Risk Factors Comparison 2025-02-26 to 2024-02-28 Form: 10-K

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An investment in our Common Stock involves a substantial risk of loss. Set forth below is a summary of the risks and uncertainties affecting our business that we currently believe to be material. We caution you to read the following risk factors, which have affected, and / or in the future could affect, our business, prospects, operating results, and financial condition. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also affect our business, prospects, operating results, and financial condition. Additional risks and uncertainties are described under other captions in this report and should also be considered by our stockholders. If any of these risks materialize, our business, financial condition or operating results could suffer. In this case, the trading price of our Common Stock could decline, and you may lose part or all of your investment. Risks Related to Our Business and Industry If we do not successfully execute our priorities, our business, operating results and financial condition could be adversely affected. Our priorities in our Wound & Surgical business are to address large, underpenetrated market opportunities, domestically and internationally, including by launching new organic or inorganic products. We intend to implement and maintain rigorous quality standards throughout our entire supply chain and continue to advance the scientific body of evidence substantiating clinical efficacy, economic viability and the underlying mechanism of action for our PURION processed placental tissue platform through additional peer- reviewed publications, rigorous scientific research and clinical studies. We have sought and may continue to seek capital to implement our priorities. In developing our priorities, we evaluated many factors including, without limitation, those related to developments in our industry, customer demand, competition, regulatory developments, and general economic conditions. Actual conditions may be different from our assumptions, and we may not be able to successfully execute our priorities. If we do not successfully execute our priorities, or if actual results vary significantly from our assumptions, our business, operating results and financial condition could be adversely impacted. We are in a highly competitive and evolving field and face competition from well- established tissue processors and medical device manufacturers, as well as new market entrants. Our business is in a very competitive and evolving field. Competition from other tissue processors, medical device companies, and biotherapeutic companies, and from research and academic institutions, is intense, expected to increase and subject to rapid change and could be significantly affected by new product introductions as well as changes in reimbursement that could favor certain products and competitors over others. Established competitors and newer market entrants are investing in additional clinical research that may allow them to gain further clinician usage, adoption and payer coverage of their products. In addition, consolidation and cost containment measures in the healthcare industry may cause hospitals to consolidate their purchases with suppliers that have a broad portfolio of products. This would continue to give rise to demands for price concessions, which could have an adverse effect on our business, results of operations and financial condition. Further, competitors may introduce placental- based membrane products in the future at lower prices, adding new features or gaining additional reimbursement coverage, or utilize sales and marketing practices that negatively impact the industry. Further, they may copy our products outside the United States. The presence of this competition may lead to pricing pressure, which could have an adverse effect on our business, results of operations and financial condition. Rapid technological change could cause our products to become obsolete and, if we do not enhance our product offerings through our research and development efforts or business development and inorganic activities, we may be unable to compete effectively. The technologies underlying our products are subject to rapid technological change. Competition intensifies as technical advances in each field are made and become more widely known. Others may develop services, products or processes with significant advantages over the products, services and processes that we offer or are seeking to develop. Any such occurrence could have an adverse effect on our business, results of operations and financial condition. We plan to enhance and broaden our product offerings as part of a strategy that involves responding to changing customer demands and competitive pressure and technologies, among other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to: • properly identify and anticipate physician and patient needs; • acquire, through licensing, co- development or outright purchase, new technology developed outside of MIMEDX; • develop and introduce new products or product enhancements in a timely manner; • adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; • demonstrate the safety and efficacy of new products; and • obtain the necessary regulatory clearances or approvals for new products or product enhancements. If we do not develop and, when necessary, obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations and financial condition will suffer. Our research and development efforts may require a substantial investment of time and resources, including additional capital, before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs of development, or they may never receive required regulatory approval and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. Many of our products depend on the availability of tissue from human donors, and any disruption in supply could adversely affect our business. The success of our human tissue products depends upon, among other factors, the availability of tissue from human donors. Any failure to obtain tissue from our sources will interfere with our ability to effectively meet demand for our products incorporating human tissue. The availability of donated tissue could also be adversely impacted by regulatory changes, public opinion of the donor process and our own reputation in the industry. We may not be successful in our ability to scale tissue recovery efforts to meet the

potential future demand of our pipeline. Obtaining adequate supplies of human tissue involves several risks, including limited control over availability (due to for example, access to hospital accounts and the number of consenting mothers), quality, delivery schedules, and eligibility requirements. In addition, any interruption in the supply of any human tissue component could harm our ability to manufacture our products until a new source of supply, if any, could be found. We also utilize third- party providers of placental donations on an as- needed basis to mitigate risks but there can be no assurance that these third parties will be able to provide donated tissues at all times. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have an adverse effect on our business, results of operations and financial condition. We depend on our senior leadership team and **key employees and** may not be able to retain or replace these employees or recruit additional qualified personnel, which would harm our business, results of operations and financial condition. Our business and success are materially dependent on attracting and retaining members of our senior leadership team to formulate and execute the Company' s business plans **and** ~~. Since June 2018, we have made significant changes to~~ our **sales** ~~senior leadership~~ team **to market** ~~, and hired several new senior leaders, including~~ our **products** ~~CEO and CFO in 2023~~ . Leadership changes can be inherently difficult to manage and may cause material disruption to our business or management team. Changes in senior management could also lead to an environment that presents additional challenges in recruiting and retaining employees, which could have an adverse effect on our business, results of operations and financial condition. ~~Our future~~ **Recruiting and retaining qualified scientific, clinical, and sales and marketing personnel are critical to our** success ~~will also depend~~ **. The loss of the services of our executive officers or other key employees could impede the achievement of our research** , ~~in part, upon~~ **development and commercialization objectives and seriously harm** our ability to ~~attract~~ **successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take** ~~and~~ **an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train,** retain ~~skilled~~ **or motivate these key** personnel ~~, including sales, managerial~~ **on acceptable terms given the competition among numerous pharmaceutical** and ~~technical~~ **biotechnology companies for similar** personnel. **Furthermore, to the extent our executive officers or key personnel with access to our proprietary or confidential information are hired by our competitors, they may share such information with our competitors requiring us to initiate litigation to prevent any use of such information by our competitors. For example, in December 2024, MIMEDX filed a lawsuit against Surgenex, LLC in the United States District Court for the District of Arizona.** ~~There~~ -- **The** ~~can~~ **complaint asserts that several of Surgenex' s placental allograft products infringe the Company' s patents and seeks permanent injunctive relief and monetary damages. On the other hand, if we hire personnel from competitors, we may** be ~~no assurance~~ **subject to allegations** that ~~we will be able to continue to find and attract additional qualified~~ **they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former** ~~employees~~ **employers own their research output** ~~to support our expected growth or retain any such personnel~~ . Our revenues depend on adequate reimbursement from public and private insurers and health systems and changes to the ways in which our products are reimbursed in various sites of service could adversely impact our financial results. Our success depends on the extent to which our customers receive adequate reimbursement for the costs of our products and related treatments from third- party payers, including government healthcare programs, such as Medicare and Medicaid, as well as private insurers and health systems. Government and other third- party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement of medical products, particularly new products. Therefore, significant uncertainty may exist as to the reimbursement status of new healthcare products by third- party payers. Although EPIFIX and EPICORD have coverage with the majority of large payers, a significant number of public and private insurers currently do not cover or reimburse our other products. The reimbursement landscape for our products varies depending upon the site in which the products are administered. If we are not successful in obtaining adequate coverage and reimbursement for our products from these third- party payers in one or more of the sites of service where our products are used, it could have an adverse effect on market acceptance of our products. Inadequate reimbursement levels would likely also create downward price pressure on our products. Even if we do succeed in obtaining widespread coverage and reimbursement rates or policies for our products, future changes in coverage or reimbursement rates or policies could have a negative impact on our business, financial condition and results of operations. Further, we have experienced some reluctance by payers to cover our products under certain circumstances, including for applications other than those for which we have published clinical efficacy data. Since 2022, several wide- ranging proposals have been published for public comment, including relating to payment methodology within the physician office, with potential to change how CMS reimburses for skin substitute products at a national level. ~~At a regional level, three Medicare Administrative Contractors (MACs) signaled their intent to change coverage guidance by moving Local Coverage Determinations (LCDs) through the process. While these were ultimately withdrawn, the same MACs signaled their intent to revisit the issue. If the national reimbursement proposals were to be adopted, it would significantly change Medicare policies governing the reimbursement of skin substitute products principally when used for wound treatment in the private physician office setting. If MACs proceed to change coverage policies, this could significantly change guidance within the affected regions.~~ Changes in the coverage and reimbursement environment as described above could result in declines in our revenue that would adversely affect our business, financial condition and results of operation. Our revenue, results of operations and cash flows may suffer upon the loss of a Group Purchasing Organization or Integrated Delivery Network. As with many manufacturers in the healthcare space, the Company contracts with Group Purchasing Organizations (" GPOs ") and Integrated Delivery Networks (" IDNs ") to establish contracted pricing and terms and conditions for the members of GPOs and IDNs. Approximately ~~79~~ **76** % of our sales in the year ended December 31, ~~2023~~ **2024** came from customers that are members of our primary GPOs or IDNs. Our agreements with GPOs and IDNs allow us to sell our products efficiently to large groups of

customers. Our agreements with GPOs and IDNs typically provide their members with favorable ordering terms and conditions and access to favorable product pricing. These customers purchase our product through GPO and IDN arrangements in part because of the favorable pricing and terms and conditions. If our agreement with any GPO or IDN is terminated or expires without being extended, renewed or renegotiated, this could adversely affect our revenue, results of operations and cash flows. We contract with and are dependent upon independent sales agents and distributors. In ~~2023~~ **2024** , approximately 24 % of our sales were through our relationships with independent agents, and we also use a small number of distributors, primarily outside the United States, and may use more in the future. Sales agents act directly on behalf of MIMEDX to arrange sales, while distributors take title to product and may set their own prices. If our relationships with our independent sales agents were terminated for any reason, it could materially and adversely affect our revenues and profits. Because the independent agent often controls the customer relationships within its territory, there is a risk that if our relationship with the agent ends, our relationship with the customer will be lost. Because our agents and distributors are not employees, there is a risk we will be unable to ensure that our sales processes, compliance safeguards, and related policies will be adhered to despite our communication and training of agents and distributors regarding these requirements. Furthermore, if we fail to maintain relationships with our key independent agents, or fail to ensure that our independent agents adhere to our sales processes, compliance safeguards and related policies, there could be an adverse effect on our business, results of operations, and financial condition. We may obtain the assistance of additional distributors and independent sales representatives to sell products in certain sales channels, particularly in territories and fields where agents are commonly used. Our success is partially dependent upon our ability to train, retain and motivate our independent sales agencies, distributors, and their representatives to appropriately and compliantly sell our products in certain territories or fields. They may not be successful in implementing our marketing plans or compliance safeguards. Some of our independent sales agencies and distributors do not sell our products exclusively and may offer similar products from other companies. Our independent sales agencies and distributors may terminate their contracts with us, may devote insufficient sales efforts to our products or may focus their sales efforts on other products that produce greater commissions for them, which could have an adverse effect on our business, results of operations and financial condition. We also may not be able to find additional independent sales agencies and distributors who will agree to appropriately and compliantly market or distribute our products on commercially reasonable terms, if at all. If we are unable to establish new independent sales representative and distribution relationships or renew current sales agency and distribution agreements on commercially acceptable terms, our business, financial condition, and results of operations could be materially and adversely affected. Disruption of our processing facilities could adversely affect our business, financial condition and results of operations. Our business depends upon the continued operation of our processing facilities in Marietta, Georgia and Kennesaw, Georgia **, located less than ten miles apart** . Risks that could impact our ability to use these facilities include the occurrence of natural and other disasters, the outbreak of pandemics, and the need to comply with the requirements of directives from government agencies, including the FDA. Either of our two processing facilities can serve as a redundant processing facility for most of our products in the event the other facility experiences a disaster event. However, if our processing facilities were to become unavailable, this could have a material adverse effect on our business, financial condition and results of operations during the period of such unavailability. To be commercially successful, we must educate physicians, where appropriate, how and when our products are proper alternatives to existing treatments and that our products should be used in their procedures. We believe physicians will only use our products if they determine, based on their independent medical judgment and experience, clinical data, and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other treatments. Physicians may be hesitant to change their existing medical treatment practices for the following reasons, among others: • their lack of experience with advanced therapeutics, such as our placenta- based allografts **or xenografts** ; • lack of evidence supporting additional patient benefits of advanced therapeutics, such as our placenta- based allografts **or xenografts** , over conventional methods in certain therapeutic applications; • perceived liability risks generally associated with the use of new products and procedures; • limited availability of reimbursement from third- party payers; • more favorable reimbursement for other market- available products; and • the time that must be dedicated to physician training in the use of our products. If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted. In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third- party components included in our products, as any quality issues or defects may negatively impact physician use of our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. If the quality of our products does not meet the expectations of physicians or patients, then our brand reputation could suffer and our business could be adversely impacted. We must also ensure any promotional claims made for our products comport with government regulations. The formation of physician- owned distributorships (“ PODs ”) could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships. PODs are medical product distributors that are owned, directly or indirectly, by physicians. These physicians derive a proportion of their revenue from selling or arranging for the sale of medical products for use in procedures they perform on their own patients at hospitals that agree to purchase from or through the POD, or that otherwise furnish ordering physicians with income that is based directly or indirectly on those orders of medical products. The Office of Inspector General (“ OIG ”) of the Department of Health & Human Services has issued a Special Fraud Alert on PODs, indicating that they are inherently suspect under the federal Anti- Kickback Statute. Our commercial strategy emphasizes selling directly to healthcare providers and, to a limited extent, through distributors. To our knowledge, we do not directly sell to or distribute any of our products through PODs. The number and strength of PODs in the industry may continue to grow as economic pressures increase throughout the industry and hospitals, insurers and physicians search for ways to reduce costs, and, in the case of the physicians, identify additional sources to increase their incomes. These companies and the physicians who

own, or partially own, PODs may have significant market knowledge, access to and influence on the physicians who use our products and the hospitals that purchase our products, and we may not be able to compete effectively for business from physicians who own PODs. We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance. While we have had a low product complaint and adverse event rate historically, our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing and marketing of human tissue products. We may be subject to such claims if our products cause, or appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Product liability claims can be expensive to defend (regardless of merit), divert our management' s attention, result in substantial damage awards against us, harm our reputation, and generate adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance at an acceptable cost or on acceptable terms or be able to secure increased coverage (if needed), nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims or we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business. Even if a claim is not successful, defending such claim would be time- consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management' s attention. The products we ~~process~~ **offer** are derived from human **and animal** tissue and therefore have the potential for disease transmission. The utilization of human tissue creates the potential for transmission of communicable disease, including, without limitation, human immunodeficiency virus, viral hepatitis, syphilis and other viral, fungal or bacterial pathogens. We **and our contract manufacturers** are required to comply with federal and state regulations intended to prevent communicable disease transmission. We maintain strict quality controls designed in accordance with CGTP to ensure the safe procurement and processing of our tissue, including terminal sterilization of our products. These controls are intended to prevent the transmission of communicable disease. However, risks exist with any human tissue implantation. Also, negative publicity concerning disease transmission from other companies' improperly processed donated tissue could have a negative impact on the demand for our products and adversely affect our business, financial condition and results of operations. We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation, disrupt our business and adversely affect our business, results of operations and financial condition. The processing and marketing of our tissue products involves an inherent risk that our tissue products or processes may not meet applicable quality standards and requirements. In the event that one or more of our products experiences a failure to meet such standards and requirements, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall or market withdrawal of one of our products could be costly and may divert management resources. A recall or withdrawal of one of our products, or a similar product processed by another entity, also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety. A cyberattack or significant disruptions of our information technology systems could adversely affect our business, results of operation and financial condition. A cyberattack, a disruption in availability, or the unauthorized alteration of systems or data could adversely affect our business, results of operations and financial condition. We rely on technology for day- to- day operations as well as positioning to enhance our stance in the market. We generate intellectual property that is central to the future success of the business and transmit large amounts of confidential information. Additionally, we collect, store and transmit confidential information of customers, patients, employees and third parties. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure, and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The continually changing threat landscape of cybersecurity today makes our systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, partners, and vendors, and from attacks by malicious third parties, including supply chain attacks originating at our third- party partners. Such attacks are of ever- increasing levels of sophistication. Attacks are made by individuals or groups that have varying levels of expertise, some of which are technologically advanced and well- funded including, without limitation, nation states, organized criminal groups and hacktivists organizations. To ensure protection of our information, we have invested in cybersecurity and have implemented processes and procedural controls to maintain the confidentiality and integrity of such information. We measure these controls and their success through a cybersecurity framework that is based on industry standards. While we have invested in the protection of our data and technology, there can be no guarantees that our efforts will prevent all service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal and reputational harm to our business, including legal claims and proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties, as well as remediation costs. We also maintain cyber liability insurance. However, this insurance may not be sufficient to cover the financial, legal or reputational losses that may result from an interruption or breach of our systems. We may expand or contract our business through acquisitions, divestitures, licenses, investments, and other commercial arrangements with other companies or technologies, which may adversely affect our business, results of operations and financial condition. We periodically evaluate opportunities to acquire companies or divest divisions, technologies, products, and rights through licenses, distribution agreements, investments, and outright acquisitions to grow our business **, although we may not successfully identify or negotiate any such transaction** . In connection with one or

more of those transactions, we may, subject to the requirements and limitations set forth in our Citizens Credit Agreement (as defined below in Management' s Discussion and Analysis of Financial Condition and Results of Operations (" MD & A "), Liquidity and Capital Resources): • divest or license existing products or technology; • use cash that we may need in the future to operate our business; • incur debt that could have terms unfavorable to us or that we might be unable to repay; • structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step- up in the tax basis for the assets acquired; • be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales; **• be unable to successfully integrate, operate, maintain, and manage our newly acquired operations; • divert management' s attention from the existing business; • acquire unknown liabilities that could subject us to government investigations and / or litigation or other actions that make it impossible to realize the anticipated benefits of the transaction;** and • be unable to secure the services of key employees related to the transaction (s). Any of these items could adversely affect our revenues, results of operations and financial condition. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Incurring unknown liabilities or the failure to realize the anticipated benefits of any transaction could adversely affect our business if we are unable to recover our initial investment. Inability to recover our investment, or any write off of such investment, associated goodwill or assets could have an adverse effect on our business, results of operations and financial condition **. In addition, if the benefits of any proposed acquisition do not meet the expectations of investors and analysts, our stock price may decline** . A portion of our revenues and accounts receivable come from government accounts. Some of our revenues are derived from sales, both direct and through a distributor, to the government. Any disruption of our products on the FSS or any change in the way the government purchases products like ours or the price it is willing to pay for our products could adversely affect our business, results of operations and financial condition. New lines of business or new products and services may subject us to additional risks. From time to time, we may implement or may acquire new lines of business or offer new products and services within existing lines of business. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and marketing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive alternatives, and shifting market preferences, may also impact the successful implementation of a new line of business or a new product or service. Failure to successfully manage these risks in the development and implementation of new lines of business or new products or services could have an adverse effect on our business, results of operations and financial condition. Our international expansion and operations outside the U. S. expose us to risks associated with international sales and operations. We are pursuing further expansion outside the U. S., including in Japan. Managing a global organization is difficult, time consuming and expensive. Our ability to conduct international operations is affected by many of the same risks we face in our U. S. operations, as well as unique costs and difficulties of managing international operations, including the relationships and operations of distributors we elect to work with in these markets. Adoption of our products in new geographic regions could take longer and cost more than we anticipate. Risks inherent in international operations also include, among others, potential adverse tax consequences, greater difficulty in enforcing intellectual property rights, risks associated with the Foreign Corrupt Practices Act and local anti- bribery law compliance, and other international regulations. These regulations may limit our ability to market, sell, distribute or otherwise transfer our products to prohibited countries or persons. International regulations may also limit what promotional claims we may make for our products. Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, without limitation, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating outside of the U. S. also requires significant management attention and financial resources. Risks Related to Regulatory Approval of Our Products and Other Government Regulations The FDA has in the past determined, and may in the future determine, that certain of our products that are, or are derived from, human cells or tissues, do not qualify for regulation solely under Section 361 ~~of the Public Health Service Act (" Section 361 ")~~ , and may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA pre- market clearance or approval is obtained, which could adversely affect our business, results of operations, and financial condition. ~~The~~ **Many of the** products we manufacture and process are derived from human tissue. Amniotic and other birth tissue have in the past generally been regulated as HCT / P and were therefore eligible to be subject to regulation solely under Section 361 (" Section 361 HCT / P ") depending on whether the specific product at issue and the claims made for it were consistent with the applicable criteria. HCT / Ps that do not meet these criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products. These HCT / Ps must comply with both the FDA' s requirements for HCT / Ps and the requirements applicable to biologics, devices or drugs, including pre- market clearance or approval from the FDA. Obtaining FDA pre- market clearance or approval involves significant time and investment by the Company. In ~~accordance~~ **March 2024, the FDA issued a determination letter in connection** with the **RFD process related to AXIOFILL, a human- derived particulate wound dressing. In the letter,** FDA **reaffirmed** ~~Guidance, as discussed above in " Business — Government Regulation, " after May 31, 2021, the Company no longer markets or sells~~ its ~~products~~ **position** that **AXIOFILL** ~~were impacted by enforcement discretion in the United States, has requested the return of unused consignment inventory as of that date, and~~ does not **meet** ~~intend to sell such products in the United States until the FDA grants pre- market approval. Our sales of such products for all uses was $ 0. 5 million, $ 2. 4 million, and $ 17. 6 million, respectively, in 2023, 2022, and 2021. Prior to May 31, 2021, these~~ -- **the regulatory** ~~sales were primarily in the United States. The loss of our ability to market and sell our micronized products previously had an adverse impact on our revenues, business, financial~~

~~condition and results of operations. Also, we are engaged with the FDA regarding the~~ classification ~~of AXIOFILL and certain of our other products. If the FDA makes a final determination that any of these products do not meet the~~ requirements ~~for regulation solely~~ under Section 361 **. In response to the RFD determination letter** , **the Company has filed suit** in ~~order~~ **the U. S. District Court for the Northern District of Georgia and intends to exhaust all legal options available, given the arbitrary and capricious manner in which FDA is regulating like- kind products. Notably, while these proceedings are taking place, the Company has been permitted** to continue **marketing AXIOFILL. Depending on the outcome of this legal proceeding, we may no longer be able** to market **AXIOFILL** ~~the products, we would be required to obtain the appropriate FDA approval or clearance~~ . The loss of our ability to market and sell ~~these~~ **this or any other** ~~products~~ **product in our portfolio** would have an adverse impact on our revenues, business, financial condition and results of operations. Any future regulatory changes could also have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre- market clearance or approval and compliance with additional post- market regulatory requirements with respect to those products. For example, the FDA may in the future impose conditions, such as labeling restrictions, and the requirement that a product be manufactured in compliance with CGMP, which would require significant additional time and cost investments by the Company. Moreover, increased regulatory scrutiny within the industry in which we operate could lead to increased regulation of HCT / Ps, including Section 361 HCT / Ps, which could ultimately increase our costs and adversely impact our business, results of operations and financial condition. **HELIOGEN, our first xenograft product offering, falls into an FDA classification that requires the submission of a Premarket Notification (510 (k)) to the FDA. The 510 (k) was obtained and is owned by our contracted manufacturing partner, Regenity Biosciences. To date, the Company has neither applied for, nor received any 510 (k)' s from the FDA, however we have efforts underway to explore our ability to do so with certain of the products in our pipeline. The 510 (k) process requires us to demonstrate that the device to be marketed is at least as safe and effective as, that is, substantially equivalent to, a legally marketed device. We must submit information that supports our substantial equivalency claims. Before we can market the new device, we must receive an order from the FDA finding substantial equivalence and clearing the new device for commercial distribution in the U. S. Obtaining clearances or approvals is time consuming, expensive, and uncertain. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses of the product, which may limit the potential customers for the product. If we are unable to obtain required FDA clearance or approval for a product or are unduly delayed in doing so, or the uses of that product were limited, our business could suffer.** Obtaining and maintaining the necessary regulatory approvals, including conducting clinical trials, for certain of our products or potential products could be expensive and time consuming. The process of obtaining regulatory clearances or approvals to market a biological product or medical device from the FDA or similar regulatory authorities outside of the U. S. may be costly and time consuming, and such clearances or approvals may not be granted on a timely basis, or at all. The FDA may take the position that some of the products that we currently market require ~~a BLA~~ **FDA regulatory clearance or approval** . Some of the future products and enhancements to our current products that we expect to develop or may acquire and market may require marketing clearance or approval from the FDA. However, clearance or approval may not be granted with respect to any of our products or enhancements and further FDA review may add delays that could adversely affect our ability to market such products or enhancements. The process of obtaining ~~an~~ **formal FDA clearance or** ~~approved~~ **approval , such as a 510 (k),** BLA **, or equivalent** , including clinical trial development and execution as well as manufacturing processes, requires the expenditure of substantial time, effort and financial resources and may take years to complete, including costs incurred on top of those fees incurred as part of conducting various clinical studies. The fee for filing ~~a BLA~~ **such submissions** and program fees payable with respect to any establishment that manufactures biologics are substantial. The FDA may not grant approval on a timely basis, or at all, or we may decide not to pursue ~~a BLA~~ **this pathway** for certain products or indications, or need to conduct additional trials for a given indication. Additionally, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. If we do receive approval, some types of changes to the approved product, such as adding new indications or doses, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. Our revenues could be adversely affected if we fail to obtain ~~BLA~~ approvals **and clearances** on a timely basis or at all, or if the FDA limited the indications for use or required other conditions that restrict the commercial application of our products. Additionally, there are significant costs associated with clinical trials that can be difficult to accurately estimate until a BLA is approved. Clinical trials may not be successful or may return results that do not support approval. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. Our interpretation of data and results from our clinical trials does not ensure that we will achieve similar results in future clinical trials. In addition, clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in earlier clinical trials or retrospective studies have nonetheless failed to replicate results in later clinical trials. Our business is subject to extensive regulation by the FDA and other authorities, which is costly, and our failure to comply could result in negative effects on our business, results of operations and financial condition. As discussed above, the FDA has specific regulations governing our tissue- based products, or HCT / Ps. The FDA has broad post- market and regulatory and enforcement powers, even for Section 361 HCT / Ps. The FDA' s regulation of HCT / Ps includes requirements for registration and listing of products, donor screening and testing, processing and distribution, labeling, record keeping and adverse- reaction reporting, and inspection and enforcement. HCT / Ps that are regulated as drugs, biological products or medical devices are subject to even more stringent regulation by the FDA. Even if pre- market clearance or approval is obtained, the approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, may require warnings to accompany the product or impose additional restrictions on the sale or use of the product. In addition, regulatory approval is subject to continuing compliance with regulatory standards, including the FDA' s quality system

regulations. If we fail to comply with the FDA regulations regarding our tissue products, the FDA could take enforcement action, including, without limitation, any of the following sanctions and the manufacture of our products or processing of our tissue could be delayed or terminated: • untitled letters, warning letters, cease and desist orders, fines, injunctions, and civil penalties; • recall or seizure of our products; • operating restrictions, partial suspension or total shutdown of production; • refusing our requests for clearance or approval of new products; • withdrawing or suspending current applications for approval or approvals already granted; • refusal to grant export approval for our products; and • criminal prosecution. The FDA' s regulation of HCT / Ps may continue to evolve. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have an adverse effect on our business, results of operations and financial condition. The AATB has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become an accredited tissue bank. In addition, some states have their own tissue banking regulations. In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the NOTA, which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks, hospitals and physicians for their services associated with the recovery and storage of donated human tissue. Although we have independent third- party appraisals that confirm the reasonableness of the service fees we pay, if we were to be found to have violated NOTA' s prohibition on the sale or transfer of human tissue for valuable consideration, we could potentially be subject to criminal enforcement sanctions, which could adversely affect our results of operations. Finally, we and other manufacturers of skin substitutes are required to provide average **sales price (“** ASP **”)** information to CMS on a quarterly basis. The Medicare payment rates are updated quarterly based on this ASP information. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, such manufacturer is subject to civil monetary penalties of up to $ 10, 000 for each misrepresentation for each day in which the misrepresentation was applied, and potential False Claims Act liability. See “ We and our sales representatives, whether employees or independent contractors, must comply with various federal and state anti- kickback, self- referral, false claims and similar laws, any breach of which could cause an adverse effect on our business, results of operations and financial condition. ” We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off- label, uses. As a general rule, FDA regulations require that the marketing of 361 HCT / Ps only be for appropriate homologous uses, and that the promotion of pre-approved biological products or devices only be for FDA- approved indications. Generally, unless the products are approved by the FDA for alternative uses, the FDA contends that we may not make claims about the safety or effectiveness of our products, or promote them as safe or effective for uses other than those specifically approved by the FDA. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the ~~federal~~ **Federal** ~~FD~~ **Food Drug** & ~~C~~ **Cosmetic** Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, prior marketing materials, arrangements with institutions and doctors, educational and training programs and other activities. Investigations concerning the promotion of unapproved product uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant legal action, fines, penalties, and even criminal liability and may be required to substantially change our sales, promotion, grant and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or any of our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. ~~However, under the Guidance, as discussed above in “ Business — Government Regulation, ” after May 31, 2021, the Company no longer markets or sells its products that were impacted by enforcement discretion in the United States, and does not intend to sell such products in the United States until the FDA grants pre- market approval. We will ultimately only be able to market such products for indications that have been cleared or approved by the FDA.~~ Nevertheless, while we believe we are fully in compliance with the FDA' s Guidance on HCT / Ps, there can be no assurance that we have correctly interpreted the FDA Guidance, or that we will not need to discontinue marketing a product and / or may be subject to fines, penalties, injunctions, and other sanctions if we are deemed to be promoting the use of our products for unapproved uses. Such regulatory penalties by the FDA could adversely affect our business and results of operations. Our relationships with physicians, hospitals and other healthcare providers are subject to various federal and state healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex and, in some instances, even minor or inadvertent violations can give rise to liability. Possible sanctions for violation of the healthcare fraud and abuse laws include, without limitation, monetary fines, civil and criminal penalties, exclusion from participating in the federal and state healthcare programs, including, without limitation, Medicare, Medicaid, the VA health programs and TRICARE (the healthcare program administered by or on behalf of the U. S. Department of Defense for uniformed service members, including both those in active duty and retirees, as well as their dependents), and forfeiture of amounts collected in violation of such prohibitions. Many states have similar fraud and abuse laws, imposing substantial penalties for violations. A finding of a violation of one or more of these laws, or even a government investigation or inquiry into the same, would likely result in a material adverse effect on the market price of our Common Stock, as well as on our business, results of operations, and financial condition. **We are subject to the** ~~The federal Anti- Kickback Statute (“~~ AKS **as amended** ~~”) is a criminal law that prohibits, among other things, any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward referrals, purchases or orders or arranging for or recommending the purchase, order or referral of any item or service for which payment may be made in whole or in part~~ by ~~a federal healthcare program, such as~~ the ~~Medicare and Medicaid programs. The term “ remuneration ” has been broadly interpreted to include anything of value. The~~ Patient Protection and Affordable Care Act (the “ PPACA ”) ~~amended the federal~~

~~AKS to clarify the intent that is required to prove a violation. Under the federal AKS as amended, a person or entity need not have actual knowledge of this statute or specific intent to violate it. The PPACA also amended the federal AKS to provide that any claims for items or services resulting from a violation of the federal AKS are considered false or fraudulent for purposes of the federal FCA~~ . A conviction for violation of the AKS results in criminal fines and requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exceptions and regulatory safe harbors to the federal AKS that protect certain common industry practices from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. We have entered into consulting agreements, speaker agreements, research agreements and product development agreements with physicians, including some who may order or recommend our products or make decisions to use them. In addition, some of these physicians own our stock, which they purchased in arm' s- length transactions on terms identical to those offered to non- physicians, or received stock awards from us in the past as consideration for services performed by them. While we believe these transactions generally meet the requirements of applicable laws, including the federal AKS and analogous state laws, it is possible that our arrangements with physicians and other providers may be questioned by regulatory or enforcement authorities under such laws, which could lead us to redesign the arrangements and subject us to significant civil or criminal penalties. We have designed our policies and procedures to comply with the federal AKS, FCA, and industry best practices. In addition, we have conducted training sessions on these principles. If, however, regulatory or enforcement authorities were to view these arrangements as non- compliant with applicable laws, there would be risk of government investigations / inquiries or penalties. There is also risk that one or more of our employees or agents will disregard the rules we have established. Because our strategy relies on the involvement of physicians who consult with us on the design of our products, perform clinical research on our behalf or educate other health care professionals about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with physicians who refer or order our products to be in violation of applicable laws. This could harm our reputation and the reputations of the physicians we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally- funded healthcare programs, including Medicare, Medicaid, VA and TRICARE. The FCA imposes civil liability on any person or entity that knowingly submits, or causes the submission of, a false or fraudulent claim to the U. S. government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity to sue on behalf of the government to recover civil penalties and treble damages as a whistleblower. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of between $ ~~11~~ **13** , ~~181~~ **946** and $ ~~22~~ **27** , ~~363~~ **894** per false claim or statement for penalties assessed after ~~January 29~~ **February 12** , ~~2018~~ **2024** , with respect to violations occurring after November 2, 2015. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to " cause " the submission of false or fraudulent claims. The PPACA provides that claims tainted by a violation of the federal AKS are false for purposes of the FCA. The DOJ on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off- label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare programs such as Medicare and Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into onerous corporate integrity agreements with the government that require, among other things, substantial reporting and remedial actions, as well as oversight and review by an outside entity, an Independent Review Organization (" IRO "), at substantial expense to the Company. Under the HIPAA criminal federal healthcare fraud statute, it is a crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items or services. There are federal and state laws requiring detailed reporting of manufacturer interactions with and payments to healthcare providers, such as the ~~federal Physician Payments~~ Sunshine Act ~~(" Sunshine Act ")~~ . The Sunshine Act requires, among others, " applicable manufacturers " of drugs, devices, biological products, and medical supplies reimbursed under Medicare, Medicaid or the Children' s Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to " covered recipients. " The term covered recipients includes U. S.- licensed physicians and teaching hospitals, and, for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives. There is the risk that CMS or another government agency may take the position that our products are not human cell and tissue products regulated solely under Section 361, and thereby assert that we are currently subject to the Sunshine Act, which could subject us to civil penalties and the administrative burden of having to comply with the law **. Additionally, the Sunshine Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many which differ from each other in significant ways, are often not pre- empted, and may have a more prohibitive effect than the Sunshine Act, thus further**

complicating compliance efforts . There are state law equivalents to the AKS and FCA. There are also so- called state " all- payer " anti- kickback laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, as well as when no insurer is involved (i. e. cash- pay patients). The enforcement of all of these laws is uncertain and subject to rapid change. Federal or state regulatory or enforcement authorities may investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going- forward basis only. Our results of operations may be adversely affected by current and potential future healthcare reforms. In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the U. S. federal government, state governments, regulators and third- party payers to control these costs and, more generally, to reform the U. S. healthcare system. **Notably, the COVID- 19 pandemic had a significant impact on the nation' s health sector expenditures, beginning in 2020, primarily driven by increased federal spending, including financial assistance to providers to make up for lost revenue through the Provider Relief Fund, the Paycheck Protection Program, and increased federal public health spending such as spending for vaccine development, COVID testing, and health facility preparedness. As a result, growth in federal government spending on healthcare increased 36 % in 2020. Within our industry, Medicare expenditures on skin substitute products have increased dramatically from 2019, when annual spending on these products administered in private physician offices and associated care settings was approximately $ 0. 5 billion. By 2023, annual expenditures for this class of products totaled over $ 4 billion, and more recently, spending by Medicare has reached an excess of $ 1 billion per month in the category. As a result, CMS ") and the MACs have sought ways to implement coverage and payment reform in order to curb the dramatically increasing expenditures in our industry. CMS could alter the reimbursement dynamics in outpatient care settings through the Physician Fee Schedule (" PFS "), which is published on an annual basis and regulates payments to healthcare providers for services furnished in these settings.** In **2022** ~~the U. S.~~ , **CMS, through its publication of** the ~~PPACA~~ **PFS proposals for CY 2023, indicated that it** was ~~enacted in 2010~~ **considering a revision of the payment system for skin substitutes. Specifically, CMS proposed to change the terminology of skin substitutes to ' wound care management products', and to treat and pay for these products as incident to supplies under the PFS beginning on January 1, 2024. Ultimately, CMS decided to provide interested parties** with **more opportunities to comment on the specific details of changes in coding and payment mechanisms prior to finalizing any changes. To date, CMS has not altered the existing policies. In August 2023, three MACs issued updated LCDs entitled: " Skin Substitute Grafts / Cellular and / or Tissue- Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, " which would regulate our products' Medicare coverage in the private physician office and associated care settings. Following** a ~~goal of reducing~~ **comment period and lengthy discussions with industry and clinician stakeholders,** ~~the~~ **these** ~~cost~~ **LCDs were ultimately withdrawn ahead** of ~~healthcare and substantially changing the~~ **their scheduled effective date** ~~way healthcare is financed by both government and private insurers~~ . In ~~addition~~ **November 2024** , **all seven MACs proposed revised LCDs in unison with support from CMS, which took into consideration many of** ~~other~~ -- **the** ~~legislative changes~~ **findings and commentary from the withdrawn 2023 LCDs. These LCDs are scheduled to become effective on April 13, 2025. In the past, LCDs** have been ~~proposed and adopted in~~ **delayed or terminated. If these LCDs were to be delayed or terminated,** ~~the~~ **they may not go** ~~U. S. since the PPACA was enacted. The Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2 % per fiscal year, which went~~ into effect ~~on~~ **in** April **2025** ~~1, 2013~~ . **Changes to** ~~In January 2013, the American Taxpayer Relief Act was signed into law, which, among other~~ -- **the manner and amounts** ~~things, further reduced~~ Medicare **reimburses** ~~payments to several provider types, including hospitals. In addition to the ACA, the Medicare Access and CHIP Reauthorization Act of 2015 (" MACRA ") repealed the Sustainable Growth Rate formula used to calculate Medicare payment updates~~ for **our products could** ~~physicians providing services to Medicare beneficiaries. In its place, MACRA introduced the Quality Payment Program (" QPP "), which is a value- based program that focuses on quality and outcomes as a metric for physician reimbursement. The Centers for Medicare and Medicaid Services released its final rules for the QPP in October 2016. The QPP, which impacts more than 600, 000 physicians and other practice- based clinicians, represents a fundamental change in physician reimbursement, transitioning from a system that solely rewards volume of care to one that also rewards quality and value of care. The rule may~~ have an impact on ~~our revenue in the future. The program' s increased emphasis on quality and cost of care may encourage physicians to merge practices or seek direct employment with hospitals. In addition, the ACA encourages hospitals and physicians to work collaboratively through shared savings programs as well as other~~ - **their utilization** ~~bundled payment initiatives~~ . **We** ~~These shifts could lead to a consolidation of hospital providers into larger delivery networks with increased price negotiation strength resulting in downward pressure on our selling prices. Although we~~ believe that ~~we are well positioned to minimize any such~~ **substantial uncertainty remains regarding the specific reform measures and proposed legislation that could** impact ~~on~~ our **industry** ~~business, our inability to address the consolidation trend could materially and adversely affect our business and results of operations~~ . **Any** ~~There is uncertainty with respect to the impact the U. S. Administration, the executive order, and the attempted legislation may have, if any, and any~~ changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services, including our products. ~~We~~ **Furthermore, we** believe that substantial uncertainty remains regarding the net effect of the PPACA, or its repeal and potential replacement, on our business, including uncertainty over how benefit plans purchased on exchanges will cover our products, how the expansion or contraction of the Medicaid program will affect access to our products, the effect of risk- sharing payment

models such as Accountable Care Organizations and other value- based purchasing programs on coverage for our ~~product~~ **products** , and the effect of the general increase or decrease in federal oversight of healthcare payers. The taxes imposed and the expansion in government' s role in the U. S. healthcare industry under the PPACA, if unchanged, may result in decreased revenues, lower reimbursements by payers for our products and reduced medical procedure volumes, all of which could have a material adverse effect on our business, results of operations and financial condition. We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries. We currently market our products in a small number of foreign countries, including in Japan. Foreign jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing. Certain of our products require clearance or approval by the FDA. However, such clearance or approval does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any foreign jurisdiction. Furthermore, many foreign jurisdictions operate under socialized medical care, and obtaining reimbursement for our products under that construct may also prove difficult. If we fail to receive necessary approvals, certifications, or reimbursements necessary to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected. Further, governmental authorities outside the U. S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non- U. S. governmental authorities in the future. U. S. or non- U. S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. Federal and state laws that protect the privacy and security of personal information may increase our costs and limit our ability to collect and use that information and subject us to liability if we are unable to fully comply with such laws. Numerous federal and state laws, rules and regulations govern the collection, dissemination, use, security and confidentiality of personal information, including protected health information and individually identifiable health information. These laws include: • provisions of HIPAA that limit how covered entities and business associates may use and disclose protected health information, provide certain rights to individuals with respect to that information and impose certain security requirements • HITECH, which strengthened and expanded the HIPAA Privacy Rule and Security Rules, imposed data breach notification obligations, created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in U. S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions ; • other federal and state laws restricting the use and protecting the privacy and security of personal information, including health information, many of which are not preempted by HIPAA ; • federal and state consumer protection laws ; and • federal and state laws regulating the conduct of research with human subjects ~~. The California Consumer Protection Act (" CCPA "), which became effective on January 1, 2020, is a privacy law that requires certain companies doing business in California to disclose information regarding the collection and use of a consumer' s personal data and to delete a consumer' s data upon request. The Act also permits the imposition of civil penalties and expands existing state security laws by providing a private right of action for consumers in certain circumstances where consumer data is subject to a breach. We are still evaluating whether and how this rule will impact our U. S. operations and / or limit the ways in which we can provide services or use personal data collected while providing services~~ . As part of our business operations, including our medical record keeping, third- party billing and reimbursement and research and development activities, we collect and maintain protected health information in paper and electronic format. Standards related to collecting and maintaining health information, whether implemented pursuant to HIPAA, HITECH, state laws, federal or state action or otherwise, could have a significant effect on the manner in which we handle personal information, including healthcare- related data, and communicate with payers, providers, patients, donors and others, and compliance with these standards could impose significant costs on us or limit our ability to offer services, thereby negatively impacting the business opportunities available to us. If we are alleged to have not complied with existing or new laws, rules and regulations related to personal information, we could be subject to litigation and to sanctions that include monetary fines, civil or administrative penalties, civil damage awards or criminal penalties. Risks Related to Our Intellectual Property Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate, which could have an adverse effect on our business, results of operations and financial condition. Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology, including our licensed technology. These legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, our pending patent applications include claims to material aspects of our products and procedures that may not be protected by issued patents. The patent application process can be time consuming and expensive. Our pending patent applications might not result in issued patents, and issued patents may later be determined to be invalid or unenforceable as a result of district court litigation or related administrative proceedings. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable or even superior to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with some of our officers, employees, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. The failure to obtain and maintain patents or protect our intellectual property rights could have an adverse effect on our business,

results of operations, and financial condition. Whether a patent claim is valid is a complex matter of science, facts and law, and therefore we cannot be certain that, if challenged in a court of law, or through an administrative proceeding, our patent claims would be upheld. If any of those patent claims are invalidated or determined to be unenforceable, our competitive advantage may be reduced or eliminated. In the event a competitor infringes upon our licensed patents, issued patents, pending patent applications or other intellectual property rights, enforcing those rights may be costly, uncertain, difficult and time consuming. Even if successful, litigation to enforce or defend our intellectual property rights could be expensive and time consuming and could divert our management' s attention. Further, bringing litigation to enforce our patents subjects us to the potential for counterclaims. Other companies or entities also have commenced, and may again commence, actions seeking to establish the invalidity of our patents and certain related claims. In the event that any of our patent claims are challenged, a court, the United States Patent and Trademark Office (" USPTO "), or the Patent Trial and Appeal Board (" PTAB ") of the USPTO may invalidate one or more challenged patent claims or determine that the patent is unenforceable, which could harm our competitive position. If the USPTO or the PTAB ultimately cancels or narrows the claim scope of any of our patents through these proceedings, it could prevent or hinder us from being able to enforce them against competitors. Such adverse decisions could negatively impact our business, results of operations, and financial condition. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in enforcing and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in some countries may be inadequate. We may become subject to claims of infringement of the intellectual property rights of others, which could prohibit us from developing our products, require us to obtain licenses from third parties or to develop non- infringing alternatives, and subject us to substantial monetary damages. Third parties could assert that our products infringe one or more claims of their issued patents or other intellectual property rights. Whether a product infringes a patent claim or other intellectual property right involves a complex combination of legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Because patent applications are not immediately published, and may take years to issue, there also may be applications now pending of which we are unaware that may later result in issued patent claims that our products or processes may infringe. There also may be existing patents or pending patent applications of which we are unaware that our products or processes may inadvertently infringe. Any infringement claim could cause us to incur significant costs, place significant strain on our financial resources, divert management' s attention from our business and harm our reputation. If the relevant patent claims at issue in such a dispute were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling any product that is found to infringe those claims through an injunction unless we could obtain licenses to use the technology covered by the asserted patent claims or other intellectual property, or are able to design around the patent claim or claims at issue or other intellectual property. We may be unable to obtain such a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, or selling products, and could enter an order mandating that we undertake certain remedial measures. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by inadvertent or court- ordered disclosure during this type of litigation. We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Some of our employees were previously employed at other medical device, pharmaceutical or tissue companies. We may also hire additional employees who are currently employed at other medical device, pharmaceutical or tissue companies, including our competitors. Additionally, consultants or other independent agents with which we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims are currently pending, we may be subject to claims that we, our employees, or our independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business, financial condition and operating results. Risks Related to Our Consolidated Financial Statements, Internal Controls and Related Matters If we fail to maintain adequate internal control over

financial reporting in the future, this could adversely affect our business, financial condition and operating results. ~~We have in the past reported material weaknesses in our internal control over financial reporting which we have since remediated.~~ If material weaknesses or deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements might contain material misstatements and we could be required to restate our financial results. Moreover, because of the inherent limitations of any control system, material misstatements due to error or fraud may not be prevented or detected on a timely basis, or at all. If we are unable to provide reliable and timely financial reports in the future, our business and reputation may be further harmed. Failures in internal controls may also cause us to fail to meet reporting obligations, negatively affect investor confidence in our management and the accuracy of our financial statements and disclosures, or result in adverse publicity and concerns from investors, any of which could have a negative effect on the price of our Common Stock, subject us to regulatory investigations and penalties or shareholder litigation, and adversely impact our business, results of operations and financial condition. Risks Related to the Securities Markets and Ownership of Our Common Stock Our indebtedness may adversely affect our financial health. As of ~~January~~ **December** 2024, the Company had aggregate borrowings outstanding of $ **19** ~~30. 0 million under its Revolving Credit Facility and $ 20~~ . 0 million under its Term Loan Facility, ~~all~~ pursuant to its Citizens Credit Agreement (as defined below in Item 7, Management' s Discussion and Analysis of Financial Condition and Results of Operations). Our outstanding debt may limit our ability to borrow additional funds or may adversely affect the terms on which such additional funds may be available. Additionally, a default under certain other indebtedness constitutes an event of default under the Citizens Credit Agreement. Consequently, the effects of a default under other debt may be amplified by the lenders exercising the remedies available to it in the Citizens Credit Agreement for events of default, including foreclosure on the collateral securing our obligations and the declaration that all amounts outstanding under the Citizens Credit Agreement are immediately due and payable. The restrictive covenants in the Citizens Credit Agreement, and the Company' s obligation to make payments under the Citizens Credit Agreement, limit our operating and financial flexibility and may adversely affect our business, results of operations and financial condition. The Citizens Credit Agreement imposes operating and financial restrictions and covenants. The Company must comply with certain financial covenants, including, a maximum total net leverage ratio and a minimum consolidated fixed charge coverage ratio. Additionally, the Citizens Credit Agreement includes certain customary restrictive covenants, including, but not limited to, limitations on indebtedness, liens, fundamental changes, dispositions, investments, loans, advances, guarantees, acquisitions, dividends and other restricted payments, transactions with affiliates, swap transactions, sale and leaseback transactions, prepayments on subordinated debt, and amendments to organizational and other material agreements. The Citizens Credit Agreement also contains certain customary events of default, including, without limitation, (i) failure to pay interest or principal when due, (i) failure to provide notice of certain material events and (iii) failure to perform or observe certain covenants under the Citizens Credit Agreement or any related loan documents (subject to a 30- day grace period in certain circumstances). If an event of default occurs and is continuing, the agent under the agreement may, and at the direction of the lenders, take one or more of the following actions: (i) terminate the commitments, (ii) declare any amounts outstanding immediately due and payable, and (iii) exercise any other right it has under the Citizens Credit Agreement or at law. Compliance with such covenants may restrict our operating flexibility, and in the event that we were unable to comply with such covenants, leading to default and acceleration, this could adversely affect our business, results of operations and financial condition. EW Healthcare Partners and its interests may conflict with those of our other shareholders. As of December 31, ~~2023~~ **2024** , EW Healthcare Partners and their affiliates owned approximately 19. 3 % of our Common Stock (calculated on the basis described in Item 12, " Security Ownership Of Certain Beneficial Owners And Management " below). Also, for as long as EW Healthcare Partners and its affiliates collectively hold at least (i) 10 % of the outstanding shares of our Common Stock, EW Healthcare Partners has the right to select two individuals that the Company must include among its nominees to serve on our Board and (ii) 5 % (but less than 10 %) of the outstanding shares of our outstanding Common Stock, EW Healthcare Partners has the right to select one individual that the Company must include among its nominees to serve on our Board. EW Healthcare Partners designated Martin P. Sutter and William A. Hawkins, III, who continue to serve on our board as directors. The interests of EW Healthcare Partners may conflict with those of our other shareholders, and EW Healthcare Partners may seek to influence, and may be able to influence, us through its director nomination rights and its share ownership. The price of our Common Stock has been, and will likely continue to be, volatile. The market price of our Common Stock, like that of the securities of many other healthcare companies that are engaged in research, development, and commercialization, has fluctuated over a wide range, and it is likely that the price of our Common Stock will fluctuate in the future. The market price of our Common Stock could be impacted by a variety of factors, including: • Fluctuations in stock market prices and trading volumes of similar companies or of the markets generally; • Our ability to successfully launch, market and earn significant revenue from our products; • Our ability to obtain additional financing to support our continuing operations; • Disclosure of the details and results of our clinical trials and our regulatory applications and proceedings; • Developments in and disclosure or publicity regarding existing or new litigation or contingent liabilities; • Changes in government regulations or our failure to comply with any such regulations; • Additions or departures of key personnel; • Our investments in research and development or other corporate resources; • Announcements of technological innovations or new commercial products by us or our competitors; • Developments in the patents or other proprietary rights owned or licensed by us or our competitors; • The timing of new product introductions; • Actual or anticipated fluctuations in our operating results, including as a result of seasonality in our business, as well as any restatements of previously reported results; • Our ability to effectively and consistently process or manufacture our products and avoid costs associated with the recall of defective or potentially defective products; • Our ability and the ability of our distribution partners to market and sell our products; • Changes in reimbursement for our products or the price for our products to our customers; • Removal of our products from the FSS, or changes in how government accounts purchase products such as ours or in the price for our products to government accounts; • Activities of market participants and investors, including analysts and MIMEDX shareholders; •

Material amounts of short- selling of our Common Stock; and • The other risks detailed in this Item 1A. Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future, including as a result of seasonality in our business. Price volatility or a decrease in the market price of our Common Stock could have an adverse effect on our ability to raise capital, liquidity, business, financial condition and results of operations. Securities analysts may elect not to report on our common stock or may issue negative reports that adversely affect the stock price. If we fail to attract the coverage of securities analysts, or if securities analysts discontinue covering our common stock, the lack of research coverage may adversely affect the actual and potential market price of our common stock. The trading market for our common stock may be affected in part by the research and reports that industry participants, industry analysts or financial analysts publish about our business. If one or more analysts elect to cover us and then downgrade the stock, the stock price would likely decline rapidly. If one or more of these analysts cease coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. Fluctuations in revenue or results of operations could cause additional volatility in our stock price. Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future. We do not intend to pay cash dividends on our Common Stock. We have never declared or paid cash dividends on our Common Stock. We currently expect to use available funds and any future earnings; in the development, operation and expansion of our business; to repay debt; and, to the extent authorized by our Board, repurchasing our Common Stock. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. As a result, capital appreciation, if any, of our Common Stock will be an investor' s only source of potential gain from our Common Stock for the foreseeable future. Certain provisions of Florida law and anti- takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to remove current management. The Florida Business Corporation Act (the " FBCA ") includes several provisions applicable to the Company that may discourage potential acquirors. Such provisions include provisions that: • allow directors to take other stakeholders into account in discharging their duties; • a requirement that certain transactions with a shareholder of 10 % or more ownership must be approved by the affirmative vote of two- thirds of the other shareholders unless approved by a majority of the disinterested directors or certain fair price requirements are met; and • voting rights acquired by a shareholder at ownership levels at or above one- fifth, one- third and a majority of voting power are denied unless authorized by the Board prior to such acquisition or by a majority of the other shareholders (excluding interested shares (as defined in the FBCA)). Additionally, our organizational documents contain provisions: • authorizing the issuance of blank check preferred stock ; • restricting persons who may call shareholder meetings ; • permitting shareholders to remove directors only " for cause " and only by super- majority vote ; and • providing the Board with the exclusive right to fill vacancies and to fix the number of directors. These provisions of Florida law and our articles of incorporation and bylaws could negatively affect our share price, prevent attempts by shareholders to remove current management, prohibit or delay mergers or other takeovers or changes of control of the Company and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders.