**Risk Factors Comparison 2024-03-15 to 2023-03-09 Form: 10-K**

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

Risks Related to our Business and our Industry We have a history of losses and expect to incur substantial future losses. We have experienced substantial operating losses since inception. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of approximately $ ~~253~~ **282**, ~~998~~ **505**, 000, which included net losses of approximately $ **28, 507, 000, $** 32, 813, 000 ~~,~~ **and** $ 24, 559 ~~, 000 and $ 7, 837~~, 000 for the years ended December 31, **2023,** 2022 ~~, and~~ 2021 ~~and 2020~~, respectively. Our losses have resulted principally from costs incurred in the research and development of our polymer technology, clinical studies and general and administrative expenses. We intend to conduct significant additional research, development, and clinical study activities which, together with expenses incurred for the establishment of manufacturing arrangements and a marketing and distribution presence and other general and administrative expenses, are expected to result in continuing net losses for the foreseeable future. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to achieve profitability will depend, among other things, on continued adoption and usage of our products in the market, obtaining additional regulatory approvals in markets not covered by the CE mark, establishing sales and marketing arrangements with third parties, satisfactory reimbursement in key territories, and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that our current CE Mark will enable us to achieve profitability, that additional regulatory approvals in other countries will be obtained, that any of our products will be manufactured at a competitive cost and will be of acceptable quality, that reimbursement will be available or satisfactory, that we will be able to achieve profitability or that profitability, if achieved, can be sustained, or our ability to raise additional capital when needed or on terms acceptable to us. Our failure with respect to any or all of these matters would have a material adverse effect on our business, operating results, financial condition and prospects. We ~~may~~ **will** require additional capital in the future to fund our operations. As of December 31, ~~2022~~ **2023**, we had current assets of approximately $ ~~33~~ **25**. ~~8~~ **7** million, including cash, cash equivalents and restricted cash on hand of approximately $ ~~23~~ **15**. ~~8~~ **6** million and current liabilities of approximately $ ~~9~~ **14**. ~~7~~ **5** million. For year ended December 31, ~~2022~~ **2023**, our cash burn, which we define as the total of cash used in operating and investing activities from our statement of cash flows, was approximately $ ~~35~~ **22. 6** million, which included approximately $ ~~6~~ **0**. ~~3~~ **5** million of capital spending and improvements related to our new manufacturing facility and corporate headquarters. Our current and historical cash burn is not necessarily indicative of our future use of cash and cash equivalents. **The Company** ~~We are currently adequately capitalized but~~ will require additional financing in the future ~~in order~~ to **support the commercialization of its products and proposed products, to initiate and** complete **new** additional clinical studies **,** and **for general working capital** ~~to support the commercialization of our proposed~~ **purposes** ~~products~~. **If the Company were to obtain such additional financing through equity financing, the current ownership interest of its stockholders would be diluted and** ~~There~~ **there** can be no assurance that ~~we~~ **the Company** will be successful in ~~our~~ **its** capital raising efforts **. Should the financing the Company requires be unavailable to the Company, or on terms unacceptable to the Company when the Company requires it, the consequences could have a material adverse effect on the Company' s business, operating results, financial condition and prospects**. The amount of long- term capital needed is expected to depend on many factors, including ~~but not limited to~~: ● rate of sales growth and adoption of ~~our~~ **the Company' s** products in the marketplace; ● product gross margin; ● continued progress and cost of ~~our~~ **the Company' s** research and development programs; ● progress ~~and costs associated~~ with **and cost of the Company' s** pre- clinical studies and clinical studies; ● the time and costs involved in obtaining regulatory clearance in other countries and / or for other indications; ● costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; ● costs ~~related to business development activities; ● costs~~ of developing sales, marketing and distribution channels; ● market acceptance and reimbursement of ~~our~~ **the Company' s** products; and ~~●~~ cost for training physicians and other health care personnel. We have an effective shelf registration statement dated July 14, 2021 with the SEC which enables us to raise up to $ 150 million in one or more offerings, through the issuance and sale of any combination of equity securities, debt securities, warrants and units. ~~All~~ **Approximately $ 135. 0 million** of this amount ~~is~~ **was** available as ~~we~~ **of December 31, 2023. We** have **also allocated** ~~not utilized the existing shelf. All of the~~ $ 25 million of our total shelf amount ~~allocated~~ to our ATM facility **. As of December 31, 2023, approximately $ 20. 3 million** was available ~~as of~~ **for use under the ATM facility. On** December ~~31~~ **13**, ~~2022~~ **2023**, ~~On July 24, 2020~~, the Company closed on ~~the~~ **a registered direct** ~~Offering~~ **offering** ~~of 6~~ **for the sale**, ~~052~~ **directly to investors**, ~~631~~ **of 7, 733, 090 registered** shares of ~~its~~ common stock ~~at~~ **and warrants to purchase up to 2, 706, 561 shares of common stock (the " Offering "). Each share of common stock and accompanying warrant to purchase up to 0. 35 shares of common stock, were sold together for** a ~~public offering~~ **combined purchase** price of $ ~~9~~ **1**. **33, for** ~~50 per share. The Company completed the Offering pursuant to the terms of~~ an **aggregate purchase price** ~~Underwriting Agreement, dated as of July 21, 2020, by and among the Company and Cowen and Company, LLC and SVB Leerink LLC, as representatives of the several underwriters named therein. The Company received gross proceeds~~ of approximately $ **10, 285, 000** ~~57. 5 million from the Offering~~. After deducting **transaction** ~~the underwriting discounts and commissions and~~ fees and expenses payable by the Company in connection with the Offering, the Company received net proceeds of approximately $ ~~53~~ **9, 785, 000, excluding any proceeds that may be received upon the exercise of the warrants**. ~~8 million~~ **Each warrant is immediately cash exercisable at an exercise price of $ 2. 00 per share and will expire on the fifth anniversary of the issue date. The Company' s executive officers, directors, and certain non- executive officer employees of the Company also participated in the Offering with a combined investment of $ 435, 000**. On December 30, 2021, we entered into an Open Market Sale Agreement with Jefferies LLC (the " Sale Agreement "). Pursuant to

the Sale Agreement we may offer to sell, from time to time, shares of our common stock, up to a maximum of $ 25, 000, 000. **During the year ended December 31, 2023, the Company sold 2, 656, 464 shares pursuant to the Sale Agreement, at an average selling price of $ 1. 76 per share, generating net proceeds of approximately $ 4, 532, 000.** There were no sales pursuant to the Sale Agreement during the year ended December 31, 2022. On January 19, 2022 (the " Fourth Amendment Closing Date "), the Company closed on the Fourth Amendment (the " Fourth Amendment ") of its Amended Loan and Security Agreement with Bridge Bank. Under the terms of the Amendment, the Company received a commitment from Bridge Bank to provide a new term loan of up to $ 15 million, if needed until December 31, 2022. On December 27, 2022, the Company drew down the first $ 5 million tranche of the Term C loans available under the terms of the Fourth Amendment. On December 28, 2022 (the " Fifth Amendment Date "), the Company entered into the Fifth Amendment of its Amended Loan and Security Agreement with Bridge Bank. The Fifth Amendment extends the draw period under the Fourth Amendment to the earlier of (i) March 1, 2023 and (ii) the occurrence of an Event of Default. On March 9, 2023, the Company entered into the Sixth Amendment of its Amended Loan and Security Agreement. The Sixth Amendment further ~~extends~~ **extended** the draw period to March 24, 2023. ~~Despite~~ **Therefore, no further draws are available as of the date of this filing. The Company is currently evaluating various financing alternatives, including debt financing, strategic partnerships and** ~~the~~ **other** ~~foregoing~~ **non- equity financing arrangements** , ~~we~~ **including royalty financing. While there can be no assurance that the Company** will ~~require additional~~ **be successful in obtaining alternative non- equity** financing **, if such** ~~in the future. Should the~~ financing **is** ~~we require be unavailable to us, or on terms unacceptable to us when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects. In addition, in the event that additional funds are~~ obtained through arrangements with collaborative partners or other non- dilutive sources, ~~we~~ **such as royalty financing, the Company** may have to relinquish economic and / or proprietary rights to some of ~~our~~ **its** technologies or products under development that ~~we~~ **it** would otherwise seek to develop or commercialize **itself** ~~by ourselves~~ . Such events may have a material adverse effect on ~~our~~ **the Company' s** business, operating results, financial condition and prospects. ~~48A~~ **49A** pandemic, epidemic or outbreak of an infectious disease, such as COVID- 19, may materially and adversely affect our business and operations. ~~The~~ **As an example,** outbreak of COVID- 19 originated in Wuhan, China in December 2019 and has since spread around the globe. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID- 19 pandemic **affected** ~~is affecting~~ the United States and global economies ~~and is likely to~~ **with lingering effects that can** continue to affect our operations and those of third parties on which we rely, including by causing disruptions in our global supply chain, our ability to obtain raw materials, the manufacturing of and short- term demand for our lead product, CytoSorb, the commercialization of CytoSorb, our research and development activities, and the conduct of current and future clinical trials. In addition, the COVID- 19 pandemic has affected and is likely to continue to affect the operations of the U. S. Food and Drug Administration and other health authorities, which could result in delays of reviews and approvals, including with respect to DrugSorb- ATR and our product candidates. The evolving COVID- 19 pandemic has impacted and **may** ~~is likely to~~ continue to directly or indirectly impact our clinical trials, including but not limited to, the anticipated completion date of these trials and the pace of enrollment in our clinical trials **nts** ~~for at least the next several months and possibly longer as patients~~ may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Such facilities and offices have and may continue to be required to focus limited resources on non- clinical trial matters, including treatment of COVID- 19 patients, and may not be available, in whole or in part, for clinical trial services. There may be new or further delays in patient enrollment in the PROCYSS and the STAR clinical trials. For example, in April 2021 we stopped the TISORB single arm study due to continued delays and poor enrollment caused by the COVID- 19 pandemic in the U. K., in favor of redirecting those resources to the U. S. STAR- T randomized, controlled trial and in November 2022 **and recently** , we **terminated** ~~temporarily paused~~ the STAR- D trial for business reasons. In addition, employee disruptions and remote working environments related to the COVID- 19 pandemic and the federal, state and local responses to such virus, could materially impact the efficiency and pace with which we work and develop our product candidates, our ability to execute and invoice upon government grants and contracts, and the manufacturing of CytoSorb. As of the date of this filing, our manufacturing facilities remain operational and we have resumed research and development activities that were temporarily suspended as a result of the COVID- 19 pandemic ~~,~~ **.** ~~however~~ **However ,** we have experienced, and may continue to experience, challenges in hiring necessary staff members to conduct our research and development activities, including technical staff. Further, while the potential economic impact brought on by, and the duration of, the COVID- 19 pandemic is difficult to assess or predict, the impact of the COVID- 19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short- term and long- term liquidity. Additionally, the stock market has been unusually volatile during and following the COVID- 19 outbreak and such volatility may continue. Macro factors have impacted, and may continue to negatively impact, our critical care and cardiac surgery markets, including in certain geographies such as Germany. For example, widespread staffing shortages, decreased availability of hospital beds, fewer patients, increased hospital restrictions resulting in decreased access of our sales representatives to hospitals and fewer sales meetings with physicians resulted in lower- than- expected sales of CytoSorb during the years ended December 31, 2022 and 2021, respectively, and may contribute to lower- than- expected sales of CytoSorb in the future. To date, during certain periods of the COVID- 19 pandemic, our stock price fluctuated significantly, and such fluctuation will likely continue to occur. The ultimate impact of the COVID- 19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely **. The Company did not have any COVID- 19 related sales in 2023** . The Company estimated that approximately $ 0. 3 million and $ 6. 3 million of its 2022 and 2021 product sales, respectively, were related to the treatment of COVID- 19 patients. As the pandemic continues to ease and the amount of our revenues attributable

to the treatment of COVID- 19 is reduced, it is uncertain whether the Company will be able to replace some or all of this revenue in the future. Our operating results are subject to seasonal fluctuation. Our total revenue and product sales are subject to seasonal fluctuation. Our sales seasonality is affected by a number of factors, including but not limited to, hospital budgets and buying patterns, customer, employee and healthcare worker vacation schedules, religious, national, and state holidays, scientific and medical conference schedules, seasonal illnesses such as influenza, seasonal or weather- related differences in hospital admissions and the timing of insurance benefits, among others. Our normal seasonality cycle has also been impacted by the COVID- 19 pandemic and related events, making it more difficult to predict and determine a more consistent seasonality trend. See " A pandemic, epidemic or outbreak of an infectious disease, such as COVID- 19, may materially and adversely affect our business and operations. " As a result, seasonality has had, and we expect it to continue to have, an impact on our results of operations. ~~49Although~~ **50Although** historically we have been a research and development company, we are in the process of commercializing our products. There can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities. We have historically been engaged primarily in research and development activities and have generated limited revenues to date. With the launch of our CytoSorb product in the EU and elsewhere, there can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercial enterprise. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by an enterprise in balancing development, which include unanticipated problems relating to testing, product registration, product labeling, regulatory compliance and manufacturing, with commercialization, which includes problems with market adoption, reimbursement, marketing problems and additional costs. Our products and product candidates will require significant additional research and testing, and we will need to overcome significant regulatory burdens prior to commercialization in other countries, such as the U. S., and for ongoing compliance for our CE Mark. Although we believe we are currently adequately capitalized, we will need to raise additional funds to complete additional clinical studies and obtain regulatory approvals in other countries before we can begin selling our products in markets not covered by our CE Mark. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any products, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products. If users of our products are unable to obtain adequate reimbursement from third- party payers, or if reimbursement is not available in specific countries, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues. The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, the future revenues and profitability of our potential customers, suppliers and collaborative partners, and the availability of capital. For example, in certain foreign markets, pricing or profitability of medical devices is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U. S. Congress and state legislatures will likely continue to focus on health care reform, the cost of medical devices and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could materially harm our business, financial condition and results of operations. Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (" HMOs "). Third- party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and medical devices, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably. Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets often have a combination of government- managed and privately- managed healthcare systems that govern reimbursement for medical devices and related procedures. Socialized medicine is common in the EU, and reimbursement and the pricing of medical devices is generally subject to governmental control. Application for reimbursement, subsequent approvals, if any, and pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. Private insurance has similar challenges. CytoSorb is currently reimbursed in Germany under government- funded insurance, and in other countries may be covered under the diagnosis- related group (" DRG "), or " lump sum payment " reimbursement, or other generalized reimbursement for acute care medical products. We are continuously working to obtain or improve upon the type and amount of reimbursement available to us in countries where CytoSorb is available, and as we attempt to move from an existing reimbursement platform to a new reimbursement platform, we may experience interruptions and / or reductions in the amount available for reimbursement. Because of this, there can be no assurance that new reimbursement will be obtained or that existing reimbursement will continue or that such reimbursement will be sufficient to adequately cover the cost of the device or treatment. As a result, our future revenues, profitability and access to capital may be negatively affected by any interruption or reduction in amounts of reimbursement. We plan to seek reimbursement for our product in other EU and non- EU countries to help further adoption. There can be no assurance when, or if, this additional reimbursement might be approved. ~~50We~~ **51We** depend upon key personnel who may terminate their employment with us at any time. As of March ~~7~~ **5**, ~~2023~~ **2024**, we had ~~198~~ **186** full- time and part- time employees as well as several consultants and temporary employees. Our success will depend to a significant degree upon the continued services of our key management team and advisors, including, Dr. Phillip Chan, our Chief Executive Officer; Kathleen P. Bloch, our Chief Financial Officer; Vincent Capponi, our President and Chief Operating Officer and Dr. Efthymios Deliargyris, our Chief Medical Officer. On July 30, 2019, we entered into amended and restated executive employment agreements with its principal executives, Dr. Phillip P. Chan, Chief Executive Officer, Vincent Capponi, President

and Chief Operating Officer, and Kathleen P. Bloch, Chief Financial Officer. Each of the agreements had an initial term of three years and were retroactively effective as of January 1, 2019. On April 12, 2020, CytoSorbents Corporation entered into an executive employment agreement with Dr. Efthymios Deliargyris, who began employment as Chief Medical Officer on May 1, 2020, with an initial term that expires on December 31, 2021. After the expiration of the initial terms, the employment agreements automatically renew for additional terms of one year unless either party provides written notice of non- renewal at least 60 days prior to a renewal. The employment agreements for the Named Executive Officers above have automatically renewed for another **one-** year term ~~. On September 30, 2022, Ms. Bloch notified the Company of her intention to retire effective March 31, 2023. A search has been initiated for Ms. Bloch' s replacement. Ms. Bloch and the Company expect to enter into a consulting arrangement under which Ms. Bloch will continue to provide services to the Company in a limited capacity following the effective date of her retirement~~ . There can be no assurance that key management personnel or other members of our management team and advisors will continue to provide services to us. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Management and other employees may voluntarily terminate their employment with us at any time. Additionally, the increasing demand for qualified personnel may make it more difficult for us to attract and retain qualified employees. Changing demographics and labor work force trends may make it difficult for us to replace departing employees at our manufacturing and other facilities and we may experience increased turnover rates. U. S. labor market conditions are currently challenging and labor shortages have been exacerbated during and following the COVID- 19 pandemic. These conditions are expected to persist into ~~2023~~ **2024** and may lead to higher labor costs. If we fail to attract and retain qualified personnel, or if we experience labor shortages, we may experience higher costs and other difficulties. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources. Acceptance of our medical devices in the marketplace is uncertain, and failure to achieve market acceptance will prevent or delay our ability to generate revenues. Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our products. Even with CE mark approval for our CytoSorb device as a cytokine adsorber, our products and product candidates may not achieve market acceptance in the countries that recognize and accept the CE mark. Additional approvals from other regulatory authorities (such as the FDA) will be required before we can market our device in countries not covered by the CE mark. There is no guarantee that we will be able to achieve additional regulatory approvals, and even if we do, our products may not achieve market acceptance in the countries covered by such approvals. The degree of market acceptance will depend upon a number of factors, including: ● the receipt of regulatory clearance of marketing claims for the uses that we are developing; ● the establishment and demonstration of the advantages, safety and efficacy of our polymer technology; ● pricing and reimbursement policies of government and third- party payers such as insurance companies, health maintenance organizations and other health plan administrators; ● the development by our competitors of products or product candidates that are similar or identical to ours; ● our ability to attract corporate partners, including medical device companies, to assist in commercializing our products; and ● our ability to effectively market our products. Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. Approval of our CytoSorb device as a cytokine adsorber as well as the data we have gathered in our clinical studies to support device usage in this indication may not be sufficient for market acceptance in the medical community. We may also need to conduct additional clinical studies to gather additional data for marketing purposes. If we are unable to obtain regulatory approval or commercialize and market our products when planned, we may not achieve any market acceptance or generate revenue. ~~51If~~ **52If** we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected. Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and / or unenforceable. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non- infringing manner. Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. We cannot be certain that our patents and patent rights will be

effective in protecting our products, product candidates and technologies. In addition, our existing patents are scheduled to expire between ~~2023~~ **2026** and 2038. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects. We may face litigation from third parties claiming that our products infringe on their intellectual property rights, or seek to challenge the validity of our patents. Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know- how, which have been developed from years of research and development. In addition to the previously settled " Purolite " litigation discussed below, we may be exposed to additional future litigation by third parties seeking to challenge the validity of our rights based on claims that our technologies, products or activities infringe the intellectual property rights of others or are invalid, or that we have misappropriated the trade secrets of others. Since our inception, we have sought to contract with large, established manufacturers to supply commercial quantities of our adsorbent polymers. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers. We believe that these disclosures, while necessary for our business, have resulted in the attempt by potential suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing rights. ~~52We~~ **53We** previously engaged in discussions with the Brotech Corporation and its affiliate, Purolite International, Inc. (collectively referred to as " Purolite "), which had demonstrated a strong interest in being our polymer manufacturer. For a period of time beginning in December 1998, Purolite engaged in efforts to develop and optimize the manufacturing process needed to produce our polymer products on a commercial scale. However, the parties eventually decided not to proceed. In 2003, Purolite filed a lawsuit against us asserting, among other things, co- ownership and co- inventorship of certain of our patents. On September 1, 2006, the United States District Court for the Eastern District of Pennsylvania approved a Stipulated Order and Settlement Agreement under which we and Purolite agreed to the settlement of the action. The Settlement Agreement provides us with the exclusive right to use our patented technology and proprietary know how relating to adsorbent polymers for a period of 18 years. Under the terms of the Settlement Agreement, we have agreed to pay Purolite royalties of 2. 5 % to 5 % on the sale of certain of our products through 2024, after which time no royalties will be due under this settlement agreement. The expiration or loss of patent protection may adversely affect our future revenues and operating earnings. We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing, and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable. Our existing patents are scheduled to expire between ~~2023~~ **2026** and 2038. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices. We have commenced the process of seeking regulatory approvals of our products and product candidates, but the approval process involves lengthy and costly clinical studies and is, in large part, not in our control. The failure to obtain government approvals, internationally or domestically, for our products and product candidates, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of our products and result in the failure to achieve revenues or maintain our operations. CytoSorb has already achieved marketing authorization in the EU under the CE marking process and the Medical Devices Directive. It is manufactured at our manufacturing facility in New Jersey under ISO 13485 Full Quality Systems certification. The manufacturing and marketing of our products is subject to extensive and rigorous government regulation in the EU, as well as in the U. S. and in other countries. In the U. S. and other countries, the process of obtaining and maintaining required regulatory approvals is lengthy, expensive, and uncertain. There can be no assurance that we will ever obtain the necessary additional approvals to sell our products in the United States or other non- EU countries. Even if we do ultimately receive FDA approval or clearance for any of our products, we will be subject to extensive ongoing regulation. While we have received approval from our notified body to apply the CE mark to our CytoSorb device, we will be subject to extensive ongoing regulation and auditing requirements to maintain the CE mark. Our products are subject to international regulation as medical devices under the Medical Devices Directive and, once our CE Mark under MDD expires in ~~May~~ **December** ~~2024~~ **2028** will be subject to the new European Union Medical Device Regulation (" MDR "). In Europe, which we expect to provide the initial market for our products, the notified body and Competent Authority govern, where applicable, development, clinical studies, labeling, manufacturing, registration, notification, clearance or approval, marketing, distribution, record keeping, and reporting requirements for medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the notified body under these laws. Current international regulations classify our CytoSorb device as a Class IIb device. Even though we have received CE mark certification of the CytoSorb device, there can be no assurance that we will be able to continue to comply with the required annual auditing requirements or other international regulatory requirements that may be applicable. In addition, there can be no assurance that government regulations applicable to our products or the interpretation of those regulations will not change. The extent of potentially adverse government regulation that might arise from future legislation or administrative action cannot be predicted. There can be no assurances that reimbursement will be granted or that additional clinical data will be required to establish reimbursement. ~~53If~~ **54If** we fail to maintain the CE Mark in the European Union, we will not be able to commercially sell and market CytoSorb. In March 2011, CytoSorb, was " CE marked " in the EU as an extracorporeal cytokine adsorber indicated for use in clinical situations where cytokines are elevated, allowing for commercial marketing. The CE Mark demonstrates that a conformity assessment has been carried out and the product complies with the Medical Devices Directive. A re- certification audit was conducted in April 2019. The successful completion of this audit CE- certifies CytoSorb under the current Medical Device Directive (93 / 42 / EEC) until

~~May~~ **December** ~~2024~~ **2028** . Prior to the expiration of such certificate, we will apply for certification under the new Medical Devices Regulation (MDR). Failure to certify CytoSorb under the Medical Devices Regulation will prevent us from using the CE mark for commercial distribution of CytoSorb in the European Union. Any new product that we submit for the CE Mark after August 2019 must be approved under the new Medical Devices Regulation. Furthermore, if: ● we are not able to obtain re-certification for CytoSorb' s current use; ● we are not able to do so in time before the existing certificate expires; ● CytoSorb does not meet the new (and more stringent) requirements under the Medical Devices Regulation; or ● any variation in the uses for which the CE Mark has been affixed CytoSorb requires us to perform further research or to modify the technical documentation required to affix the CE Mark, our revenues and operating results could be adversely affected and our reputation could be harmed. We may pursue various indications for our product candidates, and they may be subject to different FDA regulatory pathways for marketing authorization, and under the jurisdiction of different FDA review divisions within the FDA' s Office of Device Evaluation. As we seek to determine commercially viable indications for our product candidates, we may consider pursuing a variety of indications that may be approved through one of several different FDA regulatory clearance or approval pathways, and under the jurisdiction of different FDA review divisions within the FDA' s Office of Device Evaluation. We expect the pathways available to us will be impacted by the FDA regulatory history of the category of " sorbent hemoperfusion systems " and our options may also be impacted by the FDA' s interpretations and application of these and other regulatory standards to our product candidates. The regulatory pathways available to us may impact the level and type of data necessary to support our applications, and the post- marketing requirements to which we and our products will be subject. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, affect whether government agencies promptly pay amounts awarded under grants from such agencies, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new drugs and medical devices can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and medical devices to be reviewed and / or approved by necessary government agencies as well as affect whether we receive timely payment of amounts awarded to us under grants and contracts with government agencies which would adversely affect our business. For example, over the last several years, including from December 22, 2018 until January 25, 2019, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. ~~54Clinical~~ **55Clinical** study results for our CytoSorb and / or DrugSorb- ATR device may not be indicative of our future clinical study results, and we cannot assure you that any clinical study results will lead to results sufficient for necessary regulatory clearances or product sales. Additionally, clinical and pre- clinical data is susceptible to varying interpretations, which could delay, limit, reduce, or prevent additional regulatory clearances or product sales. To date, we have conducted limited clinical studies on our CytoSorb and DrugSorb- ATR product. There can be no assurance that we will successfully complete additional clinical studies or that our current or future clinical studies will lead to results necessary to receive additional regulatory approvals in markets not covered by the CE Mark. While clinical studies conducted by us and others have produced results we believe to be encouraging, data already obtained, or in the future obtained, from pre- clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre- clinical studies and clinical studies. CytoSorb, DrugSorb- ATR and our other products and product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in previous studies, which could result in decreased sales of our products and product candidates and have an adverse effect on our business and results of operations. Moreover, pre- clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals in markets not covered by the CE Mark. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of CytoSorb, DrugSorb- ATR or another product under development could delay or prevent regulatory clearance of the device, resulting in delays to commercialization, and could materially harm our business and results of operations. Even though we have received approval to apply the CE Mark to our CytoSorb device as a cytokine adsorber, there can be no assurance that we will be able to receive approval under the MDR for other potential applications of CytoSorb, or that we will receive regulatory clearance or marketing approval from authorities in other targeted regions or countries. We rely extensively on research and testing facilities at various universities and institutions, which could adversely affect us should we lose access to those facilities. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for future healthcare enforcement risk. Although we have our own research laboratories and clinical facilities, we collaborate with numerous institutions, universities and commercial entities to conduct research and studies of our products. We currently maintain a good working relationship with these parties. However, should the situation change, the cost and time to establish or locate alternative research and development facilities could be substantial and delay gaining CE Mark for other potential applications of our products, our other product candidates or technologies, and / or FDA approval and commercializing our products. In addition, our interactions, communications, and financial relationships with these individuals and entities

present future healthcare enforcement risks. We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued. Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations. We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations. Certain university and other relationships are important to our business and may potentially result in conflicts of interests. We work with many medical and clinical advisors in critical care, cardiac surgery, trauma, and other areas who are associated with healthcare institutions. Their association with these institutions may currently or in the future involve conflicting interests in the event they or these institutions enter into consulting or other arrangements with competitors of ours. ~~55We~~ **56We** have limited manufacturing experience and capabilities, we may not be able to manufacture sufficient quantities at an acceptable cost or quality, or without shut- downs or delays. In March 2011, we received approval from our notified body to apply the CE Mark to our CytoSorb device for commercial sale as a cytokine adsorber. We also achieved ISO 13485: 2003 Full Quality Systems certification, and have since upgraded to ISO 13485: 2016 Full Quality Systems certification, an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the EU. We manufacture CytoSorb at our manufacturing facilities in New Jersey for sale in the EU and around the world, as well as for additional clinical studies. Manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (" cGMP ") for medical devices, as set forth in the QSR. As such, we are subject to continual review and periodic inspections to assess compliance with cGMP / QSR requirements as required by our International notified body. Accordingly, we must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we or the third- party manufacturers of our products fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products on a timely basis, or at all. Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our products. We expect to enter into agreements with third parties for the commercial marketing, and distribution of our products. There can be no assurance that parties we may engage to market and distribute our products will: ● satisfy their financial or contractual obligations to us; ● adequately market our products; or ● not offer, design, manufacture or promote competing products. If for any reason any party we engage is unable or chooses not to perform its obligations under our marketing and distribution agreement, we would experience delays in product sales and incur increased costs, which would harm our business and financial results. Weakness in the global economy, and in particular in the United States and Europe, could negatively impact our revenue and operating results. The United States and Europe and other economies may suffer from uncertainty, volatility, disruption, and other adverse conditions, such as inflation or the rising cost of energy, and these conditions have adversely impacted and may continue to adversely impact the business community and the financial markets. Adverse economic and financial market conditions may negatively affect our markets, thereby negatively impacting our revenue and operating results. As a result, if economic and financial market conditions weaken or deteriorate, then our revenue and operating results, including our ability to grow and expand our business and operations, could be materially and adversely affected. Our results of operations can be significantly affected by foreign currency fluctuations and regulations. A significant portion of our revenues is currently derived in the local currencies of the foreign jurisdictions in which our products are sold. Accordingly, we are subject to risks relating to fluctuations in currency exchange rates. In the future, and especially as we further expand our sales efforts in international markets, our customers will increasingly make payments in non- U. S. currencies. Fluctuations in foreign currency exchange rates could affect our revenues, operating costs and operating margins. In addition, currency devaluation can result in a loss to us if we hold deposits of that currency or if it reduces the cost-competitiveness of our products. We cannot predict the effect of future exchange rate fluctuations on our operating results. ~~56If~~ **57If** we are unable to convince physicians and other health care providers as to the benefits of our products, we may incur delays or additional expense in our attempt to establish market acceptance. Broad use of our products may require physicians and other health care providers to be informed about our products and their intended benefits, often supported by clinical data. The time and cost of such an educational process, and obtaining such clinical data may be substantial. Inability to successfully carry out this education process, or obtain adequate positive clinical data, may adversely affect market acceptance of our products. We may be unable to educate physicians regarding our products in sufficient numbers or in a timely manner to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created, if at all. The market for our products is rapidly changing and competitive, and new devices and drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive. The medical device and pharmaceutical industries are subject to rapid and substantial technological change. Developments by others may render our technologies and products noncompetitive or obsolete. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Our business could be harmed by adverse economic conditions in Germany, our primary geographical

market, or by economic and / or political instability in **Germany,** the EU or elsewhere caused by **various** ~~Brexit, trade conflicts, or other~~ factors. For the year ended December 31, ~~2022~~ **2023** , we derived ~~a majority~~ **approximately 42 %** of our net product sales from sales in Germany. Despite modest European and global growth, there are many economic and political issues that could negatively impact the health of Germany' s economy, the broader EU economy, and the world economy overall. Examples include the uncertainty over the implications of the United Kingdom' s exit from the EU, also known as " Brexit, " economic instability in a number of EU member countries, and changes in the political leadership in the EU and United States. Germany and other European countries face additional risks to their local economies, some of which include the impact of foreign exchange fluctuations, unemployment, tightening of monetary policy, the economic burden of immigration, diminished liquidity and reliance on debt, the rising cost of healthcare, and other factors. In addition, the German government, insurance companies, health maintenance organizations and other payers of healthcare costs continue to focus on healthcare reform and containment of healthcare costs. ~~We~~ **For example, German state and federal governments are considering hospital reforms which would de- emphasize the direct related group payment systems and instead emphasize base payments focused on quality measures and appropriate patient care. These discussions are preliminary, and because the ultimate scope, implementation and timing of these reforms remains uncertain, we cannot accurately predict the impact that such reforms may have on our business or our results of operations. Furthermore, we** cannot predict whether Germany' s economy will continue to grow or decline consistent with the overall global economy, which decline would negatively impact the demand for medical devices and healthcare technologies generally and lead to reduced spending on the products we provide. In addition, continued healthcare cost containment efforts may result in lower prices and a reduction or elimination of reimbursement for our products. Due to the concentration of our product sales in this country, any of the foregoing may have a negative impact on our revenues, business operations and financial condition. Significant economic downturns or international trade disruptions or disputes could adversely affect our business and operating results. Significant portions of our business are conducted in Europe, including the U. K.; Asia; and other international geographies. Interruptions in international relationships such as the recent exit by the U. K. from the EU, or the **war** ~~rapidly evolving conflict~~ between Russia and Ukraine, and trade disputes such as the current trade negotiations between the U. S. and China, could result in changes to regulations governing our products and our intellectual property, disruption of our manufacturing or commercial operations, our inability to timely engage with and collect payment from customers in Russia and other affected regions, or otherwise affect our ability to do business. Additionally, global events such as the current COVID- 19 coronavirus pandemic **, war between Russia** and ~~the conflict in~~ Ukraine **, and the Israel- Hamas war** , that have or could, slow worldwide economies, disrupt travel and trade, and destabilize financial markets, may interfere with our ability to raise capital, sell and market our products, obtain reimbursement and payment of our products, or reduce the ability of our customers to pay for our product. Although these global problems transcend our company and afflict companies across industries and borders, these and similar events could adversely affect us, or our business partners or customers. ~~57Our~~ **58Our** business may be negatively affected if the United States and / or the countries in which we sell our products participate in wars, military actions or are otherwise the target of international terrorism. Involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products globally (iv) our inability to timely engage with and collect payment from our customers or (v) our inability to access capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. CytoSorb is currently distributed in Russia. While the existing sanctions do not currently prohibit the distribution of CytoSorb in Russia, additional sanctions may be imposed in the future that could prevent us from selling CytoSorb in this or other affected regions. Additionally, further escalation of geopolitical tensions **or new conflicts, such as the evolving conflict between Israel and Gaza and the surrounding areas,** could have a broader impact that extends into other markets where we do business. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and / or the countries in which we sell or distribute our products, including Russia, will result in any long- term commercial disruptions or if such involvement or responses will have any long- term material adverse effect on our business, results of operations, or financial condition. We could be adversely affected by violations of the Foreign Corrupt Practices Act and similar worldwide anti- bribery laws. We are subject to the Foreign Corrupt Practices Act (the " FCPA "), which generally prohibits companies and their intermediaries from making payments to non- U. S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to anti- bribery laws in the jurisdictions in which we operate. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with the FCPA and other anti- bribery laws, there is no assurance that such policies or procedures will protect us against liability under the FCPA or other laws for actions taken by our agents, employees and intermediaries with respect to our business or any businesses that we acquire. We do business in a number of countries in which FCPA violations by other companies have recently been enforced. Failure to comply with the FCPA, other anti- bribery laws or other laws governing the conduct of business with foreign government entities, including local laws, could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and / or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and / or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws. We are subject to governmental export and import controls that could

impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Our products are subject to export control and import laws, tariffs, and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls. Exports of our products must be made in compliance with these laws, tariffs, and regulations. If we fail to comply with these laws, tariffs, and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. In addition, changes in our products or changes in applicable export or import laws, tariffs, and regulations may create delays in the introduction and sale of our products in international markets or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any change in export or import laws and regulations, shift in the enforcement or scope of existing laws, tariffs, and regulations, or change in the countries, governments, persons, products, or technologies targeted by such laws, tariffs, and regulations, could also result in decreased use of our products, or in our decreased ability to export or sell our products to existing or potential customers. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations. ~~58Cyberattacks~~ **59Cyberattacks** and other security breaches could compromise our proprietary and confidential information which could harm our business and reputation. In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information, as well as employee personal data. The secure storage, maintenance, and transmission of and access to this information is important to our operations our day- to- day business and our reputation. Security breaches have become more common across industries. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e- mails and other electronic communications, as well as our intellectual property and business data. In addition, an employee, contractor, or other third- party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment during the COVID- 19 pandemic, the risk of cybersecurity attacks, particularly through phishing, are increased. We have recently experienced multiple attempts by third parties to penetrate our computer systems. While we have certain safeguards in place to reduce the risk of and detect cyber- attacks, as well as limit the potential exposure of proprietary and confidential information, including multi- layer security protections, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches powered by new and sophisticated technologies, or employee error or malfeasance. Further, we may not be immediately aware of any unpermitted access by hacker or other breaches and we may be unable to quickly and effectively remediate any such breaches. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business. Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management' s attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. In the U. S., even for companies that are not " covered entities " or business associates " under HIPAA, the U. S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission Act, or the FTCA, 15 U. S. C § 45 (a). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. Some state privacy and security laws apply more broadly than HIPAA and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the

CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. ~~59Risks~~ **60Risks** Connected to Our SecuritiesThe price of our common stock has been highly volatile due to factors that will continue to affect the price of our stock. Our common stock closed as high as $ 4. ~~23~~ **17** and as low as $ 1. ~~03~~ **09** per share between January 1, ~~2022~~ **2023** and December 31, ~~2022~~ **2023** on Nasdaq. On March ~~7~~ **13** , ~~2023~~ **2024** , the closing price of our common stock, as reported on Nasdaq, was $ ~~3~~ **1** . ~~80~~ **01** . Historically, medical device company securities such as our common stock have experienced extreme price fluctuations. Some of the factors leading to this volatility include, but are not limited to: ● fluctuations in our operating results; ● announcements of product releases by us or our competitors; ● announcements of clinical data, analyst or media reports; **● financial status:** ● announcements of acquisitions and / or partnerships by us and our competitors; and ● general market conditions. There is no assurance that the price of our common stock will not continue to be volatile. Directors, executive officers and principal stockholders own a significant percentage of the shares of common stock, which will limit your ability to influence corporate matters. Our directors, executive officers and principal stockholders together beneficially own a significant percentage of the voting control of the common stock on a fully diluted basis. Accordingly, these stockholders could have a significant influence over the outcome of any corporate transaction or other matter submitted to stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets and also could prevent or cause a change in control. The interests of these stockholders may differ from the interests of our other stockholders. Third parties may be discouraged from making a tender offer or bid to acquire us because of this concentration of ownership. As of December 31, ~~2022~~ **2023** , two shareholders hold ~~10~~ **11** . ~~4~~ **5** % of our shares and our directors and officers hold 6. ~~7~~ **4** % of our shares on a fully diluted basis. Our Board of Directors may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock adversely affecting the rights of holders of our common stock. On December 3, 2014, we effected a twenty- five- for- one (25: 1) reverse split of our common stock. Immediately after the reverse stock split, we changed our state of incorporation from the State of Nevada to the State of Delaware pursuant to an Agreement and Plan of Merger, dated December 3, 2014, whereby we merged with and into our recently formed, wholly- owned Delaware subsidiary. Pursuant to the Agreement and Plan of Merger effecting the merger, we adopted the certificate of incorporation, as amended and restated, and bylaws of our Delaware subsidiary as our certificate of incorporation and bylaws at effective time of the merger. As a result, our certificate of incorporation, as amended and restated, authorizes the issuance of up to 5, 000, 000 shares of " blank check " preferred stock, with such designation rights and preferences as may be determined from time to time by the Board of Directors. Currently, our certificate of incorporation, as amended and restated, which was effective June 12, 2019, authorizes the issuance of up to 100, 000, 000 shares of common stock, of which approximately ~~56~~ **45** , ~~364~~ **760** , 000 shares remain available for issuance as of December 31, ~~2022~~ **2023** and may be issued by us without stockholder approval. Anti- takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management. After giving effect to our merger into our wholly- owned Delaware subsidiary, provisions of our certificate of incorporation, as amended and restated, and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of us. For example, these provisions: ● authorize the issuance of " blank check " preferred stock without any need for action by stockholders; ● eliminate the ability of stockholders to call special meetings of stockholders; ● prohibit stockholder action by written consent; and ● establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings. ~~60~~ **61**