipation of an acquisition that is never realized. Our ability to achieve the benefits of acquisitions depends in part on the integration and leveraging of technology, operations, sales and marketing channels and personnel. Integration is a complex, time- consuming and expensive process and may disrupt our business if not completed in a timely and efficient manner. We may have difficulty successfully integrating acquired businesses, and their domestic and foreign operations or product lines, and as a result, we may not realize any of the anticipated benefits of the acquisitions we make. We cannot assure that our growth rate will equal the growth rates that have been experienced by us, and these other acquired companies, respectively, operating as separate companies in the past. Failure to raise additional capital or generate the significant capital necessary to expand our operations, invest in new products, or pursue acquisitions or other business development opportunities could reduce our ability to compete and result in less revenues. We anticipate that our financial resources, which include available cash, cash generated from operations, and debt and equity capacity, will be sufficient to finance operations and capital expenditures for at least the next twelve months. However, this expectation is premised on the current operating plan, which may change as a result of many factors, including market acceptance of new products and future opportunities with collaborators. Consequently, we may need additional funding sooner than anticipated. In addition, our borrowings under the Credit Agreement may not be sufficient to support our pursuit of potential acquisitions or other business development opportunities. In such case, our inability to raise sufficient capital on favorable terms and in a timely manner (if at all) could seriously harm our business, product development, and acquisition efforts. In addition, our Credit Agreement contains various negative covenants that, among other things, restrict our ability to incur additional indebtedness and make acquisitions for aggregate consideration in excess of $ 5. 0 million. If future financing is not available or is not available on acceptable terms, we may have to alter our operations or change our business strategy. We cannot assure you that the capital required to fund operations, or our acquisition strategy will be available in the future. ~~12If~~ **11If** we fail to retain key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenue or increased costs. Our success is highly dependent on the continued services of key management, technical and scientific personnel. Our management and other employees may voluntarily terminate their employment at any time upon short notice. The loss of the services of any member of the senior management team, including the Chief Executive Officer or ~~Interim~~ Chief Financial Officer or any of our managerial, technical or scientific staff may significantly delay or prevent the achievement of product development, our growth strategies and other business objectives. Our future success will also depend on our ability to identify, recruit and retain additional qualified scientific, technical and managerial personnel. We operate in several geographic locations where labor markets are particularly competitive, including the Boston, Massachusetts and Minneapolis, Minnesota metropolitan areas, England, and Germany where demand for personnel with these skills is extremely high and is likely to remain high. Additionally, the COVID- 19 pandemic and other macroeconomic factors have exacerbated these challenges, contributed to a sustained labor shortage, and increased turnover rates. As a result, competition for qualified personnel is intense, particularly in the areas of general management, finance, information technology, engineering and science, and the process of hiring suitably qualified personnel is often lengthy and expensive ~~,~~ and may become more expensive in the future. If we are unable to hire and retain a sufficient number of qualified employees, our ability to conduct and expand our business could be seriously reduced. Our success will depend partly on our ability to operate without infringing on or misappropriating the intellectual property rights of others. We may be sued for infringing on the intellectual property rights of others, including the patent rights, trademarks and trade names of third parties. Intellectual property litigation is costly, and the outcome is uncertain. If we do not prevail in any intellectual property litigation, in addition to any damages we might have to pay, we could be required to stop the infringing activity, or obtain a license to or design around the intellectual property in question. If we are unable to obtain a required license on acceptable terms, or are unable to design around any third- party patent, we may be unable to sell some of our products and services, which could result in reduced revenue. ~~Biostage third~~ **Third** parties may seek to hold us responsible for ~~Biostage~~ **Harvard Apparatus Regenerative Technologies,Inc.** ' s **(" HRGN ") (formerly known as Biostage,Inc.)** liabilities,including liabilities that ~~Biostage~~ **HRGN** has assumed from us.Third parties may continue to seek to hold us responsible for ~~Biostage~~ **HRGN** ' s liabilities,including any of the liabilities that ~~Biostage~~ **HRGN** agreed to retain or assume in connection with the separation of the ~~Biostage~~ **HRGN** business from our businesses,and related spin- off distribution. **For example** ~~On April 14,2017,representatives for the estate of an individual plaintiff filed a wrongful death complaint with the Suffolk Superior Court~~ ,in ~~the County~~ **April 2022,we and HRGN entered into a settlement** of ~~Suffolk,Massachusetts~~ **a litigation relating to injuries allegedly caused by products produced by us and HRGN and utilized in connection with surgeries performed by third parties** (the " **HRGN Settlement** ~~Court "),against us and other defendants,including Biostage,as well as another third party (the " Biostage Litigation~~ "). ~~The complaint sought payment~~ The **HRGN Settlement resolved and dismissed all claims by and between the parties.** ~~shares~~ **Shares** of **common** ~~Series E Preferred Stock~~ **stock** of ~~Biostage~~ **HRGN** held by the Company could fluctuate considerably in value and could become worthless. In connection with the ~~Biostage~~ **HRGN** Settlement, ~~Biostage~~ **HRGN** issued shares of its Series E Convertible Preferred Stock (the " Series E Preferred Stock ") to the Company ~~on June 10, 2022~~ in satisfaction of $ 4. 0 million of ~~Biostage~~ **HRGN** ' s total indemnification obligations to the Company. ~~The~~ **In April 2023, all of the** Series E Preferred Stock **we held** ~~is convertible at any time at the option of the Company into such number of shares of Biostage common stock determined by dividing (a) the $ 1, 000 face value of the Series E Preferred Stock plus all accrued and unpaid dividends thereon by (b) the average of the volume weighted average trading prices of Biostage' s common stock, which is currently quoted on the OTCQB Marketplace, for the 60 consecutive trading days prior to the conversion. In the event Biostage has a subsequent qualified offering of its common stock, (which is defined as an offering of Biostage common stock that coincides with its uplisting onto Nasdaq, the first subsequent public offering by Biostage, or the first subsequent private placement by Biostage resulting~~ in **HRGN were** ~~gross proceeds to Biostage of at least $ 4, 000, 000), the Series E Preferred Stock is~~ mandatorily converted into ~~Biostage~~ **shares of HRGN** common stock ~~at the applicable qualified offering price~~ **. As of December 31, 2023, we held shares of HRGN common stock with an estimated fair value of $ 3. 5 million** . Due to ~~Biostage~~ **HRGN** ' s limited operating history, their overall financial condition, (including whether it can continue as a going concern without additional capital) and the limited trading volume and liquidity of ~~Biostage~~ **HRGN** ' s common stock, the value of **this investment** ~~the Series E Preferred Stock~~ could fluctuate considerably or become worthless. Biostage third parties may seek to hold...... Litigation and the Biostage Settlement. Risks **12Risks** Related to Our Common Stock Our stock price has fluctuated in the past and could experience substantial declines in the future. The market price of our common stock has experienced significant fluctuations and may become volatile and could decline in the future, perhaps substantially, in response to various factors including, but not limited to: ● volatility of the financial markets; ● uncertainty regarding the prospects of the domestic and foreign economies; ● technological innovations by competitors or in competing technologies; ● revenues and operating results fluctuating or failing to meet ~~the~~ **our** expectations ~~of management~~ **or financial guidance** , **or the expectations of** securities analysts, or investors ~~in any quarter~~ ; ● comments of securities analysts and mistakes by or misinterpretation of comments from analysts, downward revisions in securities analysts' estimates or management guidance ~~; ● investment banks~~

~~and securities analysts becoming subject to lawsuits that may adversely affect the perception of the market~~ ; ● conditions or trends in the biotechnology and pharmaceutical industries; ● announcements of significant acquisitions or financings or strategic partnerships; ● non- compliance with the internal control standards pursuant to the Sarbanes- Oxley Act of 2002; and ● a decrease in the demand for our common stock. In addition, public stock markets have experienced extreme price and trading volatility. The stock market and the Nasdaq Global Market in general, and the biotechnology **and life science tools** industry and small cap markets in particular, have experienced significant price and volume fluctuations that at times may have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may further harm the market price of our common stock, regardless of our operating performance. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a company' s securities. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management' s attention and resources. ~~14If~~ **If** we raise additional funds through the sale of equity or convertible debt or equity- linked securities, existing percentages of ownership in our common stock will be reduced and these transactions may dilute the value of our outstanding common stock. We may raise additional funds through the sale of equity or convertible debt or equity- linked securities to repay our existing indebtedness, implement our acquisition strategy, expand our operations and / or invest in new products. If we raise additional funds through such sales, existing percentages of ownership in our common stock will be reduced and these transactions may dilute the value of our outstanding common stock. We may issue securities that have rights, preferences and privileges senior to our common stock. If we raise additional funds through collaborations or licensing arrangements, we may relinquish rights to certain of our technologies or products, or grant licenses to third parties on terms that are unfavorable **.** ~~General~~ **13General** Risks We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to ~~the ongoing~~ military ~~conflict~~ **conflicts** ~~between Russia and Ukraine~~ . Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine **, the Middle East** or any other geopolitical tensions. U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions **globally, including** ~~and the start of the~~ military **conflicts (such as the** conflict between Russia and Ukraine **and the conflicts in Israel and the Middle East)** ~~. On February 24, 2022, a full- scale military invasion of Ukraine by Russian troops was reported~~ . Although the length and impact of ~~the~~ **these** ~~ongoing military conflict~~ **conflicts** ~~is~~ **are** highly unpredictable, ~~the~~ **these** ~~conflict~~ **conflicts** ~~in Ukraine~~ could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, ~~as well as~~ supply chain interruptions **,** ~~. We are continuing to monitor the situation in Ukraine~~ and ~~globally and assessing its potential impact on our business. Additionally~~ -- **additional economic** ~~, Russia' s prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk~~ and **financial** ~~Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to~~ sanctions ~~and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People' s Republic, and the so- called Luhansk People' s Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication payment system. Additional potential sanctions and penalties have also been proposed and / or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds~~ . Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10- K. **Epidemics and pandemics such** ~~The COVID- 19 outbreak has~~ - **as the** ~~significantly impacted worldwide economic conditions and has negatively impacted our business, financial condition and results of operations. The~~ COVID- 19 pandemic ~~has~~ **have** had **, and in the future may have,** a ~~negative~~ **material adverse** impact on our **business. Our** operations ~~to date~~ and **financial performance have been, and in** the future **may be, negatively** ~~impacts of the pandemic and any resulting economic impact~~ **impacted by public health crises such as the** ~~remain largely unknown and continue to evolve. Many countries worldwide continue to issue~~ COVID- 19 ~~related restrictive orders in an attempt to control the effects of the~~ pandemic **and** ~~. In particular, during the~~ **other** ~~beginning of 2022~~ **epidemics and pandemics. Such events have caused** , **and may** ~~China implemented area- wide shutdowns~~ in ~~order to control~~ the **future cause** ~~spread of COVID- 19~~ , ~~which continued~~ **impacts such as reductions in economic activity (including volatility in demand** for ~~different parts of China throughout 2022~~ **our products, services, and solutions, disruptions in global supply chains, and volatility in financial markets)** . ~~Such shutdowns~~ **Additionally, we** have ~~had~~ **in the past experienced,** ~~an~~ **and** ~~adverse impact~~ **may in the future experience, operational challenges such as workplace disruptions, restrictions** on ~~our financial results for fiscal 2022 and if they~~ - **the** ~~continue could have~~ **movement of people, raw materials,** ~~an~~ **and** ~~adverse impact~~ **goods (both at our** ~~on~~ **own facilities and at** ~~our future financial results. Disruptions to the~~ **those of our customers and suppliers),** global supply chain ~~and the economic environment have adversely affected our financial results and cash flows. The global supply chain has experienced significant~~ disruptions ~~due to electronic component and labor shortages and other macroeconomic factors which have emerged since the onset of COVID- 19~~ , **delays** ~~leading to increased cost of freight, purchased materials and manufacturing labor costs, while also delaying customer shipments. We believe these supply chain trends will continue into 2023. These conditions, in addition to the overall impacts on the global economy, have negatively impacted our~~ - **or** ~~results of operations~~ **disruptions in orders** and **order fulfillment** ~~cash flows. Additionally~~ , **and price** ~~during 2022 the global economy has experienced high levels of~~ inflation ~~, rising interest rates, significant fluctuations in currency values, and increasing economic uncertainty, particularly in Europe. Our results of operations have been negatively impacted by higher costs of raw materials, labor and freight resulting from inflationary pressures. These factors and global events including the ongoing military conflict between Russia and Ukraine, a softening economy in Europe, and rising interest rates on our debt have had a negative impact on our results of operations. 15If~~

~~business interruptions resulting from COVID- 19 or the current macroeconomic conditions described above were to be prolonged or expanded in scope, our business, financial condition, results of operations and cash flows would likely be negatively impacted. If the impacts of the supply chain disruptions are more severe than we expect, it could result in longer lead times and further increased costs, all of which could materially adversely affect our business, financial condition and results of operations~~. If we incur higher costs as a result of trade policies, treaties, government regulations or tariffs, we may become less profitable. There continues to be uncertainty about the relationship between the United States and foreign countries, including with respect to trade policies, treaties, government regulations and tariffs. We are unable to predict whether or when tariffs will be imposed or the impact of any such future tariff increases. We may be the subject of lawsuits from counterparties to acquisitions and divestitures, including an acquiring company or its stockholders, an acquired company' s previous stockholders, a divested company' s stockholders or our current stockholders. We may be the subject of lawsuits from either an acquiring company or its stockholders, an acquired company' s previous stockholders, a divested company' s stockholders or our current stockholders. Such lawsuits could result from the actions of the acquisition or divestiture target prior to the date of the acquisition or divestiture, from the acquisition or divestiture transaction itself or from actions after the acquisition or divestiture. Defending potential lawsuits could cost us significant expense and detract management' s attention from the operation of the business. Additionally, these lawsuits could result in the cancellation of or the inability to renew certain insurance coverage that would be necessary to protect our assets. Rising commodity and precious metals costs could adversely impact our profitability. Raw material commodities **,** such as resins, and precious metal commodities **,** such as platinum **,** are subject to wide price variations. Increases in the costs of these commodities and the costs of energy, transportation and other necessary services may adversely affect our profit margins if we are unable to pass along any higher costs in the form of price increases or otherwise achieve cost efficiencies such as in manufacturing and distribution. Provisions of Delaware law, or of our charter and bylaws may make a takeover more difficult, which could cause our stock price to decline. Provisions in our certificate of incorporation and bylaws and in the Delaware corporate law may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt, which is opposed by management and the board of directors. Public stockholders who might desire to participate in such a transaction may not have an opportunity to do so. We have a staggered board of directors that makes it difficult for stockholders to change the composition of the board of directors in any one year. These anti- takeover provisions could substantially impede the ability of public stockholders to change our management and board of directors. Such provisions may also limit the price that investors might be willing to pay for shares of our common stock in the future. ~~16Item~~ **14Item** 1B. Unresolved Staff Comments.