

Risk Factors Comparison 2025-03-11 to 2024-03-12 Form: 10-K

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Described below are certain risks that we believe apply to our business and the industry in which we operate. You should carefully consider each of the following risk factors in conjunction with other information provided in this Annual Report on Form 10-K (“Annual Report”) and in our other public disclosures. The risks described below highlight potential events, trends or other circumstances that could adversely affect our business, financial condition, results of operations, cash flows, liquidity or access to sources of financing, and consequently, the market value of our Class A common stock. These risks could cause our future results to differ materially from historical results and from guidance we may provide regarding our expectations of future financial performance. The risks described below are those that we have identified as material and **is are** not an exhaustive list of all the risks we face. There may be others that we have not identified or that we have deemed to be immaterial. All forward-looking statements made by us or on our behalf are qualified by the risks described below. Risks related to our financial position ~~If we are unable to meet our current operating projections or secure other sources of liquidity, substantial doubt about our ability to continue as a going concern may arise, which may negatively affect the market value of our Class A common stock. The consolidated financial statements included elsewhere in this Annual Report have been prepared under the going concern basis of accounting, which presumes that the Company’s liquidation is not imminent. Based on our current operating plans and potential market and economic conditions, the Company believes it should be able to meet its obligations as they become due within the next twelve months from the date of issuance of the consolidated financial statements included elsewhere in this Annual Report, as evaluated under generally accepted accounting principles in the United States. While we were in compliance as of December 31, 2023 with the financial covenants as stated within the Credit and Guaranty Agreement dated as of December 6, 2019 (the “2019 Credit Agreement,” and, as amended by that certain Amendment No. 1 to Credit and Guaranty Agreement, dated as of August 29, 2021, by the Second Amendment to Credit and Guaranty Agreement, dated as of October 29, 2021, by the Third Amendment to Credit and Guaranty Agreement, dated as of July 11, 2022, by the Fourth Amendment to Credit and Guaranty Agreement, dated as of March 31, 2023 and by the Fifth Amendment, the “Amended 2019 Credit Agreement”), on January 18, 2024, the Company entered into Amendment No. 5 to the 2019 Credit Agreement (the “Fifth Amendment”) as part of its efforts to further improve its financial condition. The Fifth Amendment modified the financial covenant requirements contained in the 2019 Credit Agreement to provide additional financial covenant relief and included modifications to the Company’s leverage maintenance covenant and interest coverage ratio to provide financial and operational flexibility relative to its operating plan. However, the Company has based the above assessment on assumptions of revenues, cash flows and operating costs that may prove to be wrong. In such event, the Company may need to seek further modifications to certain of the covenants in the Amended 2019 Credit Agreement to avoid an event of default or seek waivers of any potential noncompliance. Moreover, the Company has historically relied on its ability to fund its operations primarily through cash flows from operations, as well as public and private debt and equity financings, but there can be no assurances that such financing or funding will continue to be available to the Company on satisfactory terms, or at all. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. The inability to secure alternative financing on acceptable terms or to obtain any additional required modifications to the Amended 2019 Credit Agreement in the event that we fail to meet our operating projections may raise substantial doubt about our ability to continue as a going concern and adversely affect our business and financial condition.~~ Our Amended 2019 Credit Agreement contains financial and operating restrictions that may limit our access to credit. If we fail to comply with its financial or other covenants, we may be required to repay the indebtedness, which may harm our liquidity. We are subject to certain covenants under the Amended 2019 Credit Agreement, including, but not limited to: • a minimum interest coverage ratio and a maximum debt leverage ratio requirement as defined in the Amended 2019 Credit Agreement; • a minimum Liquidity (as defined in the Amended 2019 Credit Agreement) of not less than \$ 10. 0 million as of the end of each calendar month through October 29, 2025; • restrictions on the declaration or payment of certain distributions on or in respect of our equity interests; • restrictions on acquisitions, investments and certain other payments; • limitations on the incurrence of new indebtedness; • limitations on the incurrence of new liens on property or assets; • limitations on transfers, sales and other dispositions; • limitations on entering into transactions with affiliates; and • limitations on making any material change in any of our business objectives that could reasonably be expected to have a material adverse effect on the repayment of our Amended 2019 Credit Agreement. In the absence of a waiver from our lenders, any failure by us to comply with these covenants in the future might result in the declaration of an event of default, which could adversely affect our business, results of operations and financial position. In addition, our indebtedness could have significant consequences on our financial position, including: • requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of funding growth, working capital, capital expenditures, investments or other cash requirements; • reducing our flexibility to adjust to changing business conditions or obtain additional financing; • exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under our term loan, are at variable rates, making it more difficult for us to make payments on our

indebtedness; • restricting us from making strategic acquisitions or causing us to make non- strategic divestitures; and • limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements and general corporate or other purposes. See Part II, Item 7. Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Indebtedness for further discussion concerning our indebtedness. **Failure to establish and maintain effective financial..... affect our business and financial position.** We might require additional capital to fund our financial and operating obligations and support business growth. If our expected cash from operations together with available borrowings under our Amended 2019 Credit Agreement are not sufficient to fund our current financial and operating obligations, we might require additional capital. In addition, we intend to continue to make investments to support our business growth and might require additional funds to respond to business challenges or opportunities, including the need to further develop our current products and any new products, enhance our operating infrastructure, and acquire complementary businesses. Accordingly, we might need to engage in equity or additional debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any additional debt financing secured by us could involve restrictive covenants relating to our capital- raising activities and other financial and operational matters, which might make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, we might not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited. Failure to establish and maintain effective financial controls could cause us to have material weaknesses and financial misstatements due to error, which could adversely affect our business and stock price. We are required to comply with the SEC’ s rules implementing Sections 302, 404 and 906 of the Sarbanes- Oxley Act of 2002, which require management to certify financial and other information in our quarterly and annual reports, provide quarterly and annual management reports on the effectiveness of disclosure controls and procedures, and provide annual management reports on the effectiveness of internal controls over financial reporting. Though we are required to disclose changes made in our internal controls and procedures on a quarterly basis and assess internal controls over financial reporting on an annual basis, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until we are no longer an emerging growth company pursuant to the provisions of the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We have undertaken various actions to comply with the requirements of being a public company. However, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent or avoid financial misstatements due to error or material weaknesses. If we identify any material weaknesses in the future that we cannot fully remediate, the accuracy and timing of our financial reporting may be adversely affected. Testing and maintaining financial controls can also divert our management’ s attention from other matters that are important to the operation of our business. Ineffective disclosure controls and procedures or internal control over financial reporting could cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our Class A common stock. Additionally, when evaluating our financial controls, we may identify material weaknesses in our internal controls that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. We maintain our cash **and cash equivalents** at financial institutions, ~~often in accounts where the balances~~ **balance that exceed exceeds** federally insured limits. ~~We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the Federal Deposit Insurance Corporation (“ FDIC ”). We maintain the majority of our cash and cash equivalents in accounts at a banking institution in the United States that we believe is of high quality. Cash held in these accounts exceed the FDIC~~ insurance limits. If such banking ~~institutions~~ **institution** were to fail, we could lose all or a portion of ~~the~~ amounts held in excess of such insurance limitations. **In the event** ~~The FDIC took control of two such banking institutions~~ **failure of the financial institutions** ~~institution where~~ **institution where**, Silicon Valley Bank (“ SVB ”) on March 10, 2023 and Signature Bank (“ Signature Bank ”) on March 12, 2023. While we ~~did have~~ **maintain our cash and account cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or** at SVB, we were able to recover all of ~~our~~ **or deposits when any delay in accessing the these** FDIC ~~stepped in~~ **funds could adversely affect our business and financial position.** Risks related to our business We are currently subject to **derivative shareholder lawsuits and have been defendants in** securities class action litigation ~~and derivative shareholder lawsuits~~ and may be subject to similar or other litigation in the future, which will require significant management time and attention, result in significant legal expenses and may result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. We are, and may in the future become, subject to various legal proceedings and claims that arise in or outside the ordinary course of business. **For example In particular, we are** on January 12, 2023, the Company and certain of its current and former directors and officers were named as defendants in a putative class action lawsuit filed in the Middle District of North Carolina: Ciarcicello v. Bioventus, Inc., No. 1: 23 — CV — 00032- CCE- JEP (M. D. N. C. 2023). The complaint asserts violations of

Sections 10 (b) and 20 (a) of the Exchange Act and of Sections 11 and 15 of the Securities Act and generally alleges that the Company failed to disclose certain information regarding rebate practices, its business and financial prospects, and the sufficiency of internal controls regarding financial reporting. The complaint seeks damages in an unspecified amount. On April 12, 2023, the Court appointed Wayne County Employees' Retirement System as lead plaintiff. The plaintiff's amended consolidated complaint was filed with the Court on June 12, 2023. On July 17, 2023, the defendants filed a motion to dismiss the complaint raising a number of legal and factual deficiencies with the amended consolidated complaint. In response to the defendants' motion to dismiss, the lead plaintiff filed a second amended complaint on July 31, 2023. The defendants moved to dismiss the second amended complaint on August 21, 2023, which the Court granted in part **party** and denied in part on November 6, 2023. The Court dismissed the plaintiff's Securities Act claims, but allowed the plaintiff's Exchange Act claims to proceed into discovery. On October 4, 2023, certain of the Company's current and former directors and officers were also named as defendants in a derivative shareholder **litigation described under** lawsuit (in which the Company is a nominal defendant) filed in the United States District Court for the District of Delaware, Grogan, on behalf of Bioventus Inc., v. Reali, et. al., No. 1: 23- CV- 01099- RGA (D. Del. 2023). The complaint asserts violations of Section 14 (a) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the Ciarcicello case. On January 12, 2024, the Court agreed to stay the case pending resolution of the Ciarcicello case. On February 9, 2024, another plaintiff filed a derivative shareholder lawsuit against certain of the Company's current and former directors and officers (in which the Company is a nominal defendant) filed in the United States District Court for the District of Delaware, Sanderson, on behalf of Bioventus Inc., v. Reali, et. al., No. 1: 24- cv- 00180- RGA (D. Del. 2024). Like the Grogan case, this case asserts violations of Section 10 (b) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the Ciarcicello case. The parties are in discussions to consolidate the two derivative matters and stay them- **the below heading " Legal Proceedings** on terms similar to those entered in the Grogan case. " **The Company believes the claims alleged in each of the above matters lack merit and intends to defend itself vigorously. However, the outcome of these matters is not presently determinable, and any loss is neither probable nor reasonably estimable.** The results of such lawsuits and any future legal proceedings **cannot** **might not be able to** be predicted with certainty. Also, our assets may be insufficient to cover any claimed amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. **Any** **Regardless of the merits of these claims, any** such payments or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult to finance our operations. We are highly dependent on a limited number of products **for revenue generation and profitability**. Our HA products accounted for **46 %**, 43 % **and** 42 % **and 51%** of our total revenue for the years ended December 31, **2024**, 2023 **and** 2022 **and 2021**, respectively. We expect that sales of such products will continue to account for a substantial portion of our revenue, and therefore, our ability to execute our growth strategy and maintain profitability will depend upon the continued demand for these products **in each of our current product areas**. If the supply and distribution agreements for any of our HA products were terminated **, or if our efforts to commercialize these products prove unsuccessful**, our revenue would be impaired. If our HA products fail to maintain their market acceptance for any reason, our business, results of operations and financial condition may be adversely affected. Our long- term growth **depends on** **may be limited by** our **ability** **inability** to develop, acquire and commercialize new products, line extensions or expanded indications. Our industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to introduce new products and / or enhance our existing product offerings through line extensions or expanded indications. Developing, acquiring and commercializing products is expensive, time- consuming and could divert management's attention away from our existing business. Even if we are successful in developing additional products, the success of any new product offering or enhancements to existing products will depend on several factors, including our ability to: • properly identify and anticipate the needs of healthcare professionals and patients; • develop and introduce new products, line extensions and expanded indications in a timely manner; • distinguish our products from those of our competitors; • avoid infringing upon the intellectual property rights of third parties and maintain necessary intellectual property licenses from third parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials; • obtain clearance, approval, or certification, if required, from the FDA and other regulatory agencies or notified bodies, for such new products, line extensions and expanded indications, and maintain full compliance with FDA and other regulatory requirements applicable to new devices or products or modifications of existing devices or products; • provide adequate training to potential users of our products; • market acceptance of our newly developed or acquired products or therapies; • receive adequate coverage and reimbursement for our products; and • maintain an effective and dedicated sales and marketing team. If we are unsuccessful in developing, acquiring and commercializing new products or enhancing our existing product offerings through line extensions and expanded indications **across our current product portfolio**, our long- term growth may be negatively affected. Additionally, our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. Such efforts may not result in the development of a viable product. In addition, even if we are able to successfully develop new active healing products, line extensions and expanded indications, these products may not produce sales in excess of the costs of development and they may be rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. **If we fail to properly manage growth,our** business could suffer. We may, in the future, experience periods of rapid growth and

expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, our ~~supply chain, inventory management, product services, sales processes~~ **force** and distributor network require significant management, training, financial and other supporting resources. ~~System limitations may result in increased cost, delayed execution, and errors.~~ Any failure by us to manage our growth effectively could adversely affect our ability to achieve our development and commercialization goals. To achieve our long-term revenue goals, we also will need to successfully increase supply of our products to meet expected customer demand. In the future, we may experience difficulties with yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses which could adversely affect our ability to generate revenue. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations during any growth period, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us **to execute our business strategy and our operating results and business could suffer** Demand for our existing products and any new products, line extensions or expanded indications depends on the continued and future acceptance of our products by physicians, patients, third-party payers and others in the medical community. We cannot be certain that our existing products and any new products, line extensions or expanded indications that we develop will achieve or maintain market acceptance. Third-party payers may be reluctant to continue to cover our products at their current prices. Further, new injectable therapies or oral medications may become available that help manage OA pain in a more convenient and / or cost effective manner than our HA viscosupplementation therapies. With respect to our Surgical Solutions, new allograft, DBMs, synthetics, growth factors, or other enhancements to our existing implants may never achieve broad market acceptance, which can be affected by a lack of clinical acceptance of Surgical Solutions products and technologies, introduction of competitive treatment options which render Surgical Solutions products and technologies too expensive or obsolete and difficulty training surgeons in the use of Surgical Solutions products and technologies. Media reports or other negative publicity concerning both methods of tissue recovery from donors and actual or potential disease transmission from donated tissue may limit widespread acceptance by the medical community of our allografts, growth factor and DBMs, whether directed at these products generally or our products specifically. Unfavorable reports of improper or illegal tissue recovery practices by any participant in the industry, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft based technologies by the medical community. In addition, we believe that even if the medical community generally accepts our existing portfolio of products and any new products, line extensions or expanded indications, acceptance and recommendations by influential members of the medical community will be important to their broad commercial success. If the medical community does not broadly accept our products, we may not remain competitive in the market, which could adversely affect our business, results of operations and financial condition. **We rely on a limited number of third-party manufacturers to manufacture certain of our products. Third-party manufacturers generally manufacture our HA products, Exogen components, certain** Surgical Solutions products, PNS and our rehabilitation devices. We have developed in-house assembly capabilities for ~~certain of our~~ **Exogen products, such as our EXOGEN system.** We and our third-party manufacturers are required to comply with the **Quality System Regulation (“QSR”)**, which is a set of FDA regulations that establishes cGMP requirements for medical devices and covers the methods and documentation of the design, testing, production, control, quality assurance ~~and complaint handling~~, labeling, packaging, sterilization, storage and shipping of such devices. Moreover, certain of our products may be re-classified as drugs, and we are planning to seek approval of a product pursuant to the BLA pathway. In each case, such products would be required to comply with the cGMP requirements that apply to drugs and biologics, respectively. There are a limited number of suppliers and third-party manufacturers that operate under FDA’s QSR requirements and that have the necessary expertise and capacity to manufacture our products or components for our products. As a result, it may be difficult for us to locate manufacturers for our anticipated future needs, and our anticipated growth could strain the ability of our current suppliers and third-party manufacturers to deliver products, materials and components to us. Upon expiration of our existing agreements with these third-party manufacturers, we may not be able to renegotiate the terms of our agreements with these third-party manufacturers on a commercially reasonable basis, or at all. ~~Our reliance on different contractor manufacturers to supply certain of our products and their components may result in wide variability in manufacturing processes, product quality and regulatory compliance.~~ If we or our third-party manufacturers fail to maintain facilities in accordance with the FDA’s QSR, ~~our products may suffer from product quality issues and the noncomplying party could lose the ability to manufacture our products on a commercial scale.~~ **Loss** Such issues may result in increased costs, disruptions in supply, contamination and mislabeling of products, and **this manufacturing capability would** limit our ability to sell some of our products. The manufacturing of our products may not be easily transferable to other sites in the event that any of our third-party manufacturers experience breakdown, failure or substandard performance of equipment, disruption of supply or shortages of, or quality issues with, components of our products and other supplies, labor problems, power outages, adverse weather conditions, natural disasters (including natural events caused by or intensified by climate change), global pandemics, or the need to comply with environmental and other directives of governmental agencies. From time to time, a third-party manufacturer may experience financial difficulties, bankruptcy or other business disruptions, which could disrupt our supply of finished goods or require that we incur additional expense by providing financial accommodations to the third-party manufacturer or taking other steps to seek to minimize or avoid supply disruption, such as establishing a new third-party manufacturing arrangement with another provider. The loss of any of these third-party manufacturers or the failure for any reason of any of these third-party manufacturers to fulfill their obligations under their agreements with us, including a failure to meet our quality controls and

standards, may result in disruptions to our supply of finished goods. We may be unable to locate an additional or alternate third-party manufacturing arrangement that **meets our quality controls and standards in a timely manner or on commercially reasonable terms, if at all. If this occurs, our business, results of operations and financial condition will be adversely affected.** The proposed down- classification of non- invasive bone growth stimulators, including ~~Exogen~~ **EXOGEN**, by the FDA could increase future competition for bone growth stimulators and otherwise adversely affect our sales of ~~Exogen~~ **EXOGEN**. In 2020, the FDA published a Federal Register notice announcing its proposal to reclassify non- invasive bone growth stimulators, such as ~~Exogen~~ **EXOGEN**, from Class III medical devices to Class II with special controls. Class III devices are subject to the most stringent regulatory pathway for approval for medical devices requiring, among other things, rigorous clinical studies and pre- approval manufacturing review. Class II devices may be cleared for marketing by the FDA under the 510 (k) pathway if they are determined to be substantially equivalent to a legally marketed predicate device. The 510 (k) clearance process does not always require clinical testing, and is generally less onerous than the premarket approval process applicable to Class III devices. Also in 2020, the ~~Orthopaedic~~ **Orthopedic** and Rehabilitation Devices Panel of the FDA Medical Devices Advisory Committee met and ultimately voted in favor of the FDA’ s proposal to down- classify non- invasive bone growth stimulators. While the FDA has not yet finalized its proposal to down- classify non- invasive bone growth stimulators, should such down- classification occur now or in the future, we may face additional competition from new market entrants who would be able to pursue marketing authorization through the 510 (k) clearance pathway instead of the more onerous and burdensome PMA approval process. Class II devices that qualify as durable medical equipment under the Medicare program may also be eligible for inclusion in Medicare’ s competitive bidding program for durable medical equipment, prosthetic and orthotic supplies (“ DEMPOS ”). As a result of down- classification, ~~Exogen~~ **EXOGEN** could face additional competition or we could receive lower reimbursement amounts, all of which could adversely affect our business, results of operations and financial condition. If we are unable to achieve and maintain adequate levels of coverage and / or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize, the commercial success of these products may be severely hindered. Our products are purchased by healthcare providers and customers who typically bill third- party payers or private insurance plans and healthcare networks, to cover all or a portion of the costs and fees associated with our products. These third- party payers and insurers may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure **is not deemed medically necessary or otherwise** does not meet applicable payment criteria or if the policyholder’ s healthcare insurance benefits are limited. Further, limits put on reimbursement by third- party payers, whether foreign or domestic, governmental or commercial, could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control rising healthcare costs by imposing lower payment rates and negotiating reduced contract rates with providers and suppliers. Private payers may adopt coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services (“ CMS ”), the federal agency that administers the Medicare program in the United States, as guidelines in setting their coverage and reimbursement policies. In addition, CMS periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. For some governmental programs, such as Medicaid, coverage and reimbursement differs from state to state. Medicaid payments to physicians, facilities and other providers are often lower than payments by other third- party payers and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. If CMS, other government agencies or private payers lower their reimbursement rates or establish additional limitations on coverage of our products, or if any of the proposed drug pricing executive orders or legislative reforms are enacted, the commercial success of our products may be adversely affected. Further, legislative or other regulatory reforms that have been adopted or may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies or other downward pressure on the pricing or reimbursement we or our customers receive for our products. For example, the Consolidated Appropriations Act, 2021 (“ CAA ”) was signed into law on December 27, 2020, and pursuant to implementing regulations promulgated by CMS, expanded price reporting obligations for manufacturers of certain products reimbursed under Medicare Part B beginning January 1, 2022, including all of our HA viscosupplements. In July 2022, CMS began utilizing the new pricing information we reported to it pursuant to these newly adopted reporting obligations to adjust the Medicare payment to healthcare providers using our Durolane and ~~Gelsyn~~ **GELSYN**- 3 products. As a result, the rates ~~currently~~ **beginning in July 2022 were** reduced from those previously available and ~~are will be~~ **are** subject to future reporting and adjustment, which may affect the demand for those products or our ability to sell them profitably. We cannot predict the extent to which this law, or other reimbursement reform proposals or other healthcare cost containment measures that might be enacted in the future, may impact the demand or commercial success of our HA viscosupplements and other products we sell or plan to commercialize in the future. In addition, due to the manner in which rebates are calculated and paid under certain of our contracts with private payers, changes in the ASP for our HA viscosupplements may result in larger than expected rebates payments for the sale of these products. In addition, we are dependent on these payers to provide timely and accurate invoices for the rebates that we are obligated to pay under these contractual relationships. If the information is not received timely or is inaccurate, we may not be able to correctly forecast the amounts due under those agreements, which may adversely affect our operating results and financial condition. CMS, which administers the Medicare program, has continued efforts to implement a competitive bidding program for selected DEMPOS items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Bone growth stimulation products like ~~Exogen~~ **EXOGEN** are currently exempt from this competitive bidding process, but may be eligible for inclusion if the FDA’ s proposed down- classification order becomes effective. We cannot predict which products from any of our businesses may ultimately be affected or whether or when the competitive bidding

process may be extended to our businesses. CMS periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that these assessments could have on Medicare or third- party payer coverage determinations for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare or other insurance coverage for our products. In addition, there can be no assurance that we or our distributors will not experience significant coverage or reimbursement impediments in the future related to these or other programs and policies of CMS. Specifically, drug pricing reform legislation and executive orders, which could negatively affect the reimbursement rates paid for our HA viscosupplements, have been issued by the White House and proposed and enacted by Congress. Private payers may adopt coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. In addition, for some governmental programs, such as Medicaid, coverage and reimbursement differs from state to state. Medicaid payments to physicians, facilities and other providers are often lower than payments by other third- party payers and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. If CMS, other government agencies or private payers lower their reimbursement rates, or if any of the proposed drug pricing executive orders or legislative reforms are enacted, the commercial success of our products may be adversely affected. Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a Group Purchasing Organization (“ GPO ”), third- party payers or other similar entities exclude us from being a supplier. Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third- party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may increase requests for pricing concessions or risk vendor exclusion. For example, non- clinical staff at hospitals are increasingly involved in the evaluation of products and product purchasing decisions. In order for us to sell our products, we must convince such staff as well as physicians and hospitals that our products are attractive alternatives to competing products for use in surgical procedures. Additionally, GPOs, ~~integrated delivery networks (“ IDNs ”)~~ and large single accounts may continue to use their market power to consolidate purchasing decisions for physicians. Third- party payers may also continue to use their market power to reduce the reimbursement for our products by increasing the rebates we are required to pay them when our products are covered, which may negatively impact our results. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products. We may be unable to complete proposed acquisitions or to successfully integrate proposed or recent acquisitions in a cost- effective and non- disruptive manner. Our success depends on our ability to enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies , **which may vary significantly across our product portfolio** . We continue to search for viable acquisition candidates or strategic alliances that would expand our market sector and / or global presence, as well as additional products appropriate for current distribution channels. Accordingly, we have previously and may in the future pursue the acquisition of, or joint ventures relating to, new businesses, products or technologies instead of developing them internally. Our future success will depend, in part, upon our ability to manage the expanded business following these acquisitions, including challenges related to the management and monitoring of new operations and associated increased costs and complexity associated with ~~the acquisition of Misonix, Bioness, and other~~ potential acquisitions. Other risks involving potential future and completed acquisitions and strategic investments include: • risks associated with conducting due diligence; • problems integrating the purchased technologies, products or business operations; • inability to achieve the anticipated synergies and overpaying for acquisitions or unanticipated costs associated with acquisitions; • invalid net sales assumptions for potential acquisitions; • issues maintaining uniform standards, procedures, controls and policies; • diversion of management’ s attention from our core business; • adverse effects on existing business relationships with suppliers, distributors and customers; • risks associated with entering new markets in which we have limited or no experience; • potential loss of key employees of acquired businesses; and • increased legal, accounting and compliance costs. We compete with other companies for these opportunities, and we may be unable to consummate such acquisitions or joint ventures on commercially reasonable terms, or at all. In addition, acquired businesses may have ongoing or potential liabilities, legal claims (including tort and / or personal injury claims) or adverse operating issues that we fail to discover through due diligence prior to the acquisition. Even if we are aware of such liabilities, claims or issues, we may not be able to accurately estimate the magnitude of the related liabilities and damages. In particular, to the extent that prior owners of any acquired businesses or properties failed to comply with or otherwise violated applicable laws or regulations, failed to fulfill their contractual obligations to their customers, or failed to satisfy legal obligations to employees or third parties, we, as the successor, may be financially responsible for these violations and failures and may suffer reputational harm or otherwise be adversely affected. Acquisitions also frequently result in the recording of goodwill and other intangible assets which are subject to potential impairment in the future that could harm our financial results. If we were to issue additional equity in connection with such acquisitions, this may dilute our stockholders. **We may not realize the anticipated strategic or financial benefits from our business divestitures, which may adversely affect our results of operations and financial condition. We have in the past divested of certain of our businesses, including most recently our Advanced Rehabilitation business, to help improve our focus on our core businesses and improve our liquidity. However, we may be unable to achieve some or all of the anticipated strategic and financial benefits following our business divestitures, as their anticipated benefits are based on a number of assumptions, some of which may prove incorrect. Any divestiture we undertake is subject to a variety of known and unknown risks and uncertainties. In addition, the anticipated benefits related to any divestiture may take longer to realize than expected, and a failure to achieve the anticipated financial and strategic benefits of a divestiture could be disruptive to our operations and could have a material adverse impact on our business, results of operations, financial condition and cash flows. Further, even if we do realize some or all of the anticipated strategic and**

financial benefits following our divestitures, we may face indemnity and other liability claims by the acquirer or other parties. Pricing pressure from our competitors or hospitals may affect our ability to sell our products at prices necessary to support our current business strategies. Medical device companies, healthcare systems, IDNs and GPOs have intensified competitive pricing pressure as a result of industry trends and new technologies. Purchasing decisions are ~~gradually~~ shifting to hospitals, IDNs and other hospital groups, with surgeons and other physicians increasingly acting only as “employees.” Changes in the purchasing behavior of hospitals or the amount that third- party payers are willing to reimburse our customers for procedures using our products, including as result of healthcare reform initiatives, could create additional pricing pressure on us. In addition to these competitive forces, we continue to see pricing pressure as hospitals introduce new pricing structures into their contracts and agreements, including fixed price formulas, capitated pricing and episodic or bundled payments intended to contain healthcare costs. If such trends continue to drive down the prices we are able to charge for our products, our profit margins will shrink, adversely affecting our business, results of operations and financial condition. If we fail to successfully enter into purchasing contracts for our Surgical Solutions products or engage in contract bidding processes internationally, we may not be able to receive access to certain hospital facilities and our sales may decrease. In the United States, the hospital facilities where physicians treat patients with our Surgical Solution products typically require us to enter into purchasing contracts. The process of securing a satisfactory contract can be lengthy and time- consuming and require extensive negotiations and management time. In certain international jurisdictions, from time to time, certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities through these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may stagnate or decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time- consuming processes and still may not obtain a purchase contract from such hospitals. Governments outside the United States may not provide coverage or reimbursement of our products, which may adversely affect our business, results of operations and financial condition. Acceptance of our products in international markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government- sponsored healthcare and private insurance. Our products may not obtain international coverage and reimbursement approvals in a timely manner, if at all, which may require consumers desiring our products to purchase them directly. Third- party coverage and reimbursement for our products or any of our products in development for which we may receive regulatory approval may not be available or adequate in international markets, which could adversely affect our business, results of operations and financial condition. Our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost- effectiveness of our products. We focus our sales, marketing and training efforts on physicians, surgeons and other ~~health~~ **healthcare care** professionals. The acceptance of our products depends in part on our ability to educate physicians as to the distinctive characteristics, benefits, safety, clinical efficacy and cost- effectiveness of our products compared to alternative products, procedures and therapies. If physicians, surgeons or other healthcare professionals are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. In addition, a failure to educate physicians, surgeons or other healthcare professionals regarding our products may impair our ability to achieve market acceptance of our products. We compete and may compete in the future against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration or improved operating results. The medical device industry is characterized by intense competition, subject to rapid change and is significantly affected by market activities of industry participants, new product introductions and other technological advancements. We believe that our competitors have historically dedicated and will continue to dedicate significant resources to promote their products or to develop new products. We have competitors in the United States and internationally, including major medical device and pharmaceutical companies, biotechnology companies and universities and other research institutions. These companies and other industry participants may develop alternative treatments, products or procedures that compete directly or indirectly with our products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products could be adversely affected and our results of operations could suffer. Our competitors may also develop and patent processes or products earlier than we can or obtain regulatory clearances, approvals or certifications for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. Many of our current and potential competitors are major medical device and pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. It is also possible that our ~~competition~~ **competitors** will be able to leverage their large market share to set prices at a level below that which is profitable for us. Some of our competitors have several competitive advantages over us, including: • greater financial, human and other resources for product research and development, sales and marketing and litigation; • significantly greater name recognition; • control of intellectual property and more expansive portfolios of intellectual property rights, which could impact future products under development; • greater experience in obtaining and maintaining regulatory clearances, approvals or certifications for products and product enhancements; • established relationships with hospitals and other healthcare providers, physicians, suppliers, customers and third- party payers; • additional lines of products, and the ability to bundle products to offer greater incentives to gain a competitive advantage; and • more established sales, marketing and worldwide distribution networks. The potential introduction by competitors of products that compete with our existing or planned products may also make it difficult to market or sell our products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the market generally. As a result, our ability to

compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third- party payers, and are safer, less invasive and more effective than alternatives available for similar purposes. If we are unable to do so, our sales or margins could decrease, which would adversely affect our business, results of operations and financial condition. The reclassification of our HA products from medical devices to drugs in the United States by the FDA could negatively impact our ability to market these products and may require that we conduct costly additional clinical studies to support current or future indications for use of those products. On December 18, 2018, the FDA published notice in the Federal Register announcing its intention to reconsider the appropriate classification of HA intra- articular products intended for the treatment of pain in OA of the knee. Although HA products intended for this use have previously been regulated as medical devices, in its notice the FDA stated that current published scientific literature supports that HA products achieve their primary intended purpose of treatment of pain in OA of the knee through biological action in the body which would require such products being classified as drugs. The FDA has encouraged organizations intending to submit applications for changes in indications for use, formulation, or route of administration of their HA products to obtain from the FDA an informal or formal classification and jurisdiction determination as a drug or device through a pre- request for designation or request for designation, respectively, prior to submission of such application. However, the FDA to date has taken no action to reclassify HA products from medical devices to drugs, or indicated what the potential ramifications would be for currently marketed HA products if a reclassification were to occur. If the reclassification of HA products were to occur, the FDA may not allow us to continue to market our HA products without submitting additional clinical trial data, obtaining approval of a NDA for these products, or without otherwise complying with new conditions or limitations on how those products are marketed. Clinical testing can take years to complete, can be expensive and carries uncertain outcomes, and there is no guarantee that would be able to successfully obtain and maintain any required regulatory approvals. These new regulatory obligations could result in increased regulation and would subject our HA products to a new set of regulatory requirements to which they have not been previously subject. These changes could ultimately increase our costs, change levels of coverage and / or reimbursement for our HA products and adversely impact our business, results of operations and financial condition if they were to be implemented. See Part I, Item 1A. Risk Factors — Risks related to our business — If we are unable to achieve and maintain adequate levels of coverage and / or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize, the commercial success of these products may be severely hindered. Our ability to maintain our competitive position **and to execute our strategic plans,** depends on our ability to attract, retain and motivate our senior management team and **other** highly qualified personnel, and our failure to do so could adversely affect our business, results of operations and financial condition. We believe that our continued success depends to a significant extent upon the skill, experience and performance of members of our senior management team, who have been critical to the management of our operations and implementation of our strategy, as well as our ability to continue to attract, retain and motivate additional executive officers, and other key employees and consultants, such as those individuals who are engaged in our research and development efforts. The replacement of any of our key personnel likely would involve significant time and ~~costs-~~ **cost** and may significantly delay or prevent the achievement of our business objectives and could therefore adversely affect our business, results of operations and financial condition. In addition, we do not carry any “ key person ” insurance policies that could offset potential loss of service under applicable circumstances. Competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified employees, we may utilize equity- based incentive awards **such as, including** employee stock options. If the value of such equity incentive awards does not appreciate as measured by the performance of the price of our Class A common stock, ~~as seen in current market conditions,~~ such awards may cease to be viewed as valuable and our ability to attract, retain and motivate our employees could be adversely impacted, which could adversely affect our business, results of operations and financial condition and / or require us to increase the amount we expend on cash and other forms of compensation. **If we fail to properly manage..... our operating results and business could suffer.** We may not be able to strengthen our brand and the brands associated with our products. We believe that strengthening the Bioventus brand and the brands associated with our products is critical to achieving widespread acceptance of our products, particularly because of the rapidly developing nature of the market for active healing products as well as the expansion of our product portfolio due to our recent acquisitions. Promoting and positioning our brand will depend largely on the success of our marketing efforts and the reliability of our products. Historically, our efforts to build our brand have involved marketing expenses, and it is likely that our future marketing efforts will require us to incur additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand and our products. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand and the brands of our products, our products may not be accepted by healthcare providers, which would cause our sales to decrease and would adversely affect our business, results of operations and financial condition. We face the risk of product liability claims that could be expensive, divert management’ s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of our products. This risk exists even if a product is cleared, approved or certified for commercial sale by the FDA, foreign regulatory authorities or notified bodies and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our products in development could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot assure you that we will not face product liability claims. We may be subject to product liability claims if our products or products in development cause, or merely appear to have caused, patient injury or death, even if such injury or death was as a result of supplies or components that are produced by third- party suppliers. Product liability claims

may be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: • costs of litigation; • distraction of management’s attention from our primary business; • the inability to commercialize existing or new products; • decreased demand for our products or, if cleared or approved, products in development; • damage to our business reputation; • product recalls or withdrawals from the market; • withdrawal of clinical trial participants; • substantial monetary awards to patients or other claimants; and • loss of net sales. While we have attempted and may continue to attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. For example, we have in the past instituted a voluntary recall for certain of our products. We cannot assure you that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for product safety or be perceived by patients as a safety risk when considering the use of our products, either of which could adversely affect our business, results of operations and financial condition. In addition, although we have product liability and clinical study liability insurance **policies** that we believe ~~is~~ **provide** appropriate **levels of coverage**, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could adversely affect our business, results of operations and financial condition. Fluctuations in the demand for our products or our inability to forecast demand accurately may influence the ability of our suppliers to meet our delivery needs or result in excess product inventory. We are required by some of our contracts with suppliers of our products to forecast future product demand or meet minimum purchase requirements. Our HA product supply agreements are subject to minimum volumes based in part on forecasts, annual minimum purchase requirements and purchase amounts based on rolling annual forecasts. Our forecasts are based on multiple assumptions of product and market demand, which may cause our estimates to be inaccurate. If we underestimate demand, we may not have adequate supplies and could have reduced control over pricing, availability and delivery schedules with our suppliers, which could prevent us from meeting increased customer or consumer demand and harm our business. However, if we overestimate our demand, we may have underutilized assets and may experience reduced margins. If we do not accurately align our supplies with demand and / or fail to meet contractual minimum purchase requirements, our business, results of operations and financial condition may be adversely affected. We may face issues with respect to the supply of our products or their components, including increased costs, disruptions of supply, shortages, contamination or mislabeling. We are dependent on a limited number of suppliers for our products and components used in the manufacturing process of our products. Our top three single- source third- party manufacturers supply us with our HA products and constituted **46 %, 43 %, and 42 % and 51%** of total net sales for the years ended December 31, **2024, 2023 ,and 2022 and 2021**, respectively ~~. Many of the acquired Bioness and Misonix products are also dependent on a limited number of suppliers for these products and their components~~. We may not be able to renew or enter into new contracts with our existing suppliers following the expiration of such contracts on commercially reasonable terms, or at all. Additionally, certain of our devices require circuit boards and other electronic components that could be in short supply. The unavailability of such components from our suppliers may impact our ability to meet the customer demand for these products. The success of certain ~~Surgical~~ **of our bone graft substitute** products depends on our suppliers continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards in their processing methodology. The supply of such donors can fluctuate over time. We cannot be certain that our current suppliers who rely on allograft bone, plus any additional sources that our suppliers identify in the future, will be sufficient to meet our product needs. Our dependence on a limited number of third- party suppliers and the challenges that they may face in obtaining adequate supplies of allograft bone tissue involve several risks, including limited control over pricing, availability, quality and delivery schedules. We may be unable to find an alternative supplier in a reasonable time period or on commercially reasonable terms, if at all, which would adversely affect our business, results of operations and financial condition. If any of our products or the components used in our products are alleged or proven to include quality or product defects, including as a result of improper methods of tissue recovery from donors and disease transmission from donated tissue or illegal harvesting, we may need to find alternate supplies, delay production of our products, discard or otherwise dispose of our products, or engage in a product recall, all of which may adversely affect our business, results of operations and financial condition. If our products or the components in our products are affected by adverse prices or quality or other concerns, we may not be able to identify alternate sources of components or other supplies that meet our quality controls and standards to sustain our sales volumes or on commercially reasonable terms, or at all. **We rely on a limited number of..... financial condition will be adversely affected.** If we fail to maintain our numerous contractual relationships, our business, results of operations and financial condition could be adversely affected. We are party to numerous contracts in the normal course of our business, including our supply and distribution agreements. We have contractual relationships with suppliers, distributors and agents, as well as service providers. In the aggregate, these contractual relationships are necessary for us to operate our business. From time to time, we amend, terminate or negotiate our contracts. We may also periodically be subject to, or make claims of breach of contract, or threaten legal action relating to our contracts. These actions may result in litigation. At any one time, we have a number of negotiations under way for new or amended commercial agreements. We devote substantial time, effort and expense to the administration and negotiation of contracts involved in our business. However, these contracts may not continue in effect past their current term or we may not be able to

negotiate satisfactory contracts in the future with current or new business partners, which may adversely affect our business, results of operations and financial condition. Actual or attempted breaches of security, unauthorized access to or disclosure of information, cyberattacks, or other incidents or the perception that personal and / or other sensitive or confidential information in our possession or control or in the possession or control of our ~~third-party~~ vendors or service providers is not secure, could result in a material loss of business, substantial legal liability or significant harm to our reputation. We receive, collect, process, use and store directly and through third- party vendors and service providers a large amount of information, including personally identifiable information, protected health information and other sensitive and confidential information. This data is often accessed by us through transmissions over public and private networks, including the ~~Internet~~ **internet**. The secure transmission of such information over the ~~Internet~~ **internet** and other mechanisms is essential to maintain confidence in our information technology systems. Despite the privacy and security measures we have in place to comply with applicable laws, regulations and contractual requirements, our facilities and systems, and those of our third- party vendors and service providers, are vulnerable to privacy and security incidents including, but not limited to, computer hacking, breaches, acts of vandalism or theft, computer viruses and other malware, including ransomware and other forms of cyberattacks, misplaced or lost data, programming and / or human errors, and other similar events. A party, whether internal or external, that is able to circumvent our security measures or those of our third- party vendors and service providers could, among other things, misappropriate or misuse sensitive or confidential information, misappropriate user information or other proprietary information, or cause significant interruptions in our operations. Internal or external parties have and will continue to attempt to circumvent our security systems and those of our vendors and service providers, and we expect that we may in the future continue to experience, among other things, external attacks on our network, and attempts to gain unauthorized access to sensitive and confidential information, such as reconnaissance probes, denial of service attempts, malware attacks, malicious software attacks and phishing attacks, such as an external phishing incident that occurred in January 2023, targeting an employee with plausible- sounding prompts to send information to Company leadership. This security incident did not expose protected health information, or affect any of the company' s systems, and was reported to authorities in the relevant regions. Because the techniques used to circumvent security systems can be highly sophisticated and change frequently, and often are not recognized until launched against a target and may originate from less regulated and remote areas around the world, we may be unable to proactively address all possible techniques or implement adequate preventive measures for all situations. Attacks upon information technology systems are also increasing in their frequency, level of persistence, and sophistication, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Recent, well- publicized cyberattacks on companies have resulted in the unauthorized access to and acquisition of significant amounts of sensitive and confidential information and the disruption of important systems and services. These incidents demonstrate the sophistication of the threat actors and magnitude of the threat posed to companies across the nation, including the health care industry. For example, a ~~third-party~~ vendor ~~recently~~ informed us that Change Healthcare, a subsidiary of UnitedHealth Group that acts as an intermediary for processing certain of our claims for reimbursement related to our ~~Exogen~~ **EXOGEN** device to commercial payers, experienced an incident in which a cybersecurity threat actor gained access to some of its information technology systems. As a result of the Change Healthcare incident, certain of our patient billing and collections processes ~~were have been~~ disrupted. ~~We While we~~ have identified an alternative claim processing intermediary and ~~have resumed claims submissions to some payers,~~ ~~but this incident event may cause~~ **caused** delays in a portion of our claims submissions to some commercial payers thereby delaying the related cash remittances to us. As of the date of this Annual Report, UnitedHealth Group is still investigating this incident, including any potential impact on claims and patient data. ~~On March 7, 2024, UnitedHealth Group issued a statement indicating that it expects to begin testing and reestablish connectivity to the effected claims network to restore service beginning March 18, 2024.~~ We do not presently believe that the Change Healthcare incident has materially affected, or is reasonably likely to materially affect the Company, including with respect to our claims collection and cash flows. We continue to evaluate the impact of the Change Healthcare incident on our Company. If ~~someone~~ **an individual or entity** is able to gain unauthorized access to our systems or those of our ~~third-party~~ vendors or service providers, ~~they~~ **the individual or entity** could access, acquire, or alter any information located therein or cause interruptions to our operations. Security breaches and ~~other incidents attempted security breaches thereof~~ could also damage our reputation and expose us to a risk of monetary loss and / or litigation, fines, sanctions, and reputational damage. We also face risks associated with security breaches ~~and other incidents~~ affecting third parties that conduct business with us or our customers and others who interact with our data. ~~While we maintain insurance that covers certain security and privacy breaches~~ **, as well as** we may not carry or maintain sufficient coverage to compensate for all potential liability. Additionally, ~~the costs incurred to remediate any data security or privacy incident~~ **incidents could be substantial affecting service providers of these third parties**. We cannot assure you that our ~~vendors third-party service providers~~ or service providers with access to our or our customers', suppliers', trial patients', and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches, ~~cyberattacks cyber-attacks~~ or other incidents negatively impacting the privacy or security of sensitive or confidential information or our ~~vendors' or~~ service providers' ability to provide services to us, which could have a corresponding effect on our business including putting us in breach of our obligations under privacy laws and regulations and / or which could in turn adversely affect our business, results of operations and financial condition. While we attempt to address the associated risks by performing security assessments and detailed due diligence, we cannot assure you that these contractual

measures and our own privacy and security-related due diligence safeguards will protect us from the risks associated with the processing, storage and transmission of such information by **vendors**, service providers and others acting on our behalf. **While we maintain insurance that covers certain security and privacy breaches, we may not carry or maintain sufficient coverage to compensate for all potential liability. Additionally, the costs incurred to remediate any data security or privacy incident could be substantial.** Failure of a key information technology and communication system, process or site could adversely affect our business, results of operations and financial condition. We rely extensively on information technology and communication systems and software and hardware products, including those of external providers, to conduct business. These systems and software and hardware impact, among other things, ordering and managing components of our products from suppliers, shipping products to customers on a timely basis, processing transactions, coordinating our sales activities across all of our products, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. Despite any precautions we may take, our systems and software and hardware could be exposed to damage or interruption from circumstances beyond our control, such as fire, natural disasters, systems failures, power outages, **cyberattacks** ~~cyber-attacks~~, terrorism, energy loss, telecommunications failure, security breaches ~~and attempts thereof~~, computer viruses and similar disruptions affecting the global Internet. Although we have taken steps to prevent system failures and have back-up systems and procedures to prevent or reduce disruptions, such steps may not prevent an interruption of services and our disaster recovery planning may not be adequate or account for all contingencies. Additionally, our insurance may not adequately compensate us for all losses or failures that may occur. If our systems or software and hardware are damaged or cease to function properly and our business continuity plans do not effectively compensate on a timely basis, we may suffer interruptions in our operations, which could adversely affect our business, results of operations and financial condition. We will need to improve and upgrade our systems and infrastructure as our operations grow in scale in order to maintain the reliability and integrity of our systems and infrastructure. The expansion of our systems and infrastructure will require us to commit substantial financial, operational and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. Any service outages or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology could adversely affect our business, results of operations and financial condition. ~~The ongoing conflict in Israel could have an adverse impact our business and the extent to which the conflict will impact our future operations and financial condition remains uncertain. We have a manufacturing facility in Hod Hasharon, Israel which produces certain of our rehabilitation products, including with product components from third-party suppliers located elsewhere in Israel. Together, these products account for less than 10% of our total net sales for the year ended December 31, 2023. In October 2023, Hamas infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas. In addition, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict. Hostilities involving Israel could have an adverse impact on our future operations and financial condition. In the event that the Company's facility in Hod Hasharon is damaged or otherwise materially disrupted as a result of hostilities in Israel, the Company's ability to manufacture and deliver certain rehabilitation products to its customers could be materially adversely affected. The conflict in Israel also could cause situations where medical product certifying or auditing bodies cannot visit our manufacturing facility in Israel in order to review relevant certifications or clearances, which could lead to temporary suspensions or even cancellations of our product clearances or certifications. The conflict in Israel could result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Delays and disruptions as related to exports from Israel also may be imposed in the future and adversely impact our ability to manufacture and deliver some rehabilitation products in a timely manner. In addition, approximately 25 of our employees currently reside in Israel and work at the manufacturing facility in Hod Hasharon. Government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our employees' ability to effectively perform their daily tasks. The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Some of our employees may be subject to military service in the IDF and may be called to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor at our manufacturing facility in Israel. The ultimate impact of the ongoing hostilities in Israel on our operations and financial condition remains uncertain and depends on many factors, including, but not limited to, the duration and severity of the conflict in Israel, the extent to which we can successfully rely on our other manufacturing facilities and third-party suppliers with respect to certain of our rehabilitation products and the cost of any necessary mitigation efforts. To the extent the conflict in Israel adversely impacts our business, operations and financial condition, they may also have the effect of heightening many of the other risks described in our SEC filings. Our business subjects us to economic, political, regulatory and other risks associated with international sales and operations that could adversely affect our business, results of operations and financial condition. Since we sell our products in many different jurisdictions outside the United States, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a portion of our total net sales. In addition, some of our manufacturing facilities and suppliers of our products and product components are located outside the United States, including in Israel. Accordingly, our future results could be harmed by a variety of factors associated with international sales and operations, including: • economic weakness, including inflation, or political instability in particular foreign economies and markets ; • **unexpected changes in tariffs, trade barriers and regulatory requirements, export licensing requirements or other restrictive actions by the United States or foreign governments** ; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and~~

other obligations incident to doing business in another country; • customers in some foreign countries potentially having longer payment cycles; • exposure of our foreign operations to liability under U. S. laws and regulations, including the U. S. Foreign Corrupt Practices Act (“FCPA”), regulations of the U. S. Office of Foreign Assets Controls, and U. S. anti- money laundering regulations, as well as disadvantages of competing against companies from countries that are not subject to these regulatory regimes; • training of third parties on our products and the procedures in which they are used; • reduced protection for and greater difficulty enforcing our intellectual property rights ; ~~• unexpected changes in tariffs, trade barriers and regulatory requirements, export licensing requirements or other restrictive actions by foreign governments~~; • difficulty in staffing and managing widespread operations, including compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • workforce uncertainty in countries where labor unrest is more common than in the United States; • exposure to liability under a variety of local, national and multinational laws and regulations in multiple jurisdictions, including data privacy laws, healthcare and pharmaceutical laws, antitrust and competition laws, anti- bribery and anti- corruption laws and international trade laws; • international regulators and third- party payers requiring additional clinical studies prior to approving or allowing reimbursement for our products; • complexities associated with managing multiple payer reimbursement regimes, government payers or patient self- pay systems; • production shortages resulting from any events affecting material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism (including the current conflicts between Russia and Ukraine and between Israel and Hamas), global pandemics or natural disasters including earthquakes, hurricanes, floods and fires. If the current conflicts between Russia and Ukraine and between Israel and Hamas escalate or spill over to or otherwise impacts additional regions, it could heighten many of the other risk factors included in our SEC filings. In addition, further expansion into new international markets may require significant resources and the efforts and attention of our management and other personnel, which may divert resources from our existing business operations. As we expand our business internationally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our operations outside of the United States. We are exposed to foreign currency risks, which may adversely affect our business, results of operations and financial condition. External events such as the withdrawal by the United Kingdom from the EU, global pandemics, the ongoing uncertainty regarding actual and potential shifts in U. S. and foreign trade, economic and other policies and the passage of U. S. taxation reform legislation have caused, and may continue to cause, significant volatility in currency exchange rates. Because some of our revenue, expenses, assets and liabilities are denominated in foreign currencies, we are subject to exchange rate and currency risks. Our financial statements are presented in U. S. ~~dollars~~ **Dollars** which may result in currency gain or loss, the outcome of which we cannot predict. Furthermore, to the extent that we incur expenses or earn revenue in currencies other than in U. S. ~~dollars~~ **Dollars**, any change in the values of those foreign currencies relative to the U. S. ~~dollar~~ **Dollar** could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we face potential foreign exchange exposure. To minimize such exposures, we have entered, and may in the future enter, into derivative instruments related to forecasted foreign currency transactions or currency hedges from time to time. Losses from changes in the value of the Euro or other foreign currencies relative to the U. S. ~~dollar~~ **Dollar** could adversely affect our business, results of operations and financial condition. International tariffs, **including tariffs** applied to goods traded between the United States and **countries such as Mexico, Canada, China for, and, other countries and** restrictions on goods imported from certain regions of China may adversely affect our business, results of operations and financial condition. International tariffs, including tariffs applied to goods traded between the United States and **countries such as Mexico, Canada, China, and other countries**, may adversely affect our business, results of operations and financial condition. Since the beginning of 2018, there has been increasing discussion, in some cases coupled with legislative or executive action, from several U. S. and foreign leaders regarding the possibility of instituting tariffs against foreign imports of certain materials. **In 2025, the new political administration in the United States has indicated that it intends to impose tariffs in pursuing government policy and has already imposed several new tariffs, including tariffs on goods and materials from Mexico, Canada and China. When changes are made to United States tariffs, other countries may reciprocate, and have reciprocated, with tariffs imposed against the United States. Whether and to what extent these tariffs will remain in place or additional tariffs will be imposed remains uncertain, but if tariffs are imposed or increased by either the United States or other countries, it may impact the cost of goods, the price of our products and demand for our products, particularly in countries impacted by such tariffs.** The institution of trade tariffs ~~both globally~~ **also** and between the U. S. and ~~China specifically~~ carries the risk of adversely affecting overall **global economic condition conditions**, which could have a negative impact on us ~~as imposition of tariffs could cause an increase in the cost of our products and the components for our products, specifically with respect to our Exogen system, which may adversely affect our business, results of operations and financial condition~~. In addition, the U. S. has previously enacted, and it or other countries may in the future enact legislation that limits or prohibits the use of foreign manufactured equipment or supplies from China, such as the Uyghur Forced Labor Prevention Act, which imposes a ban on virtually all imports from the Xinjiang region of China unless companies are able to prove that the products were not made with forced labor, which is expected to have an adverse effect on our ability to conduct our business and our results of operations. Risks related to government regulation The risk factors listed below describe the risks we face related to government regulation. The companies who manufacture or produce certain of the products we distribute face similar risks with respect to government regulation relating to such products. If such suppliers are unable to comply with government regulations, they may not be able to continue to supply us with products, which could adversely affect our business, results of operations and financial condition. Our products and operations are subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer. The healthcare industry, and in particular the medical device industry, are regulated extensively by governmental authorities, principally the FDA and corresponding state

and foreign regulatory agencies and authorities. The FDA and other U. S. and foreign governmental agencies and authorities regulate and oversee, among other things: • design, development and manufacturing; • testing, labeling, content and language of instructions for use and storage; • clinical trials; • product safety; • marketing, sales and distribution; • premarket clearance, approval and certification; • conformity assessment procedures; • record- keeping procedures; • advertising and promotion; • recalls and other field safety corrective actions; • post market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; • post market studies; and • product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: • administrative or judicially imposed sanctions; • unanticipated expenditures to address or defend such actions; • injunctions, consent decrees or the imposition of civil penalties or fines; • recall or seizure of our products; • total or partial suspension of production or distribution; • refusal to grant pending or future clearances, approvals or certifications for our products; • withdrawal or suspension of regulatory clearances, approvals or certifications; • clinical holds; • untitled letters or warning letters; • refusal to permit the import or export of our products; and • criminal prosecution of us or our employees. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, results of operations and financial condition. Moreover, governmental authorities outside the United States 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 adversely affect our business, results of operations and financial condition. The European Commission has harmonized national regulations for the control of medical devices through European Medical Device Regulations with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a “ Notified Body ” in order to be able to sell products within the member states of the EU. This certification allows manufacturers to stamp the products of certified plants with a “ CE ” mark. Products covered by European Commission regulations that do not bear the CE mark cannot be sold or distributed within the EU. Refer to Part I, Item 1A. Risk Factors — Risks related to government regulation — Regulatory reforms, such as the EU Medical Devices Regulation, could limit our ability to market and distribute our products after clearance, approval or certification is obtained and make it more difficult or costly for us to obtain regulatory clearance, approval or certification of any future products, which could adversely affect our competitive position and materially affect our business and financial results. We may be subject to enforcement action if we engage in improper claims submission practices and resulting audits or denials of our claims by government agencies could reduce our net sales or profits and could lead to significant civil or criminal penalties and other liability. In connection with our Exogen-EXOGEN system, we submit claims directly to, and receive payments directly from, the Medicare and Medicaid programs and private payers. Therefore, we are subject to extensive government regulation, including detailed requirements for submitting claims under appropriate codes and maintaining certain documentation, including evidence that all medical necessity requirements are met to support our claims. Billing for our Exogen-EXOGEN system is complex, time-consuming and expensive, particularly for items and services provided to government healthcare program beneficiaries, such as Medicare and Medicaid. Reimbursement claims may be adversely affected by improper completion of the Certificates of Medical Necessity (“ CMN ”) required in connection with Medicare claims for the Exogen-EXOGEN system and we may be subject to investigations by governmental authorities or third- party payers and required to prove the validity of the claims or the authenticity of the signatures on the CMNs under investigation. Reimbursement claims may also be adversely affected by the promotion of our devices for unapproved or off- label uses or assistance with the reimbursement process that could result in false or fraudulent claims for reimbursement being submitted to government or private payers. Depending on the billing arrangement and applicable law, we bill various payers, all of which may have different prior authorization, patient qualification and medical necessity requirements, as well as patients for any applicable co- payments or co- insurance amounts. In addition, we may also face increased risk in our collection efforts, including potential write- offs of doubtful accounts and long collection cycles, any of which could adversely affect our business, results of operations and financial condition. We are also required to implement compliance procedures and to oversee, train and monitor our employees’ compliance with those procedures, appeal coverage and payment denials, and perform internal audits periodically to assess compliance with applicable laws and regulations as well as internal compliance policies and procedures. We are required to report and return any overpayments received from government payers within 60 days of identification and exercise of reasonable diligence to investigate credible information regarding potential overpayments. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. For example, in February 2021 we entered into a settlement agreement with the United States Attorney’ s Office for the Middle District of North Carolina and the Office of Inspector General of the U. S. Department of Health and Human Services (“ OIG ”) to resolve potential liabilities associated with a self- disclosure we made to the OIG in November 2018 regarding violations of certain Medicare claim submission requirements. See Part I, Item 1A. Risk Factors — Risks related to government regulation — We are subject to federal, state and foreign laws and regulations relating to our healthcare business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would adversely affect our business, results of operations and financial condition. Moreover, Medicare contractors and state Medicaid agencies periodically conduct pre- and post- payment reviews and other audits of claims and are under increasing pressure to more closely scrutinize healthcare claims and supporting documentation. We may be subject to prepayment and post- payment reviews, as well as audits of claims in the future. Private payers may from time to time conduct similar reviews and audits. Any third- party payer reviews and audits of our claims could result in material delays in payment, material recoupments, overpayments, claim denials, fines, revocations of billing privileges, bars on re- enrollment in federal or state healthcare programs, cancellation of our agreements or damage to our reputation, any of which would reduce our net sales and profitability.

The FDA regulatory process is expensive, time- consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products. Before we can market or sell a new medical device or other product or a new use of or a claim for or significant modification to an existing medical device in the United States, we must obtain either clearance from the FDA under **the 510 (k) pathway** or approval of **a PMA application for Pre- Market Approval** (“ PMA ”), unless an exemption applies. In the United States, we have obtained 510 (k) clearance from the FDA to market certain of our products such as **Signafuse-SIGNAFUSE Bioactive Bone Graft Putty**, **Interface Bioactive Bone Graft** and **Signafuse-SIGNAFUSE Mineralized Collagen Scaffold**. Our Pain Treatment products, including Durolane, GELSYN- 3 and SUPARTZ FX, and our **Exogen-EXOGEN** system, have **an** obtained **a PMA**. In the 510 (k) clearance process, the FDA must determine that a proposed device is “ substantially equivalent ” to a legally- marketed predicate device. To be “ substantially equivalent, ” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. In the PMA process, the FDA must determine that a proposed product is safe and effective for **our its** intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for products that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. Both the PMA approval and the 510 (k) clearance process can be expensive, lengthy and uncertain. The FDA’ s 510 (k) clearance process usually takes from three to twelve months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510 (k) clearance process and generally takes from six to eighteen months, or even longer, from the time the application is filed with the FDA. **If the mass layoffs that began at the FDA in February 2025 continue, or are not reversed, then the clearance and approval process may be extended even longer.** In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Any modification to one of our 510 (k) - cleared products that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device would require us to obtain a new 510 (k) marketing clearance and may even, in some circumstances, require the submission of a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510 (k) submission in the first instance, but the FDA may review any manufacturer’ s decision. We may make changes to our 510 (k)- cleared products in the future that we may determine do not require a new 510 (k) clearance or PMA **approval**. If the FDA disagrees with our decision not to seek a new 510 (k) or PMA **approval** for changes or modifications to existing devices and requires new clearances or approvals, we may be required to recall and stop marketing our products as modified, which could require us to redesign our products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. If there is any delay or failure in obtaining required clearances or approvals or if the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our ability to introduce new or enhanced products in a timely manner would be adversely affected, which in turn would result in delayed or no realization of revenue from such product enhancements or new products and could also result in substantial additional costs which could decrease our profitability. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: • if we are unable to demonstrate to the FDA’ s satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; • if the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and • if the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared or approved products on a timely basis. Even after clearance or approval for our products is obtained, we and the products are subject to extensive post market regulation by the FDA, including with respect to advertising, marketing, labeling, manufacturing, distribution, import, export, and clinical evaluation. We are also required to timely file various reports with regulatory agencies. If these reports are not timely filed, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, if we initiate a correction or removal for one of our devices, issue a safety alert, or undertake a field action or recall to reduce a risk to health posed by the device, we may be required to submit a report to the FDA, and in many cases, to other regulatory agencies. Such reports could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders, which would harm our reputation and business. The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions: • adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties; • repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products; • operating restrictions, partial suspension or total shutdown of production; • customer notifications or repair, replacement or refunds; • refusing our requests for 510 (k) clearance or **applications for a PMA approvals** or foreign regulatory approvals of new products, new intended uses or modifications to existing products; • withdrawals of current 510 (k) clearances **or**, PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and adversely affect our business, results of operations and

financial condition. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance as a result of a changing regulatory landscape, we may lose any marketing approvals or clearances that we have already obtained or fail to obtain new marketing approvals or clearances, and we may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Legislative or regulatory reforms, including those currently under consideration by FDA and the EU, could make it more difficult or costly for us to obtain regulatory clearance, approval or certification of any future products and to manufacture, market and distribute our products after clearance, approval or certification is obtained, which could adversely affect our competitive position and materially affect our business and financial results. From time to time, legislation is introduced that could significantly change the statutory provisions and regulations governing the approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, propose new reclassification orders, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to market or modify our currently cleared products on a timely basis. For example, over the last several years, the FDA has proposed reforms to its 510 (k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510 (k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the 510 (k) premarket notification pathway, including plans to potentially sunset certain older devices that were used as predicates under the 510 (k) clearance pathway. In September 2019, the FDA also issued revised final guidance establishing a "Safety and Performance Based Pathway" for "manufacturers of certain well-understood device types" allowing manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria and recommended testing methodologies for each such device type, where feasible. Some of these proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any changes could impose additional regulatory requirements on us that could delay our ability to obtain clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. Our HCT / P products are subject to extensive government regulation and our failure to comply with these requirements could cause our business to suffer. In the United States, we sell human tissue-derived Surgical Solutions products, which are referred to by the FDA as human cells, tissues and cellular or tissue-based products ("HCT / Ps"). In the United States, we are marketing our HCT / Ps pursuant to Section 361 of the PHSa and 21 CFR Part 1271 of FDA's regulations. We do not manufacture these HCT / P products, but serve as a distributor for them. Section 361 HCT / Ps are not currently subject to the FDA requirements to obtain marketing authorizations as long as they meet certain criteria provided in FDA's regulations. HCT / Ps regulated as "361 HCT / Ps" are currently subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, cGMP, when processing, storing, labeling and distributing HCT / Ps, including required labeling information, stringent record keeping and adverse event reporting. If we or our suppliers fail to comply with these requirements, we could be subject to FDA enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures, and, in the most serious cases, criminal penalties. To be regulated as Section 361 HCT / Ps, these products must meet FDA's criteria to be considered "minimally manipulated" and intended for "homologous use," among other requirements. HCT / Ps that do not meet the criteria to be considered Section 361 HCT / Ps are subject to the FDA's regulatory requirements applicable to medical devices, biologics or drugs. Device, biologic or drug HCT / Ps must comply both with the requirements exclusively applicable to Section 361 HCT / Ps and, in addition, with other requirements, including requirements for marketing authorization, such as 510 (k) clearance or PMA or BLA approvals before marketing. We believe our HCT / Ps are regulated solely under Section 361 of the PHSa, and therefore, we have not sought or obtained 510 (k) clearance, a PMA approval, or licensure through a BLA for such HCT / Ps. The FDA could disagree with our determination that these human tissue products are Section 361 HCT / Ps and could determine that these products are biologics requiring a BLA or medical devices requiring 510 (k) clearance or a PMA approval, and could require that we cease marketing such products and / or recall them pending appropriate clearance, approval or licensure from the FDA. If we have to cease marketing and / or have to recall any of our Surgical Solutions products our net sales would decrease, which would adversely affect our business, results of operations and financial condition. HCT / Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSa. HCT / Ps regulated as "Section 351" HCT / Ps are subject to premarket review and approval by the FDA. In November 2017, the FDA released a guidance document entitled "Regulatory Considerations for

Human Cells, Tissues, and Cellular and Tissue — Based Products: Minimal Manipulation and Homologous Use — Guidance for Industry and Food and Drug Administration Staff. ” The guidance outlined the FDA’ s position that all lyophilized amniotic products are more than minimally manipulated and would therefore require a BLA to be lawfully marketed in the United States. The FDA resumed enforcement of IND and premarket approval requirements with respect to these products as of June 1, 2021. In addition, the FDA may in the future modify the scope of its enforcement discretion with respect to Section 361 HCT / Ps or change its position on which current or future products qualify as Section 361 HCT / Ps, or determine that some or all of our HCT / P products may not be lawfully marketed under the FDA’ s policy of enforcement discretion. Any regulatory changes could 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. If clinical studies of our future products do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to expand the indications for or commercialize these products. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for clearances, approvals or certifications of new product lines, or for the approval or certification of the use of our products in some foreign countries. Clinical testing can take many years, ~~is can be~~ expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. Conducting successful clinical studies requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, proximity of patients to clinical sites, patient ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products. Clinical failure can occur at any stage of testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical studies in addition to those we have planned. In addition, failure to adequately demonstrate the safety and efficacy of any of our devices would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that device or indication for use. Even if our future products are cleared in the United States, commercialization of our products in foreign countries would require approval or certification by regulatory authorities or notified bodies in those countries. Approval and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could adversely affect our business, results of operations and financial condition. Interim, “ top- line ” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, “ top- line ” or preliminary data from our clinical trials. Interim, top- line, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, “ top- line, ” or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, “ top- line, ” and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, interim, or “ top- line ” data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, “ top- line, ” or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed. We may be subject to enforcement action if we engage in improper marketing or promotion of our products, and the misuse or off- label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines and / or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Certain products that we currently market have been cleared, approved or certified by the FDA and other foreign regulatory authorities and notified bodies for specific treatments. We cannot prevent a physician from using our products outside of such cleared or approved indications for use, known as off- label uses. While we do not analyze the ordering practices of physicians with respect to off- label uses, we are aware of certain off- label uses of our EXOGEN and StimRouter products. As a result, we could be subject to regulatory or enforcement actions if we are determined to have engaged in promotion of our products for off- label uses, or otherwise determined to have made false or misleading statements about our products. There may be increased risk of injury to patients if physicians attempt to use our products off-

label. Furthermore, the use of our products for indications other than those cleared, approved or certified by the FDA or any foreign regulatory authority or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased liability risks to us for product and medical malpractice related claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability and related claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. Further, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off- label use. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off- label use, the FDA could request that we modify our training, promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Such enforcement actions may include, but are not limited to, criminal, civil and administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could materially harm our business. Some of our marketed products are subject to medical device reporting obligations, which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR **medical device reporting** regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA could take action including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances, seizure of our products, or delay in clearance of future products. We and our third- party manufacturers and suppliers are subject to various governmental regulations related to the manufacturing of our products. Our products and the manufacturing processes, reporting requirements, post- approval clinical data and promotional activities for such products, will be subject to continued regulatory review, oversight and periodic inspection by the FDA and other domestic and foreign regulatory bodies. In particular, the methods used in, and the facilities used for, the manufacture of the products that we own and distribute that are regulated as medical devices must comply with the FDA's **Quality System Regulation** ("QSR"), which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical devices. The FDA enforces the QSR through periodic announced or unannounced inspections of manufacturing facilities, and both we and our third- party manufacturers and suppliers are subject to such inspections. Similarly, the devices we distribute on behalf of third- party manufacturers that are regulated as Section 361 HCT / Ps must be manufactured in compliance with FDA's cGTP requirements and other related requirements. Moreover, should any of our HA products be re- classified as drugs, such products would be required to comply with a different set of manufacturing requirements under FDA's cGMP requirements for drugs. The need to comply with different manufacturing requirements may require us to seek new suppliers. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or the manufacturing processes of our third- party manufacturers and suppliers, including any failure to take satisfactory corrective action in response to an adverse regulatory inspection, can result in, among other things: • injunctions or the imposition of civil penalties or fines; Any of these actions could prevent or delay us from marketing, distributing or selling our products and would likely harm our business. Furthermore, our suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. Our products may be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could adversely affect us. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized drugs, devices and similar products in the event of material deficiencies or defects in their design or manufacture. For example, the FDA's authority to require a recall for medical devices must be based on a finding that there is reasonable probability that the device would cause serious injury or death. In addition, we have in the past and may in the future decide to voluntarily recall our products if certain deficiencies are found. For example, in December 2020 we undertook a voluntary Class II recall of certain vials of ultrasound gel that we provide with our **Exogen-EXOGEN** system due to particulates, which were microbial in nature, found in the gel. The gel was manufactured by a third- party supplier, and we have discontinued the use of that suppliers' gel and have replaced that gel with that of another manufacturer and notified patients to discard gel bottles from affected lots. A government- mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and could adversely affect our reputation and business, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that could adversely affect our business, results of operations and financial condition. Companies are required to maintain certain records

of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary recalls or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagree with our determinations, they could require us to report those actions as recalls and we may be subject to enforcement action. As we conduct clinical studies designed to generate long- term data on some of our existing products, the data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy. Data we generate may ultimately not be favorable, or could even hurt the commercial prospects for our products. We are currently collecting and plan to continue collecting long- term clinical data regarding the quality, safety and effectiveness of some of our existing products. The clinical data collected and generated as part of these studies will further strengthen our clinical evaluation concerning safety and performance of these products. If the results of these clinical studies are negative, these results could reduce demand for our products and significantly reduce our ability to achieve expected net sales. Surgeons and physicians could be less likely to purchase our products than competing products for which longer- term clinical data are available. Also, we may not choose or be able to generate the comparative data that some of our competitors have or are generating and we may be subject to greater regulatory and product liability risks. If we are unable to or unwilling to collect sufficient long- term clinical data supporting the quality, safety and effectiveness of our existing products, our business, results of operations and financial condition could be adversely affected. We may rely on third parties to conduct our clinical studies and to assist us with preclinical development and if they fail to perform as contractually required or expected, we may not be able to obtain regulatory clearance, approval or certification to commercialize our products. We have relied upon and may continue to rely upon third parties, such as contract research organizations (“ CROs ”), medical institutions, clinical investigators and contract laboratories to assist in conducting our clinical studies, which must be conducted in accordance with applicable regulations, including GCP and our preclinical development activities. We rely on these parties for execution of our studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. GCPs are regulations and guidelines enforced by the FDA and other regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, trial sites, and CROs. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable manufacturing requirements. If these third parties fail to successfully carry out their contractual duties, comply with applicable regulatory obligations, including GCP requirements, or meet expected deadlines, or if these third parties must be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to clinical protocols or applicable regulatory requirements or for other reasons, our pre- clinical development activities or clinical studies may be extended, delayed, suspended or terminated. Under these circumstances we may not be able to obtain regulatory clearance, approval or certification for, or successfully commercialize, our products on a timely basis, if at all, and our business, results of operations and financial condition may be adversely affected. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. In addition, our third- party contractors are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our on- going clinical, ~~non- nonclinical~~ **clinical** and preclinical programs. Switching or adding additional third- party contractors involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or other third- party vendor commences work. As a result, delays occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our third- party vendors, including CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Healthcare regulatory reform may affect our ability to sell our products profitably and could adversely affect our business, results of operations and financial condition. In the United States and **abroad** in certain ~~foreign jurisdictions~~, there have been a number of legislative and regulatory **reforms** proposals to change the regulatory and ~~healthcare systems in ways that~~ could prevent or delay marketing approval or certification of our products in development, restrict or regulate post- approval or certification activities of our products and impact our ability to sell our products profitably. In the United States ~~in recent years~~, new legislation has been proposed and adopted at the federal and state level that is effecting major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. By way of example, the Affordable Care Act (“ ACA ”) substantially changed the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. Among other things, the ACA: • increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; • created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; • extended manufacturers’ Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations; • expanded eligibility criteria for Medicaid programs; • established a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and • implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Since its enactment, there have been judicial, executive and **Congressional** **congressional** challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. ~~Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period for purposes of~~

obtaining health insurance coverage through the ACA marketplace, from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Efforts to reform the marketplace for healthcare services **is are ongoing and are expected to increase in the new administration**, and we cannot predict with certainty what impact any U. S. federal and state health reforms will have on us, but such changes could impose new and / or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. In addition, ~~other -- the legislative changes have been proposed and adopted since the ACA was enacted.~~ The Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2 % per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional **Congressional congressional** action is taken. **The** Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Third- party payers also regularly update payments to physicians and hospitals where our products are used. By way of example, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. Legislative and regulatory reforms and executive actions intended to reduce the costs of prescription drugs and medical devices are also ongoing in the United States and abroad. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows. These and other payment updates could directly impact the demand for our products or any products we may develop in the future, if cleared or approved. We expect that other healthcare reform measures that may be adopted in the future, could result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any cleared or approved products. Furthermore, we believe that many individuals who have obtained insurance coverage through the health insurance exchanges which arose as a result of the ACA have done so with policies that have significantly higher deductibles than policies they may have obtained prior to its enactment. Because the out-of-pocket costs of undergoing certain procedures for patients who have not met their deductible for a given year would be significantly higher than they historically would have been, these patients may be discouraged from undergoing certain procedures due to the cost. Any reluctance on the part of patients to undergo procedures utilizing our products due to cost could impact our ability to expand sales of our products and could adversely impact our business, results of operations and financial condition. In our capacity as a pharmaceutical and medical device manufacturer, as a supplier of covered items and services to federal ~~health healthcare care~~ program beneficiaries, and with respect to items and services for which we submit claims for reimbursement from such programs, we are subject to healthcare fraud, waste and abuse regulation and enforcement by federal, state and foreign governments, which could adversely impact our business, results of operations and financial condition. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include: • the federal Anti-Kickback Statute ("AKS"), which prohibits the knowing and willful offer, payment, solicitation or receipt of any bribe, kickback, rebate or other remuneration for referring an individual, in return for ordering, leasing, purchasing or recommending or arranging for or to induce the referral of an individual or the ordering, purchasing or leasing of items or services covered, in whole or in part, by any federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Penalties for violating the AKS include civil penalties of up to \$ **120,124, 816-732** per violation plus three times the amount of the improper remuneration, criminal penalties up to \$ 100,000 per violation, prison terms of up to ten years, and exclusion from participation in the ~~Federal federal health healthcare care~~ programs. Under the Civil Monetary Penalties statute, physicians who pay or accept kickbacks also face penalties of up to \$ 50,000 per kickback plus three times the amount of the prohibited remuneration; • the federal physician self-referral law, the Stark Law, which, subject to certain enumerated statutory and regulatory exceptions, prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain designated health services, or "DHS", which includes both prescription drugs and medical devices, if the physician or a member of such physician's immediate family has a direct or indirect financial relationship (including an ownership interest or a compensation arrangement) with the entity, and prohibits the entity from billing Medicare or Medicaid for such DHS. In addition to reimbursing the government any associated overpayment, violations of the Stark Law can lead to: (1) civil penalties of nearly \$ **29-30,000-868** per claim (in **2023-2024**, adjusted annually for inflation); (2) three times the amount of damages suffered by the government; and (3) potential exclusion from participation in federal healthcare programs; • the False Claims Act, or "FCA", which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly make, or cause to be made, a false statement in order to have a false claim paid, including qui tam or whistleblower suits. Penalties for a violation of the FCA include fines up to \$ 27,894 for each false claim, plus up to three times the amount of damages caused by each false claim. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS or Stark Law constitutes a false or fraudulent claim for purposes of the FCA; • the beneficiary inducement provisions of the Civil Monetary Penalties Law, which prohibits, an individual or entity from offering remuneration to a federal healthcare program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive healthcare items or services from a particular provider. Violations of the CMPL may result in **CMPs of \$ 24,947 and in** administrative penalties ranging **up from \$ 5,000** to \$ 100,000 per violation

depending on the conduct involved; • the criminal healthcare fraud provisions of Health Insurance Portability and Accountability Act, or “ HIPAA ”, and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the federal Physician Payments Sunshine Act, which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by such physicians and their immediate family members. Civil monetary penalties of up to \$ 1, 000, 000 as adjusted annually may be imposed on reporting entities if they fail to report information in a timely, accurate or complete manner; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; • federal government price reporting laws; • **privacy and data security requirements imposed by HIPAA, including the Privacy Rule, the Security Rule, and the Breach Notification Rule promulgated pursuant to HIPAA;** and • analogous state law equivalents of each of the above federal laws, state anti- kickback and false claims laws; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers. The risk of us being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may impose additional restrictions or adopt interpretations of existing laws that could adversely affect us. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and financial arrangements with physicians and other healthcare providers, some of whom recommend, use, prescribe or purchase our products, and other customers, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’ s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to substantial penalties, including administrative, civil and criminal penalties, damages, fines, additional reporting requirements and oversight if we become subject to a Corporate Integrity Agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from governmental healthcare programs, disgorgement and related overpayment obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely impact our business, results of operations and financial condition. In 2018, we identified non-compliance with certain U. S. federal statutes and requirements governing the Medicare program in related to improper completion of Certificate for Medical Necessity (“ CMN ”) forms. In November 2018, we made a voluntary self-disclosure related to this matter to the ~~Office of Inspector General of the U. S. Department of Health and Human Services (“~~ **OIG** ~~)~~ pursuant to the ~~OIG’ s~~ **OIG** ~~’ s~~ Provider Self- Disclosure Protocol. After settlement discussions with the Office of the United States Attorney in the Middle District of North Carolina (“ USAO ”) and ~~OIG~~, on February 22, 2021, we entered into a formal settlement agreement, which included releases from associated False Claims Act liability and further Civil Monetary Penalties that are customary in self- disclosures of this type, and agreed to pay \$ 3. 6 million in resolution of this matter. We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business. We are subject to diverse laws and regulations relating to privacy and data security, including, in the United States, HIPAA and, in the EU, the GDPR. New privacy laws and regulations are being enacted in the United States, particularly at the state level, and globally, and existing ones are being updated and strengthened. Complying with these numerous, complex, and often changing regulations is expensive and difficult. We strive to comply with all applicable laws and other legal obligations relating to privacy, data security, and data protection. However, given that the scope, interpretation, and application of these laws and regulations are often uncertain and may be conflicting, it is possible that these obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and / or in a manner that conflicts with our practices. Failure or perceived failure by us or our **vendors or** service providers to comply with any privacy, data security, or data protection laws or other obligations, or any security incident or data breach experienced by us, one of our **vendors** service providers, or another party, could adversely affect our business. Such impacts include but are not limited to: investigation costs, legal fees, fines and penalties; compensatory, special, punitive, and statutory damages; enforcement actions; litigation; reputational damage; consent orders regarding our privacy and security practices; requirements that we provide consumer notices, credit monitoring services, and / or credit restoration services or other relevant services to individuals impacted by a data breach; adverse actions against our licenses to do business; and injunctive relief. In the United States, HIPAA, as amended, and regulations implemented thereunder (collectively referred to as “ HIPAA ”) imposes, among other things, certain standards relating to the privacy, ~~and~~ **and** security, ~~transmission and breach reporting~~ of protected health information (“ PHI ”) on certain healthcare providers, health plans, and

healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that generally involve creating, receiving, maintaining or transmitting PHI for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities, such as us, as well as business associates, to develop and maintain administrative, physical and technical safeguards to protect PHI. **HHS recently updated, and meet certain notification requirements in the event of a breach of unsecured PHI. HIPAA Privacy Rule and proposed updates to the HIPAA Security Rule. These developments could pose compliance challenges for us.** Additionally, under the HIPAA **Breach Notification Rule**, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach or, if earlier, the date on which the breach would have been discovered through the exercise of reasonable diligence. Notification also must be made to the U. S. Department of Health and Human Services Office for Civil Rights and, in certain circumstances, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents or, if earlier, the date on which the breach would have been discovered through the exercise of reasonable diligence. All U. S. states, the District of Columbia, Guam, Puerto Rico, and the U. S. Virgin Islands have enacted data breach notification laws. Some of these breach notification laws impose notification obligations that are in addition to, or inconsistent with, the HIPAA Breach Notification Rule, which can present compliance challenges. Entities that are found to be in violation of HIPAA, which may occur in connection with, among other things, a breach of unsecured PHI, a complaint about privacy practices or an audit by the U. S. Department of Health and Human Services (“ HHS ”), may be subject to significant civil, criminal, and administrative fines and penalties and / or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non- compliance. The HHS Office for Civil Rights actively enforces HIPAA and frequently issues significant fines and penalties. HIPAA also authorizes state Attorneys General to file suit on behalf of residents of their states. Courts may award damages, costs, and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits, such as those for negligence or recklessness in the misuse or breach of PHI. U. S. states have adopted various privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act (“ CCPA ”) ~~creates individual privacy rights for California residents and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as amended by~~ well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (“ CPRA ”), ~~which amended the CCPA,~~ **creates individual privacy rights for California residents and** imposes additional ~~data protection~~ **privacy and security** obligations on covered businesses, including **data use additional consumer rights processes, limitations and on data uses, new audit requirements. The CCPA provides for higher risk civil penalties for violations, as well as a private right of action for data breaches, and opt-out rights for certain uses of sensitive data. It also** ~~The CPRA~~ created the California Privacy Protection Agency, which is authorized to issue substantive regulations and enforce law. Additional states, including Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, **Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah,** and Virginia have enacted similar comprehensive privacy laws. Other states, including Nevada and Washington, have recently enacted robust health privacy laws. Legislation has been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These developments are likely to result in increased privacy and data security enforcement. Additional compliance investment and potential business process changes may be required, and the enactment of new laws could have potentially conflicting requirements that would make compliance challenging and burdensome. The Federal Trade Commission (“ FTC ”) and many state Attorneys General also continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination, and security practices, **including based on allegations** that ~~appear to be~~ **companies are engaged in** unfair or deceptive **trade practices**. For example, according to the FTC, failing to take appropriate steps to keep consumers’ personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the FTC Act. The FTC expects a company’ s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. In addition to enforcing against organizations, the FTC has made clear that it may seek to hold officers personally liable for privacy or security violations of their organizations, having done so in the past. In Europe, the GDPR imposes strict requirements for processing the personal data ~~of individuals within the EEA~~. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield. In **July 2020**, the Court of Justice of the EU (“ CJEU ”) limited how organizations could lawfully transfer personal data from the EU / EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (“ SCCs ”). The European Commission issued revised SCCs **in on June 4, 2021** to account for the decision of the CJEU and recommendations made by the European Data Protection Board (“ EDPB ”). The United States and the EU ~~recently~~ agreed to a new data transfer mechanism to replace the Privacy Shield known as the EU- U. S. Data Privacy Framework, which may be subject to legal challenges. **In addition to the GDPR, EU member states**

impose additional, and sometimes inconsistent, data protection requirements. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and take additional enforcement actions, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, **impose challenges associated with** the geographical location or segregation of our relevant systems and operations, and ~~could~~ adversely affect our financial results. **Failure to comply with the GDPR can result in fines up to the greater of € 20 million (approximately \$ 21 million), or 4 % of global revenue.** Additionally, ~~from January 1, 2021,~~ following the United Kingdom's departure from the EU, we have **also** had to comply with ~~the GDPR and the UK GDPR~~ (i. e., the GDPR as implemented into UK law). Failure to comply with the UK GDPR can result in fines up to the greater of £ 17. 5 million (approximately \$ ~~21~~**22** million), or 4 % of global revenue. However, the relationship between the United Kingdom and the ~~EU European Union~~ in relation to certain aspects of data protection law remains unclear. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission extends that decision. Failure to comply with the FCPA and laws associated with our activities outside the United States could adversely affect our business, results of operations and financial condition. We are subject to the FCPA and other anti- bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended, among other things, to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of " off books " slush funds from which such improper payments can be made. As we conduct our business in jurisdictions outside of the United States, we face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors clearly state our expectations for our distributors' compliance with U. S. laws, including the FCPA, and provide us with various remedies upon any non- compliance, including the ability to terminate the agreement, we also cannot guarantee our distributors' compliance with U. S. laws, including the FCPA. Therefore, there can be no assurance that our employees and agents, or those companies to which we outsource certain of our business operations, have not and will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. Any violation of the FCPA, other anti- bribery legislation, including the UK Bribery Act and the Brazil Clean Company Act, or related policies could result in severe criminal or civil sanctions, which could adversely affect our business, results of operations and financial condition. Furthermore, we are subject to the export controls and economic embargo rules and regulations of the United States, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce and the Department of State. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons, or for prohibited end- uses. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines, enforcement actions, civil and / or criminal sanctions, the disgorgement of profits, the imposition of a court- appointed monitor, as well as the denial of export privileges, and may adversely affect our business, results of operations and financial condition. If we fail to meet Medicare accreditation and surety bond requirements or DMEPOS supplier standards, it could adversely affect our business, results of operations and financial condition. Our **Exogen EXOGEN** system is classified by CMS and third- party payers as durable medical equipment. Suppliers of Medicare durable medical equipment, prosthetics, orthotics and supplies (" DMEPOS ") must be accredited by an approved accreditation organization as meeting DMEPOS quality standards adopted by CMS and are required to meet surety bond requirements. In addition, Medicare DMEPOS suppliers must comply with Medicare supplier standards in order to obtain and retain billing privileges, including meeting all applicable federal and state licensure and regulatory requirements. CMS periodically expands or otherwise clarifies the Medicare DMEPOS supplier standards, and states periodically change licensure requirements, including licensure rules imposing more stringent requirements on out- of- state DMEPOS suppliers. We believe we are currently in compliance with these requirements. If we fail to maintain our Medicare accreditation status and / or do not comply with Medicare surety bond or supplier standard requirements or state licensure requirements in the future, or if these requirements are changed or expanded, it could adversely affect our business, results of operations and financial condition. Our operations involve the use of hazardous and toxic materials, and we must comply with environmental, health and safety laws and regulations, which can be expensive, and could adversely affect our business, results of operations and financial condition. We are subject to a variety of federal, state, local and foreign laws and regulations relating to the protection of the environment or of human health and safety, including laws pertaining to the use, handling, storage, disposal and human exposure to hazardous and toxic materials. Liability under environmental laws can be imposed on a joint and several basis (which could result in an entity paying more than its fair share) and without regard to comparative fault, and environmental laws are likely to become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could adversely affect our business, results of operations and financial condition. Our employees, independent distributors, independent contractors, suppliers and other third parties may engage in misconduct or other improper activities,

including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation. We are exposed to the risk that our employees, independent distributors, independent contractors, suppliers and others may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) healthcare fraud and abuse laws, or (4) laws that require the true, complete and accurate reporting of financial, billing, and claims information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, results of operations and financial condition. The EU Medical Devices Regulation, which became effective in May 2021, was adopted with the aim of ensuring better protection of public health and patient safety. Among other things, the EU Medical Devices Regulation (“MDR”) imposed changes in the clinical evidence for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, Unique Device Identification (“UDI”) for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes. While we are able to continue marketing our currently CE-marked products in the Europe after the effective date of the EU MDR until the associated CE mark certificates expire, securing renewals of our existing CE mark certificates to allow for continued marketing of the product after CE mark expiration or obtaining certifications for new products requires the performance of certain conformity assessment procedures by a notified body. Notified bodies are independent organizations designated by EU member states which are responsible for, among other things, auditing and examining a product’s technical dossiers and the manufacturers’ quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which allows the manufacturer to place the CE mark on the device and for it to be marketed throughout the EU. Given the additional requirements of the MDR, the renewal of our existing CE mark certificates once they expire or obtaining certifications for new products is more challenging, time consuming and costly. For example, technical documentation for certain of our products requiring recertification, such as our single injection HA treatment Durolane [®], and EXOGEN Bone Stimulation System have been submitted to our notified body. While **Durolane recently received EU MDR certification**, we are actively engaged with our notified body to renew the CE marks for these and our other products, ~~CE mark renewals for these products are still pending.~~ Our ~~The~~ inability to timely review and obtain CE mark certificates for these and other of our products could prohibit their distribution and marketing in EU member states, which would adversely affect our business, prospects, financial condition and results of operations. **We may be subject to environmental, social and governance (“ESG”) regulations or stakeholder requirements which may negatively impact our business or adversely affect our relationship with customers. Across industries, companies are facing increasing requirements to disclose information about social and environmental risks and increasing pressure to improve performance on aspects of sustainability, such as climate impact and product environmental performance, that go beyond currently enacted legislative or regulatory mandates. Several of our customers are adopting, or may adopt in the future, sustainability policies that influence how they make purchasing decisions. Due to the complex nature of our supply chain, we may not always have direct influence over our ability to meet new customer sustainability expectations or policies, which may harm our customer relationships and reputation and may result in an impact on our revenue. Further, new and emerging ESG reporting and disclosure requirements may be unpredictable and expensive to comply with. Our ability to meet stakeholder ESG expectations may not keep up with industry peers which may negatively impact our ability to attract and retain talent.** Recent environmental regulatory actions regarding medical device sterilization facilities could result in disruptions in the supply of certain of our products and could adversely affect our business, results of operations and financial condition. Our disposable products that are used with our neXus [®] Ultrasonic Surgical Aspirator System require sterilization using ethylene oxide prior to sale. Ethylene oxide sterilization is a common and scientifically proven sterilization method that is widely used in the medical device industry. We contract with third-party sterilizers to perform this service. Concerns about unsafe levels of ethylene oxide emissions in the air around some sterilization facilities have resulted in certain state environmental protection agency actions against those facilities that have impacted available capacity for medical device manufacturers ²to sterilize their devices. For example, recently the operations of certain of our contracted sterilization providers were temporarily suspended by the supplier as a voluntary response to a state environmental agency investigation. While such actions have not disrupted our ability to supply products and the previously shut down facilities have been permitted to resume certain operations after implementation of increased emissions controls, it is uncertain as to whether these facilities will be shut down or experience capacity reductions related to environmental, health and safety concerns. **The In March 2024, the U. S. Environmental Protection Agency finalized has proposed new rules governing emissions from ethylene oxide sterilization facilities and has announced their intent to finalize the rule during 2024.** It is unknown whether any other sterilization facilities we may contract with in the future will experience reduced capacity related to new regulatory requirements

or will be required to shut down, either temporarily related to upgrading emissions controls or permanently due to inability to comply with **the new environmental regulation regulations**. To the extent that our third- party sterilizers are unable to sterilize our products, whether due to these regulatory or other limitations (such as capacity, reductions in operations, or availability of materials for sterilization), we may be unable to transition to other third- party sterilizers, sterilizer locations or sterilization methods in a timely or cost effective manner, or at all, which could have a material adverse impact on our results of operations and financial condition. If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our products and, as a result, our business, results of operations and financial condition may be adversely affected until we are able to secure a new facility. We do not have redundant manufacturing facilities **and have one primary location for manufacturing in the Memphis, Tennessee area**. Our other facilities and equipment would be costly to replace and could require substantial lead- time to repair or replace. Our facilities may be harmed or rendered inoperable by natural disasters (including events caused by or intensified by climate change) or man- made disasters, including, but not limited to, tornadoes, flooding, fire and power outages. Such disasters may render it difficult or impossible to manufacture and commercialize our products and conduct our research and development activities for new products, line extensions and expanded indications. The inability to perform those activities, combined with our limited inventory of supplies, components and finished product, may result in the inability to continue manufacturing or supplying our products during such periods and the loss of customers or harm to our reputation. Although we possess insurance for damage to our facilities and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. Risks related to intellectual property matters Protection of our intellectual property rights may be difficult and costly, and our inability to protect our intellectual property could adversely affect our competitive position. Our success depends in part on our ability to protect our proprietary rights to the technologies and inventions used in, or embodied by, our products. To protect our proprietary technology, we rely on patent protection, **as well as a combination of** copyright, trade secret and trademark laws, **and as well as** nondisclosure, confidentiality and other contractual restrictions in our consulting **and**, employment **, and other** agreements. These legal means afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our existing confidentiality and / or invention assignment agreements with employees, contractors, and others who participate in IP development activities could be breached, or we may not enter into sufficient and adequate agreements with those individuals in the first instance, and we may not have adequate remedies for such breaches. Furthermore, we may be subject to, and forced to defend against, third- party claims of ownership to our intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or rights to use, valuable intellectual property. Such an outcome could adversely affect our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. The process of applying for patent protection is time- consuming and expensive and we cannot assure you that all of our patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us. The rights granted to us under our patents may not be meaningful or provide us with any commercial advantage, and they could be opposed, contested, narrowed, or circumvented by our competitors or declared invalid or unenforceable in judicial or administrative proceedings. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection but where such protection may not be sufficient to terminate infringing activities. Furthermore, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to us by third parties. Therefore, these patents and applications may not be prosecuted or enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, which could also adversely affect our business, results of operations and financial condition. The rights granted to us under these patents, including prospective rights sought in our pending patent applications, could be opposed, contested or circumvented by our competitors or other third parties or declared invalid or unenforceable in judicial or administrative proceedings. If any of our patents are challenged, invalidated or legally circumvented by third parties, and if we do not own other enforceable patents protecting our products, competitors could market products and use processes that are substantially similar to, superior to, or otherwise competitive with those of ours, and our business could suffer. In addition, the patents we own or have licenses to may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes comparable to those of ours without infringing on our patent property rights. Further, our patents may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. Third -parties may assert that we or the inventors of any patents licensed to us were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third -parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States

and many foreign jurisdictions are typically not published until eighteen months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications or published information which could invalidate our patents or a portion of the claims of our patents. Any such patent applications may have priority over our patent applications or issued patents, which could require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U. S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. We may be subject to a third- party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. In some cases, noncompliance with such requirements can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or the owners of any patent rights licensed to us fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would adversely affect our business, results of operations and financial condition. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. Furthermore, we do not have patent rights in certain foreign countries in which a market may exist in the future. We may need to expend additional resources to protect or defend our intellectual property rights in these countries, and the inability to protect or defend the same could impair our brand or adversely affect the growth of our business internationally. For example, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as, similar to, or competitive with our products. Patents have a limited lifespan, and the protection patents affords is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Even if patents covering our products are obtained, once the patent life has expired for patents covering a product, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Trademarks We rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, we may not be able to successfully secure trademark registrations for all such applications in each jurisdiction in which the product is marketed. Third -parties may oppose our trademark applications, or otherwise challenge our use of both registered and unregistered trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business, results of operations and financial condition may be adversely affected. Trade secrets and know- how We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, our competitors may independently develop equivalent knowledge, methods and/or know- how. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. Our competitors could use any of the information we may be required to disclose by the FDA to develop independently technology similar to ours. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be

adversely affected, as could our business, results of operations and financial condition. If we were to enforce a claim that a third party had illegally obtained, misappropriated or was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may adversely affect our business, results of operations and financial condition. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products, which could adversely impact our business, results of operations and financial condition. We are a party to license agreements under which we are granted rights to intellectual property that is material to our business, and we may need to enter into additional license agreements in the future. Our rights to use these technologies and the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which case we would not be able to market products covered by the license, which would adversely affect our business, results of operations and financial condition. As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In the event that we are not able to acquire a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business. In addition, the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation and damages. In some cases, we may not have the right to control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications prior to our acquisition of, or our entry into a license with respect to, such patents and patent applications. We cannot be certain that the drafting or prosecution of the patents and patent applications licensed to us will result or has resulted in valid and enforceable patents. Further, we do not always retain complete control over our ability to enforce our licensed patent rights against third-party infringement. In those cases, we cannot be certain that our licensor or other ultimate owner of such patents will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license. If our licensor or other ultimate owners of such patents fails to properly enforce the patents subject to our license in the event of third-party infringement, our ability to retain our competitive advantage with respect to our products may be materially and adversely affected. Licensing of intellectual property is an important part of our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property that is subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation-related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and • the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. In addition, we may become the owner of intellectual property that was obtained through assignments which may be subject to re-assignment back to the original assignor upon our failure to prosecute or maintain such intellectual property, upon our breach of the agreement pursuant to which such intellectual property was assigned, or upon our bankruptcy. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or if intellectual property is re-assigned back to the original assignor, we may be unable to successfully develop and commercialize the affected products and technologies. Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology. Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could adversely affect our business, results of operations and financial condition. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. We may in the future be a party to patent and other intellectual property litigation and administrative proceedings that could be costly and could interfere with our ability to successfully market our products. The medical device industry has been characterized by frequent and extensive intellectual property litigation and is highly competitive. Our competitors or other patent

holders may assert that our products and / or the methods employed in our products are covered by their patents or that we are infringing, misappropriating, or misusing their trademark, copyright, trade secret, and / or other proprietary rights. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our products. In the event that we become involved in such a dispute, we may incur significant costs and expenses and may need to devote resources to resolving any claims, which would reduce the cash we have available for operations and may be distracting to management and other employees, including those involved in the development of intellectual property. We do not know whether our competitors or potential competitors have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our products. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our products or technologies. There is no guarantee that patents will not issue in the future from currently pending applications that may be infringed by our technology or products. In addition, identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and difficulty in assessing the meaning of patent claims. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third- party trade secrets or infringement by us of third- party patents, copyrights, trademarks or other rights or challenging the validity of our patents, copyrights, trademarks or other rights will not be asserted against us. We may also initiate litigation against third parties to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. Our intellectual property has not been tested in litigation. If we initiate litigation to protect our rights, we run the risk of having our patents and other proprietary rights invalidated, canceled or narrowed, which could undermine our competitive position. Further, if the scope of protection provided by our patents or patent applications or other proprietary rights is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products. We may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our product. Furthermore, if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate its patent or other intellectual property rights and / or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings. These lawsuits and proceedings, regardless of merit, are time- consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business, results of operations and financial condition. Any such claim could also force us to do one or more of the following: • incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product, service, or technology at issue infringes or violates the third- party' s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third- party' s attorneys' fees; • pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non- infringing technology; • stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology; • obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all; • redesign our products, services, and technology so they do not infringe or violate the third- party' s intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; • enter into cross- licenses with our competitors, which could weaken our overall intellectual property position; • lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others; • find alternative suppliers for non- infringing products and technologies, which could be costly and create significant delay; or • relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, divert the time, attention and resources of management, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely affect our ability to raise additional funds or otherwise adversely affect our business, results of operations and financial condition. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If these results are perceived to be negative, the price of our Class A common stock could be adversely affected. In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, results of operation and financial condition. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or former employers or are in breach of non- competition or non- solicitation agreements with our competitors or former employers. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. In addition, we 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 could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the competitors or former employers. An inability to incorporate technologies or features that are important or essential to our products could adversely affect our business, results of operations and financial condition, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could adversely affect our business, results of operations and financial condition. Any product candidates that we develop as biologics subject to the BLA pathway may be subject to competition sooner than anticipated. The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products. We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products. Intellectual property rights do not necessarily address all potential threats to our business. Once granted, patents may remain open to invalidity challenges including opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third- party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: • others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue; • we, the inventors of any in- licensed patent rights, or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we, the **investors-filing party (ies)** of any in- licensed patent rights, or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • our pending patent applications may not lead to issued patents; • issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license; • parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property; • we may not develop or in- license additional proprietary technologies that are patentable; • we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and • the patents of others may adversely affect our business. Should any of these events occur, they could adversely affect our business, results of operations and financial condition. Risks related to our organizational structure and the Tax Receivable Agreement Our principal asset is our interest in BV LLC, and, accordingly, we depend on distributions from BV LLC to pay our taxes and expenses, including payments under the Tax Receivable Agreement. BV LLC’ s ability to make such distributions may be subject to various limitations and restrictions. We are a holding company and have no material assets other than our ownership of LLC Interests of BV LLC. As such, we have no independent means of generating net sales or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the financial results and cash flows of BV LLC and its subsidiaries and distributions we receive from BV LLC. There can be no assurance that BV LLC and its subsidiaries will generate sufficient cash flow to distribute funds to us or that applicable state law and contractual restrictions, including negative covenants in our debt instruments, will permit such distributions. BV LLC will continue to be treated as a partnership for U. S. federal income tax purposes and, as such, generally will not be subject to any entity- level U. S.

federal income tax. Instead, taxable income will be allocated to holders of LLC Interests, including us. Accordingly, we will incur income taxes on our allocable share of any net taxable income of BV LLC. Under the terms of the Bioventus LLC Agreement, BV LLC will be obligated to make tax distributions to holders of LLC Interests, including us, subject to any limitations or restrictions in our debt arrangements. In addition to tax expenses, we will also incur expenses related to our operations, including payments under the ~~Tax Receivable Agreement (“TRA”)~~, which we expect could be significant. See Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence- Tax Receivable Agreement in this Annual Report for further information. We intend, as its managing member, to cause BV LLC to make cash distributions to the owners of LLC Interests, including us, in an amount sufficient to (i) fund their or our tax obligations in respect of allocations of taxable income from BV LLC and (ii) cover our operating expenses, including payments under the TRA. However, BV LLC’s ability to make such distributions may be subject to various limitations and restrictions, such as restrictions on distributions that would either violate any contract or agreement to which BV LLC is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering BV LLC insolvent. If we do not have sufficient funds to pay taxes or other liabilities or to fund our operations, we may have to borrow funds, which could materially adversely affect our liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the TRA for any reason, such payments generally will be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the TRA and therefore accelerate payments due under the TRA. In addition, if BV LLC does not have sufficient funds to make distributions, our ability to declare and pay cash dividends will also be restricted or impaired. The TRA with the Continuing LLC Owner requires us to make cash payments to it in respect of certain tax benefits to which we are or may become entitled, and we expect that the payments we will be required to make could be significant. We are a party to a TRA with ~~the Smith & Nephew, Inc. (“Continuing LLC Owner”)~~. Under the TRA, we are required to make cash payments to the Continuing LLC Owner equal to 85 % of the tax benefits, if any, that we actually realize, or in certain circumstances are deemed to realize, as a result of (1) increases in the tax basis of assets of BV LLC resulting from (a) any future redemptions or exchanges of LLC Interests and (b) certain distributions (or deemed distributions) by BV LLC and (2) certain other tax benefits arising from payments under the TRA. We expect the amount of the cash payments that we will be required to make under the TRA will be significant. The actual amount and timing of any payments under the TRA will vary depending upon a number of factors, including the timing of redemptions or exchanges by the Continuing LLC Owner, the amount of gain recognized by the Continuing LLC Owner, the amount and timing of the taxable income we generate in the future, and the federal tax rates then applicable. Any payments made by us to the Continuing LLC Owner under the TRA will generally reduce the amount of overall cash flow that might have otherwise been available to us. To the extent that we are unable to make timely payments under the TRA for any reason, the unpaid amounts will be deferred and will accrue interest until paid by us. Furthermore, our obligation to make payments under the TRA could make us a less attractive target for an acquisition, particularly in the case of an acquirer that cannot use some or all of the tax benefits that are the subject of the TRA. Payments under the TRA are not conditioned on the Continuing LLC Owner’s continued ownership of LLC Interests or our Class A common stock. The amounts we will be required to pay under the TRA will depend on, among other things, the timing of subsequent redemptions or exchanges of LLC Interests by the Continuing LLC Owner, the price of our shares of Class A common stock at the time of each such redemption or exchange, and the amounts and timing of our future taxable income, and may be significantly different from the amounts described in the preceding sentence. Additionally, in certain cases such payments may be accelerated or significantly exceed the actual benefits we realize. Moreover, our organizational structure, including the TRA, confers certain tax benefits upon the Continuing LLC Owner that may not benefit the holders of our Class A common stock to the same extent as they will benefit the Continuing LLC Owner. Refer to risk factor — In certain cases, payments under the TRA to the Continuing LLC Owners may be accelerated or significantly exceed the actual benefits we realize in respect of tax attributes subject to the TRA. In certain cases, payments under the TRA to the Continuing LLC Owner may be accelerated or significantly exceed the actual benefits we realize in respect of the tax attributes subject to the TRA. The TRA provides that if (i) we materially breach any of our material obligations under the TRA, (ii) we undertake certain mergers, assets sales, other forms of business combinations or other changes of control or (iii) we elect an early termination of the TRA, then our obligations or our successor’s obligations under the TRA to make payments thereunder would be based on certain assumptions, including an assumption that we would have sufficient taxable income to fully utilize all potential future tax benefits that are subject to the TRA (or, in the case of certain mergers, assets sales, other forms of business combinations or other changes of control, that we would have taxable income at least equal to four times the highest taxable income in any of the four fiscal quarters ending prior to the closing date of such transaction (increased by 10 % for each taxable year beginning with the second taxable year following the closing date)). As a result of the foregoing, (i) we could be required to make payments under the TRA that are greater than the specified percentage of the actual benefits we ultimately realize in respect of the tax benefits that are subject to the TRA and (ii) if we materially breach any of our material obligations under the TRA or if we elected to terminate the TRA early, we would be required to make an immediate cash payment equal to the present value of the anticipated future tax benefits that are the subject of the TRA, which payment may be made significantly in advance of the actual realization, if any, of such future tax benefits. In these situations, our obligations under the TRA could have a substantial negative impact on our liquidity and could have the effect of delaying, deferring or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. There can be no assurance that we will be able to fund or finance our obligations under the TRA. We may elect to completely terminate the TRA early only with the written approval of a majority of our directors other than any directors that have been appointed or designated by the Continuing LLC Owner or any of such person’s affiliates. We may make payments to the Continuing LLC Owner under the TRA that exceed the tax benefits actually realized by us in the event that any tax benefits are disallowed by a taxing authority. Payments under the TRA are based on the tax reporting positions that we determine, and

the Internal Revenue Service (“ IRS ”) or another tax authority may challenge all or part of the tax basis increases, as well as other related tax positions we take, and a court could sustain such challenge. Pursuant to the TRA, the Continuing LLC Owner is required to reimburse us for any cash payments previously made to it under the TRA in the event that any tax benefits actually realized by us and for which payment has been made under the TRA are subsequently challenged by a taxing authority and are ultimately disallowed. In addition, but without duplication of any amounts previously reimbursed by the Continuing LLC Owner, any excess cash payments made by us to the Continuing LLC Owner will be netted against any future cash payments that we might otherwise be required to make to the Continuing LLC Owner under the terms of the TRA. However, we might not determine that we have effectively made an excess cash payment to the Continuing LLC Owner for a number of years following the initial time of such payment. Moreover, there can be no assurance that any excess cash payments for which the Continuing LLC Owner has a reimbursement obligation under the TRA will be repaid to us. As a result, payments could be made under the TRA in excess of the tax savings that we realize in respect of the tax attributes with respect to the Continuing LLC Owner that are the subject of the TRA. Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results of operations and financial condition. We are subject to taxes by the U. S. federal, state, local and foreign tax authorities, and our tax liabilities will be affected by the allocation of expenses to differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors. In addition, we may be subject to audits of our income, sales and other transaction taxes by U. S. federal, state, local and foreign taxing authorities. Outcomes from these audits could adversely affect our business, results of operations and financial condition. If we were deemed to be an investment company under the Investment Company Act of 1940, as amended, or the 1940 Act, as a result of our ownership of BV LLC, applicable restrictions could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition. As the sole managing member of BV LLC, we control and operate BV LLC. On that basis, we believe that our interest in BV LLC is not an “ investment security ” as that term is used in the 1940 Act. However, if we were to cease participation in the management of BV LLC, our interest in BV LLC could be deemed an “ investment security ” for purposes of the 1940 Act. We and BV LLC intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition. Bioventus is controlled by the Original LLC Owners, whose interests may differ from those of our public stockholders. As of December 31, ~~2023~~ **2024**, the Original LLC Owners control approximately 41.8 % of the combined voting power of our common stock through their ownership of both Class A common stock and Class B common stock. The Original LLC Owners will, for the foreseeable future, have the ability to substantially influence us through their ownership position over corporate management and affairs, and will be able to control virtually all matters requiring stockholder approval. The Original LLC Owners are able to, subject to applicable law, and the voting arrangements, elect a majority of the members of our Board, control actions to be taken by us and our Board, including amendments to our certificate of incorporation and bylaws and approval of significant corporate transactions, including mergers and sales of substantially all of our assets. The directors so elected will have the authority, subject to the terms of our indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions. It is possible that the interests of the Original LLC Owners may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, the Continuing LLC Owner may have different tax positions from us, especially in light of the TRA that could influence our decisions regarding whether and when to dispose of assets, whether and when to incur new or refinance existing indebtedness, and whether and when Bioventus should terminate the TRA and accelerate its obligations thereunder. In addition, the determination of future tax reporting positions and the structuring of future transactions may take into consideration the Continuing LLC Owner’s tax or other considerations, which may differ from the considerations of us or our other stockholders. Risks related to our ownership of our Class A common stock **The dilution of our Class A common stockholders upon the exchange of the outstanding common membership interests in BV LLC could adversely affect the market price of our Class A common stock and the resale of such shares could cause the market price of our Class A common stock to fall. As provided in the amended and restated limited liability agreement of Bioventus LLC (“ BV LLC ”), the holders (the “ Selling Securityholders ”) of common membership interests in BV LLC (the “ LLC Interests ”) may, from time to time, exchange their LLC Interests for newly issued shares of our Class A common stock on a one-for-one basis. On October 25, 2024, the Company filed a registration statement on Form S-3 (“ Form S-3 ”) to in part register for resale 35,038,052 shares of our Class A common stock held by the Selling Securityholders, of which 15,786,737 shares are issuable upon the exchange of their outstanding LLC Interests. The issuance of shares of our Class A common stock upon the exchange of LLC Interests would significantly dilute the ownership interest of our Class A common stockholders and the resale of such shares by the Selling Securityholders pursuant to the Form S-3 once declared effective, or the perception in the market that the Selling Securityholders intend to sell such shares, could adversely affect the market price of our Class A common stock.** Our stock price may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares of Class A common stock at or above the price at which you purchase them. The stock market historically has experienced extreme price and volume fluctuations. As a result of this volatility, you might not be able to sell your Class A common stock at or above the price at which you purchase it. From our initial public offering in February 2021 through February 27, ~~2024~~ **2025**, the per share trading price of our Class A common stock has been as high as \$ 19.94 and as low as \$ 0.80. It might continue to fluctuate significantly in response to various factors, some of which are beyond our control. These factors include: • our operating performance and the operating performance of similar companies; • the overall performance of the equity markets; • any major change in our management; • changes in laws or regulations relating to our

products; • announcements by us or our competitors of acquisitions, business plans, or commercial relationships; • threatened or actual litigation; • publication of research reports or news stories about us, our competitors, or our industry, or positive or negative recommendations; • general political and economic conditions. Additionally, securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in substantial costs, divert our management's attention and resources, and harm our business, operating results, and financial condition. Our amended and restated certificate of incorporation, **as amended**, to the extent permitted by applicable law, contains provisions renouncing our interest and expectation to participate in certain corporate opportunities identified or presented to certain of our Original LLC Owners. Certain of the Original LLC Owners are in the business of making or advising on investments in companies and these Original LLC owners may hold, and may, from time to time in the future, acquire interests in or provide advice to businesses that directly or indirectly compete with certain portions of our business or the business of our suppliers. Our amended and restated certificate of incorporation, **as amended**, provides that, to the fullest extent permitted by law, none of the Original LLC Owners or any director who is not employed by us or his or her affiliates will have any duty to refrain from engaging in a corporate opportunity in the same or similar lines of business as us. The Original LLC Owners may also pursue acquisitions that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. As a result, these arrangements could adversely affect our business, results of operations, financial condition or prospects if attractive business opportunities are allocated to any of the Original LLC Owners instead of to us. Certain anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of our Company more difficult, limit attempts by our stockholders to replace or remove our current management, and depress the market price of our common stock. Certain provisions of our amended and restated certificate of incorporation, **as amended, our second** amended and restated bylaws and Delaware law could render more difficult, delay or prevent transactions that stockholders consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions might also prevent or frustrate attempts by our stockholders to replace or remove management, and include provisions that: • authorize the issuance of "blank check" preferred stock that could be issued by our Board to increase the number of outstanding shares and thwart a takeover attempt; • establish a classified Board so that not all members of our Board are elected at one time, **which is currently being phased out and will be discontinued beginning with our 2026 annual meeting of stockholders**; • provide the removal of directors only for cause, **provided directors may be removed with or without cause beginning with our 2026 annual meeting of stockholders**; • prohibit the use of cumulative voting for the election of directors; • limit the ability of stockholders to call special meetings or amend our bylaws; • require all stockholder actions to be taken at a meeting of our stockholders; and • establish advance notice and duration of ownership requirements for nominations for election to the Board or for proposing matters that can be acted upon by stockholders at stockholder meetings. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management, which could in turn limit the opportunity for our stockholders to receive a premium for their shares of our common stock and affect the price that some investors are willing to pay for our common stock. Our amended and restated certificate of incorporation, **as amended**, provides that the Court of Chancery of the State of Delaware will be, to the fullest extent permitted by law, the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation, **as amended**, provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware, or the Court of Chancery, will be, to the fullest extent permitted by law, the sole and exclusive forum for: (a) any derivative action, suit or proceeding brought on our behalf; (b) any action, suit or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; (c) any action, suit or proceeding arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation ~~or~~, **as amended, or our second amended and restated** bylaws (as either may be amended from time to time); or, (d) any action, suit or proceeding asserting a claim governed by the internal affairs doctrine; provided that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision in our amended and restated certificate of incorporation, **as amended** does not designate the Court of Chancery as the exclusive forum for any claim for which the applicable statute creates exclusive jurisdiction in another forum and, accordingly, does not apply to any claims brought to enforce any liability or duty created by the Exchange Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation, **as amended**, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to us will make our Class A common stock less attractive to investors. We are an "emerging growth company" pursuant to the provisions of the JOBS Act. For as long as we are an "emerging growth company," we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies," including, for example, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations relating to the presentation of financial statements in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our periodic reports, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding advisory "say-on-pay" votes on executive compensation and shareholder advisory votes on golden parachute compensation. We have

availed ourselves of some of these reduced reporting obligations and exemptions in our SEC filings and expect to continue to do so in future SEC filings. In addition, emerging growth companies can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to “opt out” of such extended transition period, and as a result, we plan to comply with any new or revised accounting standards on the relevant dates on which non-emerging growth companies must adopt such standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable. We will continue to qualify as an emerging growth company until the earliest of:

- The last day of our fiscal year following the fifth anniversary of the date of our IPO;
- The last day of our fiscal year in which we have annual gross revenues of at least \$ 1.235 billion or more;
- The date on which we have, during the previous three-year period, issued more than \$ 1.0 billion in non-convertible debt;
- The date on which we are deemed to be a “large accelerated filer,” as such term is defined in the Exchange Act rules.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company and rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations including regarding executive compensation. We cannot predict if investors will find our Class A common stock less attractive because we may rely on the reduced disclosure requirements and exemptions applicable to emerging growth companies and / or smaller reporting companies. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile. !