Risk Factors Comparison 2023-03-01 to 2022-03-02 Form: 10-K

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The following risk factors and other information included in this Annual Report on Form 10- K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. This section contains forward-looking statements, and in considering these statements, you should refer to the qualifications and limitations on our forward-looking statements that are described in " Forward- Looking Statements " included in Part I of this Annual Report on Form 10-K. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. Risks related to our financial position We have incurred losses in the past, expect to continue to incur losses and may never achieve profitability. We have incurred significant net operating losses in every year since our inception and expect to continue to incur net operating losses for the next several years. Our net loss was $ ~~2~~ **50** million for the year ended December 31, ~~2021~~ **2022** , and $ ~~24~~ **2** million for the year ended December 31, ~~2020~~ **2021** . As of December 31, ~~2021~~ **2022** , we had an accumulated deficit of $ ~~531~~ **581** million. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing, manufacturing and other expenses as our business continues to grow and we expand our product offerings. We will need to generate significant additional revenue to achieve and then maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. **We expect to incur substantial expenditures in the foreseeable future and will require additional capital to support business growth. This capital might not be available on terms favorable to us or at all. We expect to incur substantial expenditures in the foreseeable future in connection with the following: • our sales and marketing efforts, including the expanded advertising of our Platinum Services ™ Program; • expansion of our manufacturing capacity; • funding research and development activities related to new and existing products, including our porous- coated technology for the Imprint system and Actera ™ line extensions; and • enforcing our intellectual property rights and pursuing our claims against Aetna. In addition, our general and administrative expense may continue to increase due to the additional operational and reporting costs associated with our expanded operations and being a public company. We anticipate that our principal sources of funds in the future will be revenue generated from the sale of our products, potential future capital raises through the issuance of equity or other securities, available sales of shares under the Sales Agreement, potential debt financings and revenue that we may generate in connection with licensing our intellectual property. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures. 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, and we may even be required to scale back our operations.** Our existing and any future indebtedness could adversely affect our ability to operate our business. On November 22, 2021, we entered into a Credit and Security Agreement (the " New Credit Agreement ") with MidCap Financial **Trust** ~~Services, LLC~~ (" MidCap ~~Financial Services~~ "), as **agent, and certain lender parties thereto** ~~servicer for MidCap Financial Trust to refinance our existing senior secured indebtedness~~ . The New Credit Agreement provides for a five- year, $ 21 ~~. 0~~ million secured term loan facility (the " Term Facility ") ~~,~~ **. The New Credit Agreement refinanced** and ~~replaces~~ **replaced** our ~~existing~~ **prior 2019 secured** credit facility ~~under~~ **with Innovatus (** the **"** 2019 Secured Loan Agreement **"** ~~, with Innovatus, as collateral agent and lender, East West Bank and other lenders party thereto (collectively, the" Lenders"~~). **We used** ~~The existing credit facility was repaid in full and~~ the **amounts drawn under** ~~existing revolving credit facility terminated in connection with the entry of~~ the New Credit Agreement **to repay all outstanding obligations** ~~. The full amount of the $ 21. 0 million Term Facility was borrowed on the date of entering into the New Credit Agreement and the proceeds were used for the repayment of the debt~~ under the 2019 Secured Loan Agreement ~~with the Lenders~~ **, which 2019 Secured Credit Loan Agreement has been terminated** . The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant requiring us to maintain unrestricted cash and cash equivalents in excess of $ 4. 0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. For further information regarding the New Credit Agreement with MidCap Financial Services, see " Note I — Debt and Notes Payable " in the financial statements and related notes appearing elsewhere in this Annual Report on Form 10- K. Our obligations under the New Credit Facility, and our other financial obligations and contractual commitments, including any additional indebtedness that we may incur, could increase our vulnerability to adverse changes in general economic, industry and market conditions; limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and place us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. Additionally, with respect to our current indebtedness and any future debt that we may secure, our failure to perform financially according to the terms of the loan agreement or otherwise perform or satisfy the covenants of the loan agreement could materially adversely affect us, causing us to have to repay some or

all of the principal of the loan on an accelerated basis, providing the lender with the ability to foreclose the loan, causing the lender to have recourse against some or all of our assets used as collateral in the loan, including, without limitation, our cash, our intellectual property, any other of our assets, and triggering other potentially adverse consequences under the terms of any loan agreement. Risks related to our business, industry and competitive position ~~We are~~ **With the** ~~transitioning~~ --- **transition** ~~our U. S. knee implant business~~ to Identity Imprint ™ **as our primary knee system in the U. S.** and **with the introduction of** our new Image- to- Implant ® Platinum Services ℠ Program ~~offering~~ , ~~which may expose us to~~ new operational and regulatory risks ~~.~~ **may arise** We have recently evolved our product portfolio for knee arthroplasty, launching our new Identity Imprint ™ knee system (“ Identity Imprint ”), which ~~provides~~ **is now our primary knee system in the U. S. Identity Imprint offers** a ~~data- informed~~ high- quality knee implant system that provides a level of personalization through its patient- specific instruments and proprietary algorithms for pre- surgical planning. Identity Imprint ~~is a data- informed design that~~ incorporates standard sizes developed using our clinical database of information, with implant sizing optimized for each patient using advanced algorithms. Identity Imprint ~~incorporates~~ **maintains** our “ surgery- in- a- box ” **delivery** model that we believe optimizes its efficiency for use in sites such as ambulatory surgery centers, as the product uses a minimal shelf footprint and is compatible with a reusable instrument set. Identity Imprint is designed to meet the standard of care for all patient procedures, and we believe it represents a compelling value proposition for customers. **With the** ~~We are transitioning in 2022 to make~~ Identity Imprint ~~our standard knee system. Previously, our knee product offering was a fully- personalized knee system. As part of our~~ transition ~~to Identity Imprint as our standard knee system~~ , we ~~are no~~ **now** ~~longer offering~~ --- **offer** ~~our~~ **healthcare facilities and patients the ability to obtain a** fully personalized iTotal Identity ~~system as our standard~~ knee system **through** ~~product in the U. S. market. However, we intend to continue offering patients the option of upgrading from the Identity Imprint system to~~ a ~~personalized iTotal Identity ™ knee system by requesting this product and understanding that the~~ deluxe ~~service~~ **services upgrade** ~~component is not covered by Medicare or by private insurance~~ . We are marketing this program as our Platinum Services ℠ Program (PSP). Under this program, medical facilities and surgeons enrolled in the program will have the option to charge an out- of- pocket fee to patients who request the Platinum Service Program. This fee may include an incremental margin above the cost we charge to the medical facility and / or surgeon. As part of the upgrade, we ~~will~~ provide patients a five- year limited warranty from the date of index surgery. It is important to note that the ultimate financial arrangement between the medical facilities, surgeons and their patients to pay for the PSP is between them and does not involve Conformis. While we believe that our transition to Identity Imprint and PSP creates the potential for significant product and market share growth, this transition exposes us to **various** ~~several execution and regulatory~~ risks. For example, some of our existing customers ~~may~~ **have** ~~choose~~ **chosen** not to offer **the services to obtain** our fully personalized iTotal Identity product given it ~~will require~~ **requires** an out- of- pocket patient pay upgrade ~~. We are also implementing this transition at a time when COVID- 19 has disrupted supply chains~~ and **some have chosen not** ~~the labor market, and further COVID- 19 disruption~~ to **order Identity Imprint given it is not a fully personalized knee system** ~~manufacturing or other operations as we implement this transition could negatively affect our ability to execute our plans~~ . ~~To~~ **Additionally, to** support our Identity Imprint product offering, we are implementing a" build- to- stock" manufacturing model alongside our" just- in- time" model, which ~~will create~~ **creates** an increase in complexity and ~~require~~ **requires** different talent and experience to implement **and manage the manufacturing dynamics and supply chain requirements** . In addition, our **PSP** ~~Platinum Services ℠ Program~~ model is predicated on the upgraded services constituting “ deluxe ” features under reimbursement rules promulgated by CMS, which allow providers to charge patients for services that provide added convenience or patient comfort and that are not medically necessary, while still receiving the standard reimbursement rate from Medicare or Medicaid. It is possible that CMS or insurers could disagree that the **PSP** ~~Platinum Services program~~ provides deluxe services that would permit patients to request and pay out- of- pocket for the services under the program, or conclude that **PSP** ~~the Platinum Services Program~~ otherwise violates applicable rules and regulations. Any such disagreement or allegation of noncompliance, if it were to occur, could materially disrupt our ability to implement the program, or expose us to other legal liabilities. Any of these execution and / or regulatory risks could cause us to fail to successfully implement our plan to increase product sales and market penetration through Identity Imprint and the Platinum Service Program **,** which could lead to a material adverse effect on our business, operations and financial condition. We have derived nearly all of our revenue from sales of a limited portfolio of knee and hip replacement products and may not be able to maintain or increase revenue from these products. A substantial portion of our revenue is derived from a small number of customers. To date, we have derived nearly all of our revenue from sales of our knee and hip replacement products, and we expect that sales of these products **and our new PSP** will continue to account for the majority of our revenue for at least the next several years. If we are unable to achieve and maintain significantly greater market acceptance of these products **and services** , we may be materially constrained in our ability to fund our operations and the development and commercialization of improvements and other products. Any factors that negatively impact sales or growth in sales of our current products **and services** , including the size of the addressable markets for these products, our failure to ~~convince~~ **compel** surgeons to adopt our products, competitive factors and other ~~factors~~ **considerations** described in these risk factors, could adversely affect our business, financial condition and operating results. We work to ~~significantly~~ increase our sales in targeted markets by focusing on high- volume, influential surgeons who use our products. As a result, orders from a relatively small number of surgeons provide a significant portion of our total revenue. The loss of, or significant curtailment of orders by ~~,~~ a limited number of our high- volume surgeons ~~, including curtailments due to the planned transition to our new business model~~ could adversely affect our financial condition and operating results. In addition, as part of our commercial strategy, we are targeting ASCs and outpatient facilities. These facilities have unique needs and may prefer to partner with larger, more established companies that offer a broader array of products and services. The lack of adoption from this customer segment may adversely affect our results of operations and financial condition. We may not be successful in the development of, obtaining regulatory clearance for, or commercialization of, additional products. All of the products we currently market in the United States have either received pre- market clearance

under Section 510 (k) of the federal Food, Drug, and Cosmetic Act, (the" FDCA"), or are exempt from pre- market review. The FDA' s 510 (k) clearance process requires us to show that our proposed product is" substantially equivalent" to another legally marketed product that did not require premarket approval. This process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require clinical studies. To date, we have not been required to conduct clinical studies or obtain clinical data in order to obtain regulatory clearance in the United States for our products. Additionally, to date, we have not been required to complete clinical studies in connection with obtaining regulatory clearance for the sale of our products outside the United States. If we were required to conduct clinical studies or obtain clinical data to obtain future regulatory clearances or approvals for any of our products in the United States or elsewhere, the results of such studies might not be sufficient to support such regulatory clearance, approval, or certification. In addition, our costs of developing and the time to develop our products would increase significantly. Moreover, even if we obtain regulatory clearance, approval, or CE Certificates of Conformity to market a product, the FDA, in the United States, or a Notified Body, in the EEA, has the power to require us to conduct post- marketing studies beyond those we contemplate conducting. We may need to raise additional funds to support any such clinical efforts, and if we are required to conduct such clinical efforts, our results of operations would be adversely affected. With the implementation of the EU MDR, new regulatory burden has been placed on the manufacturer for products intended to be distributed within the EU. We ~~have not yet submitted a product for CE certificate in accordance with the EU MDR, thus there is risk that insufficient data, documentation, test results, and / or information has been obtained for each applicable product will prohibit BSI from issuing CE certificates under the MDR until such information has been sufficiently produced. The time required to compile the technical files under these new regulations, in combination with the anticipated length of the review process performed by BSI (approximately 12- 15 months), may result in a gap in our ability to sell product in the EU. Due to the fact that many non- EU countries rely upon CE marking, this may also lead to a delay in obtaining non- EU country approvals. We~~ are in a highly competitive market and face competition from large, well-established companies as well as new market entrants. The market for orthopedic replacement products generally, and for knee and hip implant products in particular, is intensely competitive, subject to rapid change and dominated by a small number of large companies. Our principal competitors are the major producers of prosthetic knee and hip replacement products. We also compete with numerous smaller companies, many of whom have a significant regional market presence. Many of our larger competitors may enjoy several competitive advantages over us, including: • greater financial resources, cash flow and other resources for product research and development, sales and marketing and litigation; • significantly greater name recognition; • established **commercial** relations with, in some cases over decades, orthopedic surgeons, hospitals, ASCs and other medical facilities, third- party payors and independent sales representatives and distributors; • ~~established~~ **recognized** products that are more widely accepted by, a greater number of orthopedic surgeons, hospitals and other medical facilities and third- party payors; • more complete **product** lines ~~of products~~ for knee, hip or other joint replacements **; • a robotic surgical offering or platform; • a cementless total knee arthroplasty offering** ; • larger and more well- established distribution networks with significant international presence; • products supported by long- term clinical data and long- term product survivorship data; • greater experience in obtaining and maintaining FDA and other regulatory approvals, clearances, or certifications outside of the United States for products and product enhancements; and • more expansive portfolios of intellectual property rights and greater funds available to protect their intellectual property. As a result of these advantages, our competitors may be able to develop, obtain regulatory clearance, approval, or certification for and commercialize products and technologies more quickly than us, which could impair our ability to compete. If alternative treatments are, or are perceived to be, superior to our products, or if we are unable to increase market acceptance of our products, as compared to existing or competitive products, sales of our products could be negatively affected and our results of operations could suffer. Our competitors also may seek to discredit or copy Image- to- Implant ® Platinum Services ℠ Program, which would have the effect of reducing the market potential of our current offering. In order to become profitable, we will need to scale our business model considerably through increased **profitable** sales. In order to become profitable and increase our gross margin, we will need to significantly increase sales of our existing products **and services** , expand our manufacturing capabilities, and successfully develop **, launch,** and commercially ~~launch~~ **scale** future products ~~at a scale~~ that we have not yet achieved. In order to increase our gross margin, we will need, among other things, to: • increase sales of our products through the launch of Identity Imprint ™ and our Image- to- Implant ® Platinum Services ℠ Program; • negotiate more favorable prices for the materials we use to manufacture our products; • obtain enhanced payment for our design services; • negotiate more favorable acquisition prices for the manufacture of certain components of our products that are manufactured for us by third parties; • increasing the proportion of our CAD design activities that is performed in- house at our India facility; • deploy new versions of our software that reduce the costs associated with the design of our products; and • expand our internal manufacturing capabilities to manufacture certain components of our products at a lower unit cost than vendors we currently use **; • improve the efficiency of our internal manufacturing processes; • leverage existing manufacturing overhead costs over increased production volume** . We may not be successful in achieving these objectives, and our gross margin may not increase, or could even decrease. We may not be successful in executing on our business model, in increasing our gross margin or in bringing our sales and production up to a scale that will be profitable, which would have a material adverse effect on our financial condition, results of operations and cash flows. To be commercially successful, we must convince orthopedic surgeons that our joint replacement products are attractive alternatives to our competitors' products. Orthopedic surgeons play a significant role in determining the course of treatment and, ultimately, the type of product that will be used to treat a patient. Acceptance of our products **and services program** depends on educating orthopedic surgeons as to the distinctive characteristics, perceived clinical benefits, safety and cost- effectiveness of our products as compared to our competitors' products. If we are not successful in convincing orthopedic surgeons of the merits of our products or educating them on the use of our products, they may not use our products and we will be unable to increase our sales or reach profitability. We believe orthopedic surgeons ~~will~~ **may** not widely adopt our products unless they determine, based on **professional**

experience **, economic evidence** , clinical data and published peer- reviewed journal articles, that our products **, services,** and ~~the~~ techniques to implant ~~them~~ **our knee and hip systems** provide benefits to patients and are attractive alternatives to our competitors' products. Surgeons may be hesitant to change their medical treatment practices for the following reasons, among others: • comfort and experience with competitive products; • perceived differences in surgical technique and the need to learn a new surgical technique; • existing relationships with competitors, competitive sales representatives and competitive distributors; • lack or perceived lack of evidence supporting additional patient benefits from use of our products compared to competitive products, especially competitive products that may claim to be" individualized,"" customized,"" patient- specific,"" personalized" or" individually made"; • perceived convenience of using products from a more complete line of products than we offer, including as a result of our lack of a joint revision system; • perceived liability risks generally associated with the use of new products and procedures, including the lack of long- term clinical data; • risks of failure of timely delivery as a result of our" just- in- time" manufacturing and delivery model • unwillingness to wait for the implants to be delivered; • unwillingness to submit patients to or difficulty associated with scheduling and seeking reimbursement for computed tomography, or CT, scans needed to manufacture our products; • higher cost or perceived higher cost of our products compared to competitive products; and • the additional time commitment that may be required for surgeon training on our surgical technique. If clinical, functional or economic data does not demonstrate the benefits of using our products, surgeons may not use our products, thereby reducing our sales. To understand the clinical, functional and economic benefits of using our products, surgeons may refer to published studies sponsored by us, conducted by orthopedic surgeons who were paid consultants to us or conducted independently by orthopedic surgeons comparing our personalized products to off- the- shelf products. To the extent such studies do not report favorably on our products, surgeons may be less likely to use our products. Moreover, overall patient satisfaction with our products, as observed by individual surgeons, will continue to be an important factor in surgeons' deciding to use our products for joint replacement procedures. The success of any particular joint replacement procedure, and a patient' s satisfaction with the procedure, is dependent on the technique and execution of the procedure by the surgeon. Even if our iJigs and implants are manufactured exactly to specification, there is a risk that the surgeon makes a mistake during a procedure, leading to patient dissatisfaction with the procedure. In addition, following joint replacement procedures, fibrosis, scarring and other issues unrelated to the choice of implant product can lead to patient dissatisfaction. Furthermore, based on their prior experience using non- personalized, off- the- shelf implant products, surgeons may be accustomed to making modifications to the implant components during a procedure. Because our products are **designed** ~~already individually made~~ to fit the unique anatomy of each patient, modifications made to the implant components or the process of fitting the implant during the surgical procedure are not recommended and may result in negative surgical outcomes. If patients do not have a good outcome following procedures conducted using our products, surgeons' views of our products may be negatively impacted. The success of our products is dependent on our ability to demonstrate their clinical benefits. To date, we have collected only limited clinical data regarding our ~~Conformis Hip System~~ **Cordera and Actera hip** replacement ~~product~~ **products** . Ongoing or future clinical studies of our products may not yield the results that we expect to obtain and may not demonstrate that our products are superior to, or may demonstrate that our products are inferior to, off- the- shelf products with regard to clinical, functional or economic measures or may not be considered sufficient by patients, surgeons, hospitals or other medical facilities, or payors. We are aware of three such clinical studies on our iTotal knee replacement product, published between 2016 and 2018, in which our product did not perform as well as off- the- shelf products on some measures. Though we believe that these studies were of limited statistical significance given the limited investigations contained therein, these results could call into question the superiority of our products to traditional products. In addition, long- term device survivorship data for our products may show that the survivorship of our personalized joint replacement products is shorter than that of off- the- shelf products. Though initial six- year data from the England and Wales National Joint Registry suggests slightly higher survivorship in patients treated with the iTotal CR knee replacement implant, there is no guarantee that such high survivorship rates will continue over time or that our other products will provide high survivorship. Competitors may initiate their own clinical studies which may yield data that is inconsistent with data from our funded studies or data showing the superiority of their products over our products. The safety and efficacy of our products is supported by limited short- and long- term clinical data, and our products might therefore prove to be less safe and effective than initially thought. To date, we have obtained regulatory clearance for our products in the United States without conducting premarket clinical studies, and we do not believe that we will need premarket clinical data in order to obtain regulatory clearance in the United States for additional knee or hip products. Additionally, to date, we have not been required to complete premarket clinical studies in connection with obtaining regulatory approval or certification for the sale of our products outside the United States. As a result of the absence of premarket clinical studies, we currently lack the breadth of published long- term clinical data supporting the safety and efficacy of our products and the benefits they offer. For these reasons, orthopedic surgeons may be slow to adopt our products and third- party payors may decide to restrict medical policy coverage and payment for procedures involving our technology. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance, loss of our ability to CE Mark our products, significant legal liability or harm to our business reputation. Even if our products are approved or cleared in the United States and CE marked in the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval, clearance and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly. If we are unable to continue to develop new products and technologies in a timely manner, or if we develop new products and technologies that are not accepted by the market, the demand for our products may decrease or our products could become obsolete, and our revenue and profitability may decline. We are continually engaged in product

development, research and improvement efforts. Our ability to grow sales depends on our capacity to keep up with existing or new products and technologies in the joint replacement product markets. If our competitors are able to develop and introduce new products and technologies before us, they may gain a competitive advantage and render our products and technologies obsolete. The additional markets into which we plan to expand our business are subject to similar competitive pressures and our ability to successfully compete in those markets will depend on our ability to develop and market new products and technologies in a timely manner. We believe that offering a broad line of joint replacement products is important to convincing surgeons to use our products generally. If market acceptance of ~~either~~ our **Identity Imprint ™,** iTotal ~~PS or our Conformis~~ **Identity ™, and Actera ™** Hip System is less than we expect **or we incur delays in introducing new products** , the growth in sales of our existing products may slow and our financial results would be adversely affected. 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 or other innovation. Our research and development efforts may result in products or technologies for which market demand is lower than anticipated or for which we are otherwise unable to adequately commercialize and, as a result, abandon, defer or modify such efforts. Our competition may respond more quickly to new or emerging technologies, undertake more effective marketing campaigns, adopt more aggressive pricing policies, have greater financial, marketing and other resources than us or may be more successful in attracting potential customers, employees and strategic partners. Even in the event that we are able to successfully develop new products and technologies, they may not produce revenue in excess of the costs of development and may be quickly rendered obsolete as a result of changing customer preferences, changing demographics, slowing industry growth rates, declines in the knee, hip or other orthopedic replacement implant markets, evolving surgical philosophies, evolving industry standards or the introduction by our competitors of products embodying new technologies or features. New materials, product designs and surgical techniques that we develop may not be accepted quickly, in some or all markets, because of, among other factors, entrenched patterns of clinical practice, the need for regulatory clearance and uncertainty with respect to third- party medical policy coverage and reimbursement of procedures that utilize our products. If surgeons, hospitals and other medical facilities are unable to obtain favorable reimbursement rates from third- party payors for procedures involving use of our products, if third- party payors adopt policies that preclude payment for the use of our products, or if reimbursement from third- party payors for such procedures significantly declines, surgeons, hospitals and other medical facilities may be reluctant to use our products and our sales may decline. In the United States, surgeons and hospitals and other medical facilities who purchase medical devices such as our products generally rely on third- party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the joint replacement surgery and the products utilized in the procedure, including the cost of our products. Our customers' access to adequate coverage and reimbursement for the procedures performed using our products by government and third- party payors is central to the acceptance of our current and future products. We are aware of certain private insurers that, at this time, are not agreeing to reimburse for our products as they consider the use of custom implants or patient- specific instrumentation for knee replacement surgery as investigational, unproven or experimental or not medically necessary. For example, during 2019, denials of coverage from Aetna, the third largest commercial payor, negatively impacted our product revenue in the United States. On December 5, 2019, we learned that, although Aetna updated its policy, it did not change its coverage position with respect to our products. While we are actively reaching out to these private insurers to discuss their reimbursement policies **(and in Aetna' s case, we have commenced litigation against them)** , we may not be able convince these parties to change their reimbursement policies. In addition, the American Academy of Orthopedic Surgeons currently has published clinical guidelines that do not support the widespread use of patient- specific instrumentation in total knee arthroplasty generally, at least until additional data can be considered. We believe that these guidelines are directed to patient- specific instruments with off- the- shelf implants, not patient- specific instruments with personalized implants. Surgeons, hospitals and other medical facilities may not purchase our products if government and third- party payors deny coverage for such procedures or set reimbursement rates at unfavorable levels for procedures involving use of our products. This could have a material adverse effect on our business and operations. An initial step in the process for a patient to receive one of our joint replacement products involves a CT scan of the patient' s affected joint and one or two CT images of other biomechanically relevant joints. The cost of the CT scan is not always reimbursed by third- party payors, and some third- party payors may have policies against reimbursement of such scans when they have not been deemed medically necessary. In addition, the costs of alternative imaging techniques that we could substitute in the future for a CT scan in our iFit process, such as magnetic resonance imaging, or MRI, generally are higher than the cost of a CT scan and also not always reimbursed by third- party payors when related to joint replacement procedures. If third- party payors do not reimburse the costs of the CT scan or, in the future, any alternative imaging technique, we could find that we have to find alternative ways to pay these costs, which could have a material adverse effect on our business and operations. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 or, collectively, the ACA, has changed how some healthcare providers are reimbursed by the Medicare program and some private third- party payors. As physicians consolidate into Accountable Care Organizations, or ACOs, these physicians, through the ACOs, are taking on the financial risk for providing care to all patients in their ACO. Medicare and some private third- party payors calculate a set payment per beneficiary or member of the ACO based on the specific ACO' s historical aggregate payments for care provided to the respective beneficiaries, or, in the instance of the Comprehensive Care for Joint Replacement initiative a regional per procedure payment, known as a " bundle, " would be calculated. ACOs use these payments to provide care for their patients. When the cost of providing care is less than payments received, the ACO is able to keep the savings. ACOs are therefore incentivized to control and reduce the cost of patient care. Attempts to control and reduce the cost of care within an ACO could result in fewer referrals for elective surgery, or require the use of the least expensive implant available, either or both of which could cause our revenue to decline. Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government- managed healthcare

systems that govern reimbursement for orthopedic implants and procedures. Many countries use a system of Diagnosis Related Groups to set a price for a particular medical procedure, including orthopedic implants that will be used in that procedure. In the EEA, the pricing and approval for use of medical devices is subject to governmental control, and pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost- effectiveness of our products to other available therapies. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended collection periods. Further, reimbursement rates for our products in other jurisdictions, including in Germany, where in the past we have attained reimbursement rates at higher price points than some competitive products, has changed negatively for certain of our products in 2017, changed positively for 2019 and could further change negatively in Germany and other jurisdictions. In addition, beginning in 2016, we have seen an increase in denials of the higher reimbursement code for use of our products in Germany by the Medizinischer Dienst der Krankenkassen (translated: Medical Service of Health Insurance), or MDK, and, in such instances, the amount of reimbursement to the hospitals and other medical facilities has been lowered to that of an off- the- shelf knee. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long- term growth of our business. We are subject to cost- containment efforts of hospitals and other medical facilities and group purchasing organizations, which may have a material adverse effect on our financial condition, results of operations and cash flows. In order for surgeons to use our products, the hospitals and other medical facilities where these surgeons treat patients typically require us to enter into purchasing contracts. The process of negotiating a purchasing contract can be lengthy and time- consuming, require extensive management time and may not be successful. In addition, many of our customers and potential customers are members of group purchasing organizations that are focused on containing costs. Group purchasing organizations negotiate pricing arrangements with medical supply and device manufacturers, and these negotiated prices are made available to a group purchasing organization' s member hospitals and other medical facilities. If we do not have pricing agreements with group purchasing organizations, their member hospitals and other medical facilities may be less likely to purchase our products. Our failure to complete purchasing contracts with hospitals or other medical facilities or contracts with group purchasing organizations may cause us to lose market share to our competitors and could have a material adverse effect on our sales, financial condition, results of operations and cash flows. Our competitors may also elect to lower their prices in select accounts, thereby rendering our products non- competitive on the basis of price, with resulting losses in sales to these accounts. If we are unable to train orthopedic surgeons on the safe and appropriate use of our products or if trained surgeons do not continue to use our products, we may be unable to achieve our expected growth. An important part of our sales process includes training surgeons on the safe and appropriate use of our products. If we become unable to attract potential new surgeon customers to our training programs, or if we are unable to attract existing customers to training programs for future products, we may be unable to achieve our expected growth. The COVID- 19 pandemic ~~has~~ made it more difficult to train surgeons in- person on our products. It has also encouraged surgeons to explore virtual training options which require significant investment on behalf of the company and may not be as effective as in- person training. There is a learning process involved for orthopedic surgeons to become proficient in the use of our products. It is critical to the success of our commercialization efforts to train a sufficient number of orthopedic surgeons and to provide them with adequate instruction in the use of our products. Following completion of training, we rely on the trained surgeons to continue to use our products and advocate the benefits of our products in the broader marketplace. Convincing surgeons to dedicate the time and energy necessary for adequate training of themselves or other surgeons is challenging, and we may not be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business. If trained surgeons do not continue to use our products, this could cause our revenue to decline. Although we believe our training methods for surgeons are conducted in compliance with FDA and other applicable regulations outside the United States, if the FDA, or other similar Competent Authorities outside the United States determines that our training constitutes promotion of an unapproved use or other inappropriate promotion, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty. We rely on a limited number of direct and independent sales representatives and distributors to market and sell our products. Loss of our sales representatives and distributors could harm our business. We rely on our direct and independent sales representatives in the United States, direct sales representatives in Germany and distributors in certain other countries to market and sell our products. Our sales representatives and distributors are highly trained and possess substantial technical expertise as well as relationships with surgeons, hospitals and other medical facilities. The loss of these sales representatives or distributors to competitors or otherwise could materially harm our business. If we are unable to retain our sales representatives or distributors or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement sales representatives or distributors or such replacements are unable to develop the necessary relationships, our revenue and results of operations could be materially harmed. Not all of our independent sales representatives or distributors have been required to sell our products exclusively and many of them may also sell the products of our competitors. We cannot be certain that they will prioritize selling our products over other products they sell, including those of our competitors, and our competitors may enter into arrangements with our independent sales representatives and distributors that require them to cease distributing our products. If one or more of our independent sales representatives or distributors were to cease selling or distributing our products, our sales could be adversely affected. In such a situation, we may need to seek alternative relationships with independent sales representatives and distributors or increase our reliance on our other independent sales representatives or distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent

sales representatives or distributors to perform sales, marketing or distribution services, the terms of the arrangements could cause our operating margins to be lower than if we directly marketed and sold our products. **Technology changes and surgeon adaptation are uncertain and we may not accurately predict the changing demands by our customers. Robotic and cementless arthroplasty procedures are growing and we currently do not have these offerings. Augmented reality and advanced tracking technologies are in various stages of development and deployment. Our ability to maintain and / or grow surgeon users could be negatively impacted if we are not able to offer these or any other new options demanded by surgeons. Robotic TKA uses software (e. g., pre- operative CT or intraoperative tibia and femur mapping) to convert anatomical images of the patient' s knee into three- dimension images. These images aid the performing surgeon in bone cutting and implant placement to minimize injury to soft tissue and bone. Additionally, in conventional TKA, implant components are secured in the patient' s joint using bone cement. In cementless TKA, implant components are press fit into place to achieve " biological fixation, " permitting the bone to grow into the implant. Although we are continually engaged in product development, we do not currently have a robotic or cementless TKA option. As some of our competitors have developed robotic and cementless TKA options, they may gain a competitive advantage over our current products and technologies.** Global economic conditions may adversely affect our results of operations. Our results of operations could be substantially affected by global economic conditions and local operating and economic conditions, which can vary substantially by market. Declines in employment rates or consumer confidence both in the United States and abroad could result in reduced numbers of insured patients and the deferral of some elective joint replacement procedures. Similarly, uncertainty about the stability of global financial markets could adversely affect our operations. Challenges and pressures in the global economy could ultimately impact joint replacement procedure volumes, average selling prices and reimbursement rates from third- party payors, any of which could adversely affect our results of operations. The COVID- 19 pandemic and the response to it ~~have~~ reduced demand for our products, and as a result we reduced our operations and production capacity, and these circumstances ~~have~~ had ~~and are expected to continue to have~~ a significant negative affect on our revenue. Our business **was** ~~continues to be~~ negatively affected by the ongoing COVID- 19 pandemic. We have experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals have de- prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had **,** and is expected to continue to have a significant negative effect on our revenue. ~~Within the United States and Germany, which are our major sales markets, estimated case counts increased in the fourth quarter of 2020 and peaked in January 2021. While worldwide case counts declined since January, we saw a decline in elective procedures during the first quarter of 2021. In Germany, case counts declined after January 2021 but then increased again in the second quarter. Germany case counts began to decline mid- way through the second quarter but we saw a decline in Germany elective procedures during the second quarter of 2021. In the United States, elective procedures have improved sequentially second quarter of 2021 over first quarter of 2021 consistent with the market. However, in the third and fourth quarters of 2021, the Company experienced higher levels of deferred and rescheduled knee and hip procedures as a result of the surge in COVID- 19 cases associated with the Delta and Omicron variants. We expect that these negative effects will continue in the near- term until infection rates decline further from their current level, and more of the population is vaccinated. The future progression of the pandemic remains uncertain, including with respect to new or potential variants. To the extent that individuals in these markets continue to de- prioritize or delay deferrable procedures as a result of the COVID- 19 pandemic or otherwise, our business, cash flows, financial condition and results of operations could continue to be negatively affected.~~ The pandemic ~~has~~ also negatively affected our manufacturing and delivery timelines, in part because of additional employee turnover at our manufacturing facility, and the difficulty of finding, hiring and training new employees on a timely basis. For example, the stringent manufacturing protocols that we follow require new manufacturing employees to receive substantial training to reach proper levels of work proficiency, and thus increased employee turnover during the pandemic ~~has~~ negatively affected our ability to maintain the same pace of manufacturing. In addition, employee turnover and tight labor conditions in the third- party shipping sector ~~has~~ contributed **during the pandemic** to an increased number of delays in the timing of products we manufacture reaching surgeon recipients. Collectively, these pandemic- related factors ~~has~~ made it more difficult for us to satisfy consumer demand for our products. To the extent these pandemic- related labor constraints continue, it could adversely affect our sales and profitability for the duration of time that such conditions continue. Our inability to maintain adequate working relationships with external research and development consultants and surgeons could have a negative impact on our ability to market and sell new products. We maintain professional working relationships with external research and development consultants and leading surgeons and medical personnel in hospitals and universities who assist in product research and development and training. We continue to emphasize the development of proprietary products and product improvements to complement and expand our existing product line. It is possible that U. S. federal and state laws, and equivalent laws of foreign countries requiring us to disclose payments or other transfers of value, such as free gifts or meals, to physicians and other healthcare providers could have a chilling effect on these relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us. In addition, consultants, surgeons and medical personnel in hospitals and universities may be subject to conflict of interest policies that limit our ability to engage these individuals as our advisors and in connection with future development and training efforts. If we are unable to establish and maintain our relationships with consultants, surgeons and medical personnel, our ability to develop and sell new and improved products could decrease, and our future operating results could be unfavorably affected. Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile. We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, business interruption insurance, property insurance and workers' compensation insurance. The cost of maintaining product liability insurance on implantable medical devices has increased substantially over the past few years and could continue to substantially increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance

coverage should increase significantly in the future, our operating expenses could substantially increase, or we might need to operate our business without indemnity from commercial insurance providers. Consolidation in the healthcare industry could lead to demands for price concessions or the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results. Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third- party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and may continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. This may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or operating results. Risks related to our manufacturing We may encounter problems or delays in the manufacturing of our products or fail to meet certain regulatory requirements that could result in a material adverse effect on our business and financial results. We manufacture our products at our facilities in Wilmington, Massachusetts and Wallingford, Connecticut. Certain manufacturing processes in our facilities may require process and / or equipment validation and are subject to FDA inspections, as well as inspections and audits by international regulatory agencies or entities such as Notified Bodies for the EEA. ~~For example, in December 2019, we received a warning letter from the FDA concerning the number of sterilization cycle failures relating to Vaporized Hydrogen Peroxide (" VHP ") sterilizers that we used as a limited, alternative sterilization method for a small quantity of products. In response to the warning letter, we decommissioned the VHP sterilizers and completed all appropriate process and / or equipment validations of our manufacturing processes for implant components and instrumentation manufactured at our facilities. Our new in- house LTS- V (Low temperature sterilization vaporized hydrogen peroxide) sterilizer has been fully validated, the method cleared via 510 (k) for many of our knee products, and the warning letter has since been lifted following a full FDA inspection of our facilities and processes. Implementation of new or modified sterilization methods may require additional validation of revised or new manufacturing process, FDA clearance, that could create delays and / or could impact our ability to grow our business in the future.~~ Our current and planned future products are complex and require the integration of a number of separate components and processes. To become profitable, we must manufacture our products in increased quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to manufacture our products on this scale may require us to introduce new manufacturing processes, vertical integration of the manufacturing process by performing machining, polishing and other finishing services in- house, and to improve internal efficiencies. If we are unable to satisfy commercial demand for our products due to our inability to manufacture them in compliance with applicable laws and regulations, due to our inability to meet demand with in- house production or with outside suppliers, or due to temporary or permanent reduced manufacturing capabilities, our business and financial results, including our ability to generate revenue, would be impaired, market acceptance of our products could be diminished and customers may instead purchase our competitors' products. We are dependent on third- party suppliers for important components included in our products, as well as for services that are essential to our manufacturing processes. We purchase raw materials, including polymer powders, tibial tray blanks, and polyethylene blocks that currently are used in our 3D printing and manufacturing processes from a limited number of third- party suppliers. Possible shortages of, or our inability to obtain, the necessary raw materials that we currently use and intend to use in the future, including in our 3D printing manufacturing processes, could limit our ability to operate and grow our business. We currently depend on sole source suppliers for certain raw materials. These sole source suppliers may be unwilling or unable to supply us reliably, continuously and at the levels we anticipate or are required by the market. We may incur added costs or delays in identifying and qualifying replacement suppliers. In addition, because these suppliers supply large portions of the markets for these materials, there is competition for such supply. As a result of such competition, the prices for these supplies may increase and their availability to us may decrease. If any of our key suppliers were to decide to discontinue or limit the supply of a raw material that we use, the unanticipated change in the availability of supplies could cause delays in, or loss of, sales, increased production or related costs and damage to our reputation. In addition, because we use a limited number of suppliers, price increases by our suppliers may have an adverse effect on our results of operations, as we may be unable to find an alternative supplier who can supply us at a lower price. As a result, the loss of a limited source supplier could adversely affect our relationships with our customers and our results of operations and financial condition. Similarly, we rely on other third- party suppliers to manufacture certain implant components, packaging materials, and instrumentation used in our joint replacement products that we do not currently manufacture ourselves. Currently, our in- house manufacturing includes our iJigs, the tibial trays used in our total knee implants, polyethylene tibia tray inserts ~~for our iTotal CR and iTotal PS~~ , polishing of our femoral components and, with regard to the hip, the stems, cups and iJigs. We outsource the manufacture of the remainder of the implant components to third- party suppliers, including, for example, the casting of the femoral component. While we plan to establish additional internal manufacturing capabilities for our implant components, we also expect that we will continue to rely on third- party suppliers to manufacture and supply certain of our implant components. For us to be successful, these manufacturers must be able to provide us with these components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and, in particular, on a timely basis. Our anticipated growth could strain the ability of our suppliers to manufacture and deliver an increasingly large supply of implants and components. Manufacturers often experience difficulties in scaling up production, including problems with quality control and assurance. We generally purchase our outsourced implant components through purchase orders and do not have long- term contractual arrangements with any of our key suppliers. As a result, our suppliers have no obligation to manufacture for us or sell to us any given quantity of implant components. Without such contractual commitments, we could face difficulties in obtaining acceptance for our purchase orders,

which could impair our ability to purchase adequate quantities of our implant components. In addition, we currently depend on sole source suppliers for the supply of the reusable instrument trays and related logistics associated with our implant products. These sole source suppliers may be unwilling or unable to supply the trays and logistics services to us reliably, continuously and at the levels we anticipate or are required by the market. We produce CAD designs, and we use the CAD designs to direct most of our product manufacturing efforts. As part of our manufacturing cost reduction efforts, in 2017 and 2018, we continued transitioning our CAD labor force through a third- party CAD- designer in India and, in the fourth quarter of 2020, we established a new Conformis entity in India, Conformis India LLP, and transitioned a portion of the third- party CAD design activities to Conformis India LLP. We and our suppliers, including our CAD- designer, are subject to extensive regulation by the FDA under its Quality System Regulation, or QSR. Our quality department periodically audits our suppliers, including our CAD- designer, to ensure compliance to appropriate ISO standards, FDA regulations and to our specifications, policies and procedures for our devices. Relying on a third party for our CAD designs could harm our business for various reasons, including: • agreement may terminate prematurely due to disagreements or may result in litigation; • we may not be able to renew the existing agreement on acceptable terms; • we may not be able to expand the Indian CAD labor force as necessary to meet market demand; • the third party may not devote sufficient resources to the production of our CAD designs; • the third party may fail to follow our processes, fail to provide CAD designs that meet our specifications or fail to meet regulatory or legal requirements; • we may experience outages or other problems with our high speed network provider that may prevent or delay the third party from accessing the necessary CAD design software, which would prevent or delay the completion of the CAD designs; • the third party may be limited or prevented from access to our high speed network provider due to U. S. or foreign government intervention or regulation; and • the third party may be subject to labor disputes, strikes or other shutdowns, including related to severe weather. Because we rely on a foreign entity for CAD designs for just- in- time manufacturing of our products, there are a number of risks to our business should this entity be unable to provide CAD designs within the necessary timeframes or at all, including delayed or missed surgeries which could harm our reputation and our ability to sell products in the future. We would have difficulty and incur additional cost in quickly adding CAD designers in- house or through other third parties to address any short fall in CAD design production. As a result, our ability to manufacture our products and conduct business and our financial results, including our ability to generate revenue, would be materially impaired, market acceptance of our products could be diminished and customers may instead purchase our competitors' products. We **rely on third- party services for ethylene oxide (" EO") sterilization of some of our products. In the United States, several regulators, including the EPA, FDA, and agencies at the state and local level, play a role in regulating the use of EO sterilization. In 2016, the EPA changed the cancer risk basis for EO and determined that EO is carcinogenic to humans. Recent announcements of the temporary or permanent closure of EO sterilization facilities operated by third parties has limited the capacity of EO services. Given the nature of our just- in- time model, an impact on the timely availability of EO services could impact the cost and availability of our product. While we have alternate modalities of sterilization, for some of our products EO sterilization may be the only regulatory approved method of sterilization available to us that effectively sterilizes and does not damage the device during the sterilization process. In the event of regulatory, legislative, or legal action that curtails or eliminates EO sterilization, we may be unable to provide our products in a timely manner. Implementation of new or modified sterilization methods may require additional validation of revised or new manufacturing process, FDA clearance, that could create delays and / or could impact our ability to grow our business in the future. We** utilize a" just- in- time" manufacturing and delivery model, with minimal levels of inventories, which could leave us vulnerable to delays or shortages of key components or materials necessary for our products or delays in delivering our products. As our fully personalized products are individually made to fit an individual patient **following their receipt of personalized services** , we can manufacture our products only after we receive orders from customers and must utilize" just- in- time" manufacturing processes. We generally maintain minimal inventory levels for our personalized products, except for inventories of raw materials used in our 3D printing and manufacturing processes. As a result, an unexpected shortage of supply of key components used to manufacture our products, unexpected difficulties with manufacturing our products, or an unexpected and significant increase in the demand for our products, could lead to delays in shipping our products to customers. Any such delays could result in lost sales and harm to our relationships with surgeons, especially in the event of a missed surgery, and may also require us to seek faster, more expensive delivery methods in order to not miss surgery dates, each of which could in turn harm our profitability and financial condition. Our proprietary iFit software is critical to our business. Any delays in fixing bugs or errors and any limitations in our ability to modify such software for future products or modifications of existing products could have a material adverse impact on our business and operating results. We rely on our iFit proprietary software applications to design and manufacture our personalized implants and iJigs for each patient. These software applications require maintenance and further improvements in design automation in order to continue increasing productivity of the design process. If we fail to meet our goals for design automation and productivity, this may impact our ability to reduce production costs. Furthermore, bugs or errors in these complex iFit software applications could cause production delays or product defects, which may lead to customer dissatisfaction or possibly even product recalls. Our development of new products depends on our capability to adapt our iFit concepts and software applications to new requirements. It may be more difficult than anticipated to make such adjustments, which could lead to delays or limitations in our ability to develop new, innovative products. **Risks related to our Information Technology, Cybersecurity and Data Protection** Our information technology systems are critical to our business. System management and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results. We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems.

Moreover, changes in privacy laws could increase the risk we are exposed to in managing patient data, and could limit some of the applications of that data in our business. Experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. The costs to eliminate or alleviate security problems or viruses could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenue and operating results. A cybersecurity incident could result in a loss of confidential data, give rise to remediation and other expenses, expose us to liability under HIPAA, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business. We collect and store sensitive information, including intellectual property and personally identifiable information, on our networks. The secure maintenance of this information is critical to our business operations. We have implemented multiple layers of security measures to protect this confidential data through technology, processes, and our people; we utilize current security technologies; and our defenses are monitored and routinely reviewed by internal and external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities, and advanced new attacks against information systems create risk of cybersecurity incidents. There can be no assurance that we will not be subject to cybersecurity incidents that bypass our security measures, result in loss of personal health information or other data subject to privacy laws or disrupt our information systems or business. Risks related to our international operations We are exposed to risks related to our international sales and operations and failure to manage these risks may adversely affect our operating results and financial condition. We sell our products internationally in Germany, the United Kingdom, Austria, Ireland, Switzerland, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, Poland and other markets. We expect that our international activities will increase over the foreseeable future as we continue to pursue opportunities in additional international markets. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U. S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Therefore, we are subject to risks associated with having international operations. These international operations will require significant management attention and financial resources. Our international operations expose us to risks of fluctuations in foreign currency exchange rates. Our international operations expose us to risks of fluctuations in foreign currency exchange rates. To date, a significant portion of our international sales have been denominated in euros. We do not currently hedge any of our foreign currency exposure. As a result, a decline in the value of the euro against the U. S. dollar could have a material adverse effect on the gross margin and profitability of our international operations. In addition, sales to countries that do not utilize the euro could decline as the cost of our products to our customers in those countries increases or as the local currencies decrease. In addition, because our financial statements are denominated in U. S. dollars, a decline in the euro would negatively impact our overall revenue as reflected in our financial statements. Risks related to efforts to expand our growth We intend to grow our organization in accordance with **our** ~~a new~~ long- range business plan, and as a result, we may encounter difficulties in managing our operations. In the ~~third~~ **first** quarter of ~~2020~~ **2022** we announced **the launch of** our ~~planned~~ **new Image- to- Implant Platinum Services ℠ Program. This new program combined with our existing and future product** portfolio ~~expansion and a~~ **are the basis for our** new long- range business plan (LRP). Managing the business in accordance with the LRP has and will require significant attention by our management and we may be unable to successfully execute the LRP, which would negatively impact our ability to achieve our financial targets and could require us to seek additional financing. If our performance allows for an increase in the growth of the number of our employees and scope of our operations, our management may need to divert a disproportionate amount of its attention away from our day- to- day activities to devote time to managing these growth activities. To manage these growth activities, we will need to continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may have difficulties effectively managing the expansion of our operations or recruiting and training additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenue could be reduced, and we may not be able to implement our business strategy. In addition, we may consider further expanding our operations through potential acquisitions. Potential and completed acquisitions and strategic investments involve numerous risks, including diversion of management' s attention from our core business, problems assimilating the purchased technologies or business operations and unanticipated costs and liabilities. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth, including growth through acquisitions. Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. We are highly dependent on the managerial experience and the medical device industry expertise of principal members of our executive, scientific and development teams. If we lose one or more of our executive officers and are unable to recruit qualified talent in those positions, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us

and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited. Risks related to our intellectual property and potential litigation If we are unable to obtain, maintain or enforce sufficient intellectual property protection for our products and technologies, or if the scope of our intellectual property protection is not sufficiently broad, our competitive position could be harmed or we could be required to incur significant expenses to enforce our rights. We rely primarily on patent, copyright, trademark and trade secret laws, know- how and continuing technological innovation, as well as confidentiality and non- disclosure agreements and other methods, to protect the intellectual property related to our technologies and products. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We hold, or have in- licensed rights with respect to, patents and patent applications and have applied for additional patent protection relating to certain existing and potential products and processes. While we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable or may choose not to file in certain countries to limit expenses. If we fail to timely file a patent application in any such country or fail to properly pursue an application through to the issuance of a patent, we may be precluded from doing so at a later date. Furthermore, our patent applications may not issue as patents such that material aspects of our products and procedures may not be protected. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage and they could be opposed, contested or circumvented by our competitors or could be declared invalid or unenforceable in judicial or in a wide variety of administrative proceedings including opposition, interference, re- examination, post- grant review, inter partes review, nullification and derivation proceedings. The expiration of the term for rights granted to us under our patents with the earliest priority dates may provide opportunities for our competitors to offer products or technologies similar to our own. The failure of our patents to protect our products and technologies adequately might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to ours without infringing on our intellectual property rights. We may be involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time consuming and unsuccessful. If a competitor infringes or otherwise violates one of our patents, the patents of our licensors, or our other intellectual property rights, enforcing those patents, trademarks and other rights would be difficult, time consuming, expensive and unsuccessful. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, in whole or part, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management' s attention from managing our business. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed. In addition to the protection afforded by patents, we rely on confidential proprietary information, including trade secrets, and know- how to develop and maintain our competitive position, especially with respect to our proprietary software used in the iFit design and manufacturing aspects of our technology platform. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. Though these agreements are designed to protect our proprietary information, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business. We have entered into license agreements with third parties providing us with rights under various third- party patents and patent applications, including the rights to prosecute patent applications and to enforce patent rights. Certain of these license agreements impose royalty and insurance obligations on us as well as development and milestone obligations that we have met. In the future, we may enter into additional licensing and funding arrangements with third parties that also may impose, diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under any of our license agreements, our counterparties may have the right to seek relief or to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In the future, we may not be

able to license additional intellectual property rights that we need for our business. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could harm our business significantly. In the future, we may need to obtain additional licenses from others to expand our product lines, advance our technology or allow commercialization of our current or future products. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our products or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If **we are unable to do so, we may be unable to develop or commercialize the affected products, which could harm our business significantly.** The medical device industry is characterized by frequent patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management' s time and efforts, require us to pay damages or prevent us from marketing our existing or future products. Our commercial success depends in part on not infringing the patents or violating the other proprietary rights of others and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or products, including interference or derivation proceedings before the U. S. Patent and Trademark Office. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that may prevent, limit or otherwise interfere with our ability to make, use and sell our products. Our ability to defend ourselves or our third- party suppliers may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. In addition, patent applications in the United States and elsewhere outside the United States can be pending for many years before issuance, so there may be applications of others now pending of which we are unaware that may later result in issued patents that may prevent, limit or otherwise interfere with our ability to make, use or sell our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation increases the risk of business assets and management' s attention being diverted to patent litigation. Lawsuits resulting from allegations of infringement could, if successful, subject us to significant liability for damages and invalidate our proprietary rights. Further, as the number of participants in the joint replacement industry grows, the possibility of intellectual property infringement claims against us increases. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current manufacturing methods, products or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties. We may not be able to adequately protect our intellectual property rights throughout the world. 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 will 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 enable us to terminate infringing activities. Product liability lawsuits have been and may continue to be brought against us which may harm our reputation, divert management’ s attention, and require us to pay damages that exceed our insurance coverage, each of which may result in harm to our business. Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for joint replacement procedures. Knee and hip replacement surgery, as well as other joint replacement surgery, involves significant risk of serious complications, including bleeding, infection, instability, dislocation, nerve injury and death. In addition, joint replacement surgery involves product risks, including failures over time due to polyethylene tibia tray inserts wear and aseptic loosening, which is a condition caused by wear debris generated by the implant. Additionally, because we manufacture patient- specific instrumentation and patient- specific implants for individual patients and uniquely identify each patient’ s components, we have in the past and could face in the future, product liability claims if incorrect components are delivered for a patient. We or our suppliers could suffer breaches to our sterilization procedures, which could cause contamination of the affected components and products we market and ultimately could cause infections in patients. Moreover, patients may be dissatisfied with the results of joint replacement surgery even if there is no medical complication. We have been, and may in the future, be the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product- related risks or product- related information resulted in an unsafe condition or injury to patients. Risks related to government regulation Our medical device products are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer. Our products are classified as medical devices and are subject to extensive regulation by the FDA and other federal, state and foreign governmental authorities. These regulations relate to manufacturing, labeling, sale, promotion, distribution, importing and exporting and shipping of our products. If we fail to comply with applicable laws and regulations it could jeopardize our ability to sell our products and result in enforcement actions such as: • untitled letters, warning letters, fines, injunctions or civil penalties; • termination of distribution authorizations; • recalls, detention and / or seizures of products; • delays in the introduction of products into the market; • total or partial suspension of production; • refusal of the FDA or other regulators to grant future clearances or approvals; • withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; • non- renewal, suspension, or withdrawal of our CE Certificates of Conformity, which allow us to affix the CE Mark to our products and are necessary to sell our products within the European Economic Area, or EEA, or delay in obtaining these certificates; and • in the most serious cases, criminal penalties. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and

have a material adverse effect on our reputation, business, results of operations and financial condition. The regulations to which we are subject are complex and have tended to become more stringent over time, making obtaining clearances and maintaining compliance increasingly difficult. In particular, if we fail to obtain and maintain necessary FDA clearances, approvals or certification for our products and indications or if clearances, approvals or certification for future products and indications are delayed or not issued, our business would be harmed. Before we can place in the market or make available for sale a new regulated product or a significantly modified existing product in the United States, we must obtain either clearance from the FDA through the filing of a 510 (k) premarket notification, a de- novo request or approval from the FDA pursuant to a premarket approval application, or PMA, unless the device is specifically exempt from premarket review. The clearance or approval that is required will depend upon several factors, including how the product is classified by the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose low to moderate risk are placed in either Class I, which typically does not require clearance via a premarket notification, or Class II, which, absent an exemption, requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution, known as 510 (k) clearance. Class III devices, such as life- sustaining or life- supporting devices or devices that are of substantial importance in preventing impairment of human health or which present a potential unreasonable risk of illness or injury, require approval of a PMA to provide reasonable assurance of safety and effectiveness. In the 510 (k) clearance process, the FDA must determine that a proposed device is" substantially equivalent" to a device legally on the market, known as a" predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. If the FDA determines that the device is " not substantially equivalent " to a previously cleared device, the device is automatically designated as a Class III device. Assuming that there is no legally marketed predicate device available, the device sponsor must then fulfill more rigorous PMA requirements, or can request a risk- based classification determination for the device in accordance with the " de novo " process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including technical, pre- clinical, clinical trial, manufacturing controls and labeling data. In order to obtain a PMA approval or de novo clearance, and in some cases, a 510 (k) clearance, a product sponsor must conduct well controlled clinical trials designed to test the safety and effectiveness of the product. To date, our products have only required 510 (k) clearance and we have not been required to conduct clinical studies or to obtain clinical data in order to obtain 510 (k) clearance in the United States for our products. We have been required to complete clinical studies and / or provide clinical evaluation reports in connection with obtaining regulatory approval for the sale of our products outside the United States, for example, in Australia. Conducting clinical trials generally entails a long, expensive and uncertain process that is subject to delays and failure at any stage. If we conduct clinical trials, they may be delayed or halted or may be inadequate to support approval or clearance, for numerous reasons. The data obtained from clinical trials may be inadequate to support approval or clearance of a submission. In addition, the occurrence of unexpected findings in connection with clinical trials may prevent or delay obtaining approval or clearance. The FDA' s 510 (k) clearance process for each device or modification usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is more costly and uncertain than the 510 (k) clearance process and generally takes from one- to- three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. In the United States, all of our FDA- cleared products have been cleared without the use of a PMA under the 510 (k) clearance process. Modifications to our 510 (k) cleared products may require new regulatory approvals or clearances, including 510 (k) clearances, or de novo request clearances, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510 (k) clearance is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the product as modified, which could require us to redesign and / or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. If a manufacturer determines that a modification to an FDA- cleared device could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, then the manufacturer must file for a new 510 (k) or de novo clearance or possibly a new PMA or approval of a PMA supplement. Where we determine that modifications to our cleared products require a new 510 (k) clearance or PMA approval, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time- consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. In the EEA, we are required to comply with applicable medical device legislation (the Medical Devices Directive or EU MDD and, from May 26, 2021, the Medical Device Regulation, or EU MDR) and obtain CE Certificates of Conformity in order to affix the CE Mark and market medical devices. The CE Mark is applied to our products following certification from an independent Notified Body. In the CE marking process, a medical device manufacturer must develop a clinical plan, then carry out a clinical evaluation of its medical device and prepare a Clinical Evaluation Report to demonstrate conformity with the relevant General Safety and Performance Requirements. Any delay in, or failure to receive or maintain, clearance, approval or certification for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA, Competent Authorities of EEA countries, and other regulatory authorities outside the United States have broad enforcement powers. Regulatory enforcement or

inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products. Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post- marketing studies. Failure to conduct required studies in a timely manner could result in the revocation of the 510 (k) clearance or PMA approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States. After receiving CE Certificates of Conformity to sell our product in the EEA, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products in the EEA. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated incidents or incidents of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, non- renewal, suspension or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. The non- renewal, withdrawal, or suspension of a CE Certificate of Conformity and the recall or withdrawal of our product from the market in the EEA would prevent us from generating revenue from sales of that product in the EEA. Moreover, each CE Certificate of Conformity is valid for a maximum of five years, commonly three years. Legislative or 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 FDA or the EU may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or may impact our ability to modify our currently approved or cleared products on a timely basis. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory 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, 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 products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. FDA regulations and guidance are often revised, expanded on, 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. The FDA' s and other foreign regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance, approval or certification of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Any change in the laws or regulations that govern the clearance, approval, and certification processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance, approval, or certification or the failure to receive clearance, approval or certification for any new products would have an adverse effect on our ability to expand our business. 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, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability. The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. Under new changes instituted by the FDASIA, the FDA may now change the classification of a medical device by administrative order instead of by regulation. Although the revised process is simpler, the FDA must still publish a proposed order in the Federal Register, hold a device classification panel meeting and consider comments from affected stakeholders before issuing the reclassification order. The FDA may reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our products. We are also subject to other types of government regulation which could have an adverse effect on our business. For example, certain of our manufactured components can be sterilized using Ethylene Oxide (" EO ") sterilization. In the United States, several regulators, including the U. S. Environmental Protection Agency (" EPA "), FDA, and agencies at the state and local level, regulate the use of EO sterilization. Recent announcements of the temporary or permanent closure of EO sterilization facilities have been associated with state and / or local regulatory or other legal action related to EO emissions at those facilities. Regulatory, legislative, or legal action that curtails or eliminates EO sterilization may have a material adverse effect on our financial condition and results of operations. In the EU, Regulation (EU) 2017 / 745, or the EU MDR, entered into application on May 26, 2021. The EU MDR introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU MDR repeals and replaces the EU MDD. It is necessary for Notified Bodies to be designated by the EEA countries Competent Authorities to conduct conformity assessment procedures for medical devices in accordance with the EU MDR. The number of Notified Bodies that have been designated to conduct these assessments under the EU MDR is still

relatively small when compared to that under the EU MDD. This is currently delaying conformity assessment procedures in the EEA. The EU MDR imposes increased compliance obligations for us to access the EEA market. Complying with the requirements of this regulation may require us to incur significant expenditures. In order to continue to sell our products in the EEA, we must maintain our CE Marks and continue to comply with the EU MDR (and with the EU MDD for our legacy devices). The new requirements imposed on manufacturers of medical devices by the EU MDR may impact our activities in the EEA, the renewal of our existing CE Certificates of Conformity and conformity assessment processes. Our failure to continue to comply with applicable regulatory requirements, including those administered by the Competent Authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our Notified Body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the EU, such as the recent departure of the United Kingdom (Brexit), may impact the regulatory requirements imposed by the relevant countries and impair our business operations and our ability to market products in such countries. The UK' s withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU- UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods. The Agreement does not however, specifically address medical devices. The Agreement seeks to ensure that the parties ensure " regulatory cooperation ". Great Britain (England, Scotland and Wales) is now treated as a third country. Northern Ireland continues, with regard to EU regulations, to follow the EU regulatory rules. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self- assessment in the other territory. Given the lack of comparable precedent to Brexit, it is unclear what the financial, regulatory, and legal implications of Brexit will be and how it will affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays in marketing or selling our products in the United Kingdom. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected. Modifications to our currently FDA- cleared products or the introduction of new products may require new regulatory clearances or approvals or equivalent steps in third countries including the EEA or require us to recall or cease marketing our current products until clearances or approvals are obtained. Modifications to our products may require new regulatory approvals or clearances or require us to recall or cease marketing the modified products until these clearances or approvals are obtained. Any modification to one of our 510 (k)- cleared products that would constitute a 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) clearance and may even, in some circumstances, require the submission of a PMA. We may be required to submit extensive pre- clinical and clinical data depending on the nature of the changes. We may not be able to obtain additional 510 (k) clearances or premarket approvals for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and operating results. For those products sold in the EEA, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining certification can be a time- consuming and expensive process, and delays in obtaining required future certification would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Our cleared, approved and CE marked products are, and any future products will be, subject to post- marketing restrictions, and we may be subject to substantial penalties if we fail to comply with all applicable regulatory requirements. The products for which we have obtained regulatory clearance, approval, or CE Certificates of Conformity are, and any of our future products will be, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such products, subject to continual requirements of and review by the FDA, Competent Authorities of EEA countries, Notified Bodies and other foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, Quality System regulations relating to manufacturing, quality control and quality assurance and corresponding maintenance of records and documents. In addition, we must report corrections and removals to the FDA, or equivalent foreign authorities, where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the federal Food, Drug, and Cosmetic Act or equivalent foreign laws caused by the device that may present a risk to health, and maintain records of other corrections or removals. If we receive regulatory clearance, approval, or CE Certificates of Conformity for additional products in the future, the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of clearance, approval, or CE Certificates of Conformity and the accompanying label may limit the approved use of our product, which could limit sales of the product. We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries, which could harm our business. To market and sell our products in countries outside the United States, we must seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of those countries. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals, certifications or registrations are expensive and we cannot be certain that we will maintain or receive regulatory approvals, certifications or registrations in any foreign country in which we currently market or plan to market our products. If we or our suppliers fail to comply with ongoing FDA, EEA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to additional restrictions or withdrawal from the market, which would harm our business. Any product for which we obtain

clearance, approval, or CE Certificates of Conformity and the manufacturing processes, reporting requirements, post- approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies and Notified Bodies. In particular, we and most of our third- party suppliers are required to comply with the FDA' s Quality System Regulation, or QSR, in the US, and the applicable regulatory requirements in the EEA on product assessments and quality system assessments. In the EEA, compliance with harmonized standards prepared under a mandate from the European Commission and referenced in the Official Journal of the EU, or harmonized standards, serve as a presumption of conformity with the relevant Requirements under and the EU MDR, as amended. These FDA regulations and EU standards cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and expected future products. Compliance with applicable regulatory requirements, including the QSR, in the US, is subject to continual review and is monitored rigorously through periodic announced and unannounced inspections by the FDA. ~~Following such an inspection of our Billerica and Wilmington, Massachusetts facilities in 2019, the FDA issued to us two Form 483s with several observations, including deviations from the QSR. In December 2019, we received a warning letter to our Wilmington facility from the FDA concerning the number of sterilization cycle failures relating to Vaporized Hydrogen Peroxide (" VHP ") sterilizers at our Wilmington facility that we used as a limited, alternative sterilization method for a small quantity of products. We have responded to all observations in both the Form 483s and the warning letter, including by decommissioning the VHP sterilizers in October 2020 and conducting revalidations. We continue to take various corrective and preventative actions to improve our quality, production and design control systems; nevertheless, we cannot be certain that we will not be subject to additional inspections and / or requirements to implement additional remediation efforts.~~ Compliance with harmonized standards in the EEA is also subject to regular review through the conduct of assessments or audits by Notified Bodies or other regulatory bodies. We must permit and allow unimpeded access for Notified Body staff to conduct unannounced audits in order to maintain our CE Certificate of Conformity. If we, or our manufacturers, fail to adhere to QSR requirements in the United States or regulatory requirements in the EEA, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances or CE Certificate of Conformity, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations. BSI Group The Netherlands B. V., an independent Notified Body, conducts periodic assessments of our quality management system in order to confirm that our quality management system complies with the requirements of ISO 13485 in all material respects and preforms periodic full recertification audits of our quality management system in order to confirm that we comply with the requirements of the EU MDR. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or applicable regulatory requirements in the EEA, or the failure to timely and adequately respond to any adverse inspectional observations, nonconformances or product safety issues, could result in any of the enforcement actions or sanctions described above under the risk factor captioned" Our medical device products are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer." Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key third- party manufacturers 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. If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions, which could harm our business. Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. The decision to file an MDR involves a judgment by us as the manufacturer. We have made decisions that certain types of events are not reportable on an MDR; however, there can be no assurance that the FDA will agree with our decisions. If we fail to report MDRs to the FDA within the required timeframes, or at all, or if the FDA disagrees with any of our determinations regarding the reportability of certain events, the FDA could take enforcement actions against us, which could have an adverse impact on our reputation and financial results. Additionally, all manufacturers placing medical devices in the market in the EEA are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the Competent Authority in whose jurisdiction the incident occurred. In the EEA, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant National Competent Authorities of the EEA Member States, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to prevent or reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Under the EU MDR, a serious incident is defined as any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient' s, user' s or other person' s state of health, (c) a serious public health threat. Manufacturers must also notify competent authorities of any field safety corrective actions (including those undertaken in a third country in relation to a device which is also made available on the EEA market, if the reason for the field safety corrective action is not limited to the device made available in the third country). An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its European Authorized Representative to its customers and to the end users of the device through Field Safety Notices. Any incident involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Incidents involving our products have been reported to us in the past, and similar adverse events may occur in the future. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of

the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. We have conducted voluntary product recalls and in the future, our products may be subject to additional product recalls either voluntarily or at the direction of the FDA or another governmental authority that could have a significant adverse impact on us. The FDA, Competent Authorities of EEA countries and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. A recall may require the removal or correction of a marketed product to repair, modify, adjust, relabel, destroy or inspect the product. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, voluntary recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Competent Authorities of foreign countries impose similar deadlines. A government- mandated or voluntary recall by us 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. We are also required to follow detailed recordkeeping requirements for all company- initiated medical device corrections and removals and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations. We may initiate a market withdrawal or a stock recovery involving our products in the future that we determine do not require notification to the FDA or to the Competent Authorities of foreign countries. If the FDA or the Competent Authorities of foreign countries disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or the Competent Authorities of foreign countries could take enforcement action for failing to report the recalls when they were conducted. We may be subject to enforcement action if we engage in improper marketing or promotion of our products for which we have received regulatory clearance, approval, or CE Certificates of Conformity. Any such enforcement action could result in significant fines, costs and penalties and could result in damage to our reputation. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition against the promotion of unapproved, or off- label, use of a device. Use of a device outside its cleared or approved indications is known as" off- label" use. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, physicians may use our products off- label, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. If the FDA determines that our promotional materials or other product labeling or activities constitute promotion of an unapproved, or off- label use, it could request that we modify our materials or activities 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. Other federal, state and foreign regulatory agencies, including the U. S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our products, including how we use endorsements and testimonials. If our promotional materials are inconsistent with these guidelines or regulations, we could be subject to enforcement actions, which could result in significant fines, costs and penalties. Our reputation could also be damaged and the adoption of our products could be impaired. In addition, the off- label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management' s attention, result in substantial damage awards against us and harm our reputation. The advertising and promotion of our products in the EEA is subject to the EU MDR, to the national laws of the individual EEA counties implementing the Directive 2006 / 114 / EC concerning misleading and comparative advertising, and Directive 2005 / 29 / EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of medical devices. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. In the EEA, our medical devices may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the national Competent Authorities of EEA countries. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Our promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the EEA governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public. If our promotional materials do not comply with these laws and industry codes, we could be subject to penalties that could include significant fines. Our reputation could also be damaged and the adoption of our products could be impaired. The barrier- free trade of medical devices between the European Union and Switzerland under the Mutual Recognition Agreement (MRA) ceased to apply on May 26, 2021, which may adversely affect our financial results and our operations in Switzerland. Switzerland is a European country, but it is not part of the European Union (" EU"). It is part of the European Free Trade Association (" EFTA"), together with the three countries that make up the European Economic Area (" EEA"). The EEA follows all EU product legislation automatically, but EFTA is not bound to that requirement. Trade with Switzerland is established via multiple mutual recognition agreements. There is a Mutual Recognition Agreement (MRA) covering medical devices in order to enable these devices to move freely between the EU and Swiss markets. However, the current MRA does not cover the EU MDR and, as a result, Switzerland is considered a third country for medical device trade purposes. All foreign manufacturers must, from May 26, 2021, adhere to the revised Swiss Medical Devices Ordinance and to the requirements for the import of medical devices, namely the designation of an

importer and a Swiss authorized representative (for which certain transitional periods are in place). During a transition period, devices that comply with the EU MDD and were CE- marked according to EU MDD (legacy devices) may continue to be placed on the Swiss market, even after the entry into force of the revised Swiss Medical Devices Ordinance, provided that certain conditions are met. The need for compliance with the revised Swiss Medical Devices Ordinance could adversely affect our sales in Switzerland, as well as our existing and future customers and future employees in Switzerland. The revised Swiss Medical Devices Ordinance could lead to legal uncertainty and divergences with the EU MDR and its implementation can affect our compliance efforts. Risks related to other legal and compliance matters We have been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management' s attention and have a material adverse effect on our business, financial condition and results of operations. We have been subject to securities class actions in the past related to our voluntary recall of specific serial numbers of patient- specific instrumentation for our ~~iUni, iDuo, iTotal CR and iTotal PS~~ knee replacement product systems. We may be subject to additional securities class action suits or proceedings in the future. Monitoring and defending against legal actions, whether or not meritorious, is time- consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve such matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. The substantial costs and diversion of management' s attention in any such litigation could harm our business and a decision adverse to our interests in any such lawsuit could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. Our relationships with healthcare providers, physicians and third- party payors will be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription and use of our products and any other product candidates for which we obtain marketing clearance. Our arrangements with healthcare providers, physicians and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: • The federal Anti- Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation or arranging of the purchase, lease, or order of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. • The federal civil False Claims Act imposes penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, or making or causing a false statement or record material to a false or fraudulent claim or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus significant mandatory penalties per false claim or statement for violations for each separate false claim, and the potential for exclusion from participation in federal healthcare programs. • The federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, (collectively, HIPAA), imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payers, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document in connection with the delivery of or payment for health care benefits, items, or services. • We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA- other than with respect to providing certain employee benefits- we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. • The federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians, teaching hospitals, and other healthcare providers, and as of this year, to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives, as well as ownership interests held by physicians and their immediate family members. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for " knowing failures. " • Analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws and transparency statutes, including the General Data Protection Regulation in the EU, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers. Some state laws require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For further details about the scope and requirements of these laws, please see Part I, Item 1.- Business- Healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, and exclusion from participation in

federal healthcare programs such as Medicare and Medicaid. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. 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, including the imposition of significant fines or other sanctions. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs. We are subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended (the" FCPA"), the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third- party intermediaries to promote our clinical research activities abroad and / or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities. Noncompliance with anti- corruption and anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management' s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. If we are found to have violated laws protecting the privacy or security of patient health information or other personal data, we could be subject to civil or criminal penalties, litigation or regulatory investigations, which could increase our liabilities and harm our reputation or our business. We may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy and / or genetic privacy laws and federal and state consumer protection laws, (e. g., Section 5 of the FTC Act and the California Consumer Privacy Act (CCPA)), govern the collection, use, disclosure, and protection of health- related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and / or adverse publicity that could negatively affect our business. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space. In particular, HIPAA imposes requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA- other than with respect to providing certain employee benefits- we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. The CCPA establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The CCPA and its implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (" CPRA ") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (" CPPA "). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise

adversely affect our business. The obligations to comply with the CCPA and evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non- compliance with such laws. The Federal Trade Commission (" FTC ") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the Federal Trade Commission Act (" 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. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. The legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation, which imposes penalties up to EUR 20 million or 4 % of annual global revenue of a noncompliant company, whichever is greater. In addition, laws and regulations enacted in the United States, Europe, Asia and Latin America, including the new California Consumer Privacy Act, increases potential enforcement and litigation activity. Because of this, we may need to engage in additional compliance efforts, including data mapping to identify the personal information we are collecting and the purposes for which such information is collected and enhanced consumer controls with respect to their data. In the event we enroll subjects in our ongoing or future clinical trials in the EEA, we will be subject to additional privacy restrictions, including restrictions relating to the collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the EEA as governed by the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements on companies that process personal data, strict rules on the transfer of personal data out of the EEA, including to the U. S and fines and penalties for failure to comply with the requirements of the GDPR and the related national data protection laws of the individual EEA countries. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The obligations under the GDPR may be onerous and adversely affect our business, financial condition, results of operations and prospects. Compliance with the GDPR will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any EEA activities. The European Commission has adopted an Adequacy Decision concerning the level of data protection in the UK. Personal data may now flow freely from the EU to the UK, however, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection. Enforcement by EU and UK regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines. Because of the remote work policies we implemented due to the COVID- 19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal information, including health data. We may also need to collect more extensive health- related information from our employees to manage our workforce. If we or our third party partners fail to comply or are alleged to have failed to comply with applicable data protection and privacy laws and regulations, and related employment rules, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. In addition, our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. The GDPR generally restricts the transfer of personal data from the EEA and Switzerland to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards allowing U. S. companies to import personal data from Europe had been certification to the EU- U. S. Privacy Shield and Swiss- U. S. Privacy Shield frameworks administered by the U. S. Department of Commerce. However, the EU- U. S. Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU, in a case known colloquially as " Schrems II. " Following this decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, announced that the Swiss- U. S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. While the FDPIC does not have authority to invalidate the Swiss- U. S. Privacy Shield regime, the FDPIC' s announcement casts doubt on the viability of the Swiss- U. S. Privacy Shield as a future compliance mechanism for Swiss- U. S. data transfers. The CJEU' s decision in Schrems II also raised questions about whether one of the primary alternatives to the EU- U. S. Privacy Shield, namely, the European Commission' s Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or other third countries that are not the subject of an adequacy decision of the European Commission. While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle in Schrems II, it made clear that reliance on those Clauses alone may not necessarily be sufficient in all circumstances. Use of the Standard Contractual Clauses must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data. In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and /

or applicable European law, the decision in Schrems II and subsequent draft guidance from the European Data Protection Board, or EDPB, would require the parties to that transfer to implement certain supplementary technical, organizational and / or contractual measures to rely on the Standard Contractual Clauses as a compliant " transfer mechanism. " However, the draft guidance from the EDPB on such supplementary technical, organizational and / or contractual measures appears to conclude that no combination of such measures could be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data " in the clear " to recipients in countries where the power granted to public authorities to access the transferred data goes beyond that which is " necessary and proportionate in a democratic society " – which may, following the CJEU' s conclusions in Schrems II on relevant powers of United States public authorities and commentary in that draft EDPB guidance, include the United States in certain circumstances (e. g., where Section 702 of the US Foreign Intelligence Surveillance Act applies). At present, there are few, if any, viable alternatives to the EU- U. S. Privacy Shield and the Standard Contractual Clauses. The decision in Schrems II also affects transfers from the United Kingdom to the United States. Furthermore, following the UK' s exit from the EU, the UK became a third country to the EEA in terms of personal data transfers. The EC has adopted an Adequacy Decision concerning the level of personal data protection. However, personal data transfers from the EEA to the UK may nevertheless be at a greater risk than before because an Adequacy Decision may be suspended. If we or any of our service providers are found to be in violation of HIPAA, the GDPR, or other data protection laws in the U. S. or internationally, we could be subject to government enforcement actions, civil and / or criminal penalties, litigation, or regulatory investigations, as well as adverse publicity, which could increase our liabilities, harm our reputation, and have a material adverse effect on our business, financial condition, and operating results. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EU regulations, to provide accurate information to the FDA, Competent Authorities of EEA countries or other foreign countries, to comply with manufacturing standards we have established, to comply with federal and state health- care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, 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. 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, including the imposition of significant fines or other sanctions. Risks related to our common stock If we fail to maintain compliance with the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would adversely affect the ability to sell our stock in the public market, the liquidity of our common stock and our ability to raise additional capital. Our common stock is currently listed on the Nasdaq Capital Market under the symbol " CFMS. " ~~Until December 30, 2020, our common stock was listed on the Nasdaq Global Select Market which, along with the Nasdaq Capital Market, has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements and the $ 1. 00 minimum closing bid price requirement.~~ On December ~~30~~ **31**, ~~2020~~ **2021**, we **received a notification letter from** ~~transferred the listing of our common stock to the Nasdaq Capital Market because we did not meet~~ Nasdaq' s ~~$ 1. 00 minimum closing bid price requirement. We subsequently regained compliance with this requirement on February 17, 2021. On May 7, 2021, we received a notification letter from the Nasdaq~~ Listing Qualifications Staff notifying us that the closing bid price for ~~its~~ **our** common stock had been below $ 1. 00 for the previous 30 consecutive business days and that **we** ~~the Company~~ therefore ~~was~~ **are** not in compliance with the minimum bid price requirement for continued inclusion on ~~the~~ **The** Nasdaq Capital Market under Nasdaq Listing Rule 5550 (a) (2). We subsequently **implemented a 1- for- 25 reverse stock split, and** regained compliance with ~~this~~ **these** ~~requirement~~ **requirements** ~~on July 12, 2021~~. However ~~, on December 31, 2021, we received another notification letter from the Nasdaq Listing Qualification Staff notifying us that we no longer meet the minimum bid price requirement, as the closing bid price for the last 30 consecutive business days was below $ 1. 00. The notification also provided us a compliance period of 180 calendar days, or until June 22, 2022, in which to regain compliance. Even with the additional time~~, there can be no assurance that ~~our bid~~ **the market** price **of our common stock** will ~~regain~~ **remain at the level required for continuing** compliance **with that requirement**. **It is not uncommon for** ~~In such event, we may seek to cure~~ the ~~deficiency by effecting~~ **market price of a company' s common stock to decline in the period following** a reverse stock split ~~, if necessary~~. ~~We continue~~ **Other factors unrelated** to ~~actively monitor~~ **the number of shares of our common stock outstanding, such as negative financial** ~~our~~ **or** ~~performance with respect to~~ **operational results, could adversely affect** the ~~listing standards~~ **market price of our common stock** and ~~will consider available options~~ **thus jeopardize our ability** to **meet or** ~~resolve any deficiency and~~ maintain ~~compliance with~~ the Nasdaq ~~rules~~ **' s minimum bid price requirement**. Any ~~potential~~ **future** delisting of our common stock from the Nasdaq Capital Market would make it more difficult for stockholders to sell our stock in the public market and would likely result in decreased liquidity, limited availability of market quotations for shares of our common stock, limited availability of news and analyst coverage regarding our Company, a decreased ability to issue additional securities and increased volatility in the price of our common stock. The price of our common stock is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for medical device companies in particular

have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your original purchase price. The market price for our common stock may be influenced by many factors, including the risk factors as described in this Annual Report on Form 10- K. Our quarterly operating results are subject to substantial fluctuations, and you should not rely on them as an indication of our future results. Our quarterly operating results have historically varied and may in the future vary significantly due to a combination of factors, many of which are beyond our control. These factors include: • seasonality in demand for our products, with reduced orders during the summer months and around year- end, followed by reduced sales of our products during the first and third quarters as a result; • our ability to meet the demand for our products; • increased competition; • the number, timing and significance of new products and product introductions and enhancements by us and our competitors; • our ability to develop, introduce and market new and enhanced versions of our products on a timely basis; • changes in pricing policies by us and our competitors; • changes in the number of cancelled sales orders and surgical cases using our implants that occur in a quarter or during other reporting periods, which may adversely affect our product margins, revenue and other aspects of our business; • changes in the treatment practices of orthopedic surgeons; • changes in distributor relationships and sales force size and composition; • the timing of material expense- or income- generating events and the related recognition of their associated financial impact; • fluctuations in foreign currency rates; • ability to obtain reimbursement for our products; • availability of raw materials; • work stoppages or strikes in the healthcare industry; • changes in FDA and foreign governmental regulatory policies, requirements and enforcement practices; • import and export inspections, which could impact the timing of delivery for either supplies or finished goods; • changes in accounting policies, estimates and treatments; and • general economic factors. We believe our quarterly sales and operating results may vary significantly in the future and period- to- period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indications of future performance. We may not be able to increase our sales, sustain our sales in future periods or achieve or maintain profitability in any future period. Any shortfalls in sales or earnings from levels expected by securities or orthopedic industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2021~~ **2022** , we had federal net operating loss, or NOL, carryforwards of $ ~~446~~ **470** million and state NOL carryforwards of $ ~~249~~ **274** million. These federal and state NOL carryforwards will expire in future years if not utilized. Utilization of these NOL carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the" Code"), and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. We have completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation. The results of this study indicate that we experienced ownership changes, as defined by Section 382 of the Code, on September 16, 2004, March 10, 2009, January 11, 2012 and January 29, 2018. As a result of this ownership changes, our use of NOL carryforwards generated prior to January 28, 2018 is subject to an annual limitation of approximately $ 1. 4 million per year. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre- change NOL and tax credits carryforwards to reduce U. S. federal and state taxable income may be subject to further limitations, which could result in increased future tax liability to us. Moreover, our federal NOLs from years prior to 2018 can be carried forward for a maximum of 20 years from the year in which the NOL was incurred, and our state NOLs are subject to carryforward limitations that vary from state to state; as a result, all or a portion of those carryforwards could expire before being available to reduce future income tax liabilities. Assuming no future ownership change occurs at a time when our market capitalization is lower than it was on our last ownership change on January 29, 2018, the Company is projected to lose $ 346 million of the total federal NOL carryforwards currently subject to IRC Section 382 to the 20- year carryforward expiration rules. On February 17, 2021, the Company closed an offering of our common stock off of the Shelf Registration Statement and issued and sold ~~80~~ **3** , ~~952~~ **238** , ~~381~~ **095** shares of our common stock at a public offering price of $ ~~1~~ **26** . ~~05~~ **25** per share **(adjusted for the 1- for- 25 reverse stock split)** , for aggregate net proceeds of approximately $ 79. 6 million, the Company is currently analyzing if a Section 382 ownership change occurred and if any further limitation will need to be updated in ~~2022~~ **2023** . Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our restated certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • establish a classified board of directors such that all members of the board are not elected at one time; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call a special meeting of stockholders; • authorize our board of directors to issue preferred stock, without stockholder approval, that could be used to institute a shareholder rights plan, or so called" poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and • require the approval of the holders of at least 75 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of

incorporation or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. Our restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against our company and our directors and officers. Our restated certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, stockholders must rely on capital appreciation, if any, for any return on their investment. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. Furthermore, our current debt facility does and any future debt agreements may also preclude us from paying or place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain with respect to your investment for the foreseeable future.