Risk Factors Comparison 2024-02-26 to 2023-02-27 Form: 10-K

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Our operating and financial results are subject to various risks and uncertainties. You should carefully consider the risks described below, as well as all of the other information contained in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. RISKS RELATED TO OUR BUSINESS ~~We~~ **While we have reported net income in recent years, we** have a history of net losses, and we may ~~continue to~~ incur **net** losses **in the future** . Therefore, we may not be able to reach the point of sustainable profitability. Although we incurred net income for the ~~fiscal~~ **years ended December 31, 2023 and 2022 of $ 147. 3 million and $ 216. 0 million, respectively, we generated net losses in prior periods, including for the** year ended December 31, ~~2022, we may incur net losses in the future. For the years ended December 31, 2022 and~~ 2021 ~~, we had net income of $ 216. 0 million and a net loss of $ 9. 1 million, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $ 36. 8 million~~ . We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, seek regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, we expect to continue to incur expenses due to the compliance and governance requirements associated with being a public company ~~. We may continue to incur losses in the future, which may fluctuate significantly from period to period~~ . Although we achieved profitability for all four quarters of ~~2022~~ **2023** , we cannot be sure that we will remain profitable **, on a quarterly or annual basis,** in the future **and our results may fluctuate significantly from period to period** . If our revenue declines or fails to grow at a rate faster than increases in our operating expenses, we will not be able to achieve and maintain profitability and may incur ~~new~~ losses in future periods. ~~We cannot ensure that we will achieve profitability in the future or that, if we do remain profitable, we will be able to sustain profitability.~~ Our results of operations may fluctuate significantly **from period to period** , which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide. Our quarterly and annual results of operations, including our revenue, net income ~~(loss)~~ and cash flow, may fluctuate significantly **from period to period** , which makes it difficult for us to predict our future results of operations. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: • the level of demand for our products and any products that may be approved in the future, which may vary significantly; • **our ability to attract new customers and improve our business with existing customers; •** expenditures that we may incur to acquire **, license** , develop, or commercialize additional products and technologies; • the timing and cost of obtaining regulatory approvals or clearances for planned or future products or indications; • the rate at which we grow our sales force and the speed at which newly hired ~~salespeople~~ **sales personnel** become effective, and the cost and level of investment therein; • the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or our current or future partners; • positive or negative media coverage of our products or the procedures or products of our competitors or our industry; • coverage and reimbursement policies with respect to our current and any future products, as well as products that compete, or may in the future compete, with our products; • the timing and success or failure of preclinical studies or clinical trials for our products or any future products we **may** develop or competing products ~~; • our ability to attract new customers and improve our business with existing customers~~ ; • the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold; • seasonality, including the seasonal slowing of demand for our products we have experienced in the fourth quarter and summer months based on the elective nature of procedures performed using our products, and which we expect may become more pronounced in the future as our business grows; • the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities relating to our products, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time; • the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third- party suppliers and manufacturers; • interruption in the manufacturing or distribution of our products; • the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability, including in light of ongoing global supply- chain disruptions; • future accounting pronouncements or changes in our accounting policies; and • changes in domestic and global geopolitical and macroeconomic conditions, including as a result of **regional conflicts around** the ~~COVID- 19 pandemic and~~ **world, uncertainty with respect to** the ~~responses~~ **federal debt ceiling and budget and potential government shutdowns related** thereto, the **weakening of** ~~ongoing conflict between Russia and Ukraine and~~ the ~~responses thereto~~ **global and U. S. economies, instability in the global banking sector** , rising interest rates, inflation **, global supply- chain disruptions,** and a tightening of the global labor market. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below

the expectations of analysts or investors or below any forecasts we may provide to the market, it could have a material adverse effect on our business, financial condition and results or operations. If we do not effectively hire, integrate, train, manage and retain additional sales personnel, and expand our sales, marketing and distribution capabilities, we may be unable to increase our customer base, achieve broader market acceptance of our products, or increase our global sales. ~~We are at an early stage in our growth and have limited experience operating as a commercial company.~~ Our ability to increase our customer base, achieve broader market acceptance of our products, and increase our global sales depends to a significant extent on our ability to expand our **sales and** marketing operations. We have dedicated, and ~~will~~ **intend to** continue to dedicate, significant financial and other resources to our marketing and sales programs, including the expansion of our international field presence through new distributors, the addition of sales and clinical personnel globally, and the addition of new sales territories in the United States and select global markets. However, there are a variety of factors that could adversely impact our ability to effectively market and sell our products, including: • **continuing to** ~~building~~ **build our** ~~the requisite~~ sales, marketing or distribution capabilities is expensive and time- consuming and requires significant attention from management; • the competition for talented individuals experienced in selling and marketing medical device products is intense, and we cannot assure you that we can assemble or maintain an effective team; and • training qualified sales personnel on the use of our products, applicable federal and state laws and regulations and our internal policies and procedures ~~,~~ requires significant time, expense ~~,~~ and attention and it can take a significant amount of time before our sales representatives are fully trained and productive. Our recent hires and planned hires may not become productive as quickly as we expect, or at all, and we may be unable to hire or retain sufficient numbers of qualified individuals in the markets where we do business or plan to do business. Moreover, our international expansion may be slow or unsuccessful if we are unable to retain qualified personnel with international experience, language skills and cultural competencies in the geographic markets in which we target. Any failure or delay in the development of our sales, marketing, or distribution capabilities, to hire, train and retain our sales force, or of our sales force to meet required productivity levels within a reasonable period of time, may result in us failing to realize the expected benefits of our investments or increase our revenue, which in turn would adversely impact the commercialization of our products and harm our business. **.We are highly dependent on our senior management team and key personnel,and our business could be harmed if we are unable to attract and retain personnel necessary for our success.We are highly dependent on our senior management and other key personnel.Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future,including sales and marketing professionals,scientists,clinical specialists,engineers,and other highly skilled personnel,and to integrate current and additional personnel in all departments.If we are not successful in attracting and retaining highly qualified personnel,including members of our senior management,it would have a material adverse effect on our business,financial condition and results of operations.Competition for skilled personnel in our market is intense,especially in the San Francisco Bay Area where our headquarters are located,and may limit our ability to hire and retain highly qualified personnel on acceptable terms,or at all.Many of the companies with which we compete for experienced personnel have greater resources than we have.Our competitors also may be successful in recruiting and hiring members of our management team or other key employees,and it may be difficult for us to find suitable replacements on a timely basis,on competitive terms,or at all.We have in the past,and may in the future,be subject to allegations that employees we hire have been improperly solicited,or that they have divulged proprietary or other confidential information or that their former employers own such employees' inventions or other work product,or that they have been hired in violation of non- compete provisions or non- solicitation provisions.To induce valuable employees to remain at our company,in addition to salary and cash incentives,we have issued stock awards that vest over time.The value to employees of stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.Despite our efforts to retain valuable employees,members of our management,scientific and development teams may terminate their employment with us on short notice.Our employment arrangements with our employees provide for at- will employment,which means that any of our employees could leave our employment at any time,with or without notice,cause or good reason.The loss of services of these personnel could prevent or delay our growth plans and the implementation and completion of our strategic objectives or divert management' s attention to seeking qualified replacements.We also do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees.We have increased the size of our organization and expect to further increase it in the future,and we may experience difficulties in managing this growth.If we are unable to manage the anticipated growth of our business,our future revenue and results of operations may be adversely affected.As of December 31,2022,we had 1,001 full- time and part- time employees worldwide,compared to 657 full- time employees as of December 31,2021.In response to growth in our business,including our product portfolio,customer base and research and development programs,we have significantly expanded our employee headcount and existing operations and established new operations in other countries.In order to manage this growth,we have needed,and expect to continue to need,additional managerial,operational,sales,marketing,financial and other personnel.Future growth would impose significant added responsibilities on members of management,including,among others:• identifying,recruiting,integrating,maintaining,and motivating additional employees** ;~~• natural disasters~~ **managing our internal development efforts effectively** , ~~political~~ **while complying with our contractual obligations to contractors** and ~~economic instability~~ **other third parties;and • improving our operational,financial and management controls,reporting systems and procedures.The growth we may experience in the future may provide challenges to our organization,requiring us to rapidly expand aspects of our business** ,including **our manufacturing operations** ~~wars,terrorism,political unrest,outbreak of disease,boycotts,curtailment of trade,and other market restrictions;• regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the U~~ . **Rapid expansion** ~~S.Foreign Corrupt Practices Act of 1977,as amended (the " FCPA "),UK~~

~~Bribery Act of 2010 (the " UKBA "),and comparable laws and regulations~~ in **personnel may result** ~~other countries;• compliance risks associated with the treatment of privacy and data,including under the General Data Protection Regulation (" GDPR ") (including as it applies~~ in ~~the United Kingdom~~ **less experienced people producing and selling our products,which could result in unanticipated costs and disruptions to our operations.If we are not able to effectively expand our organization** by **hiring** ~~virtue of the Data Protection Act 2018),enacted to protect the privacy of all individuals in the European Union and the United Kingdom,and which places certain restrictions on the export of personally identifiable data outside of the European Union or the United Kingdom,as applicable;• compliance risks associated with the revised regulations in the EU' s~~ new ~~Medical Devices Regulation (Regulation 2017 / 745) (the " MDR ") that outline the requirements for medical device CE~~ **employees and expanding our groups of consultants and contractors,we may not be able to further develop and commercialize our products and,accordingly,may not achieve our research and sales and** ~~marking~~ **marketing goals** ~~;and • compliance risks associated with the UK Medical Devices Regulations 2002 (" UK MDR "),which replaced the CE marking requirements for medical devices marketed and sold in the United Kingdom with a UKCA mark following the United Kingdom' s withdrawal from the European Union.These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations~~ ,which would have a material adverse effect on our business,financial condition and results of operations.We ~~have in the past and~~ may ~~in the future~~ acquire other businesses ~~,~~ which could require significant management attention,disrupt our business,dilute stockholder value,and adversely affect our results of operations.As part of our business strategy,we ~~have in the past and~~ may in the future make acquisitions or investments in companies,products or technologies that we believe could complement or expand our business model,enhance our technical capabilities,or otherwise offer growth opportunities and ways to further address the needs of our customers and potential customers. ~~For example,in April 2023 we acquired Neovasc Inc.~~ We cannot predict the number,timing or size of ~~any~~ future acquisitions or investments,or the effect that any such transactions might have on our operating results,and this strategy poses a number of risks and uncertainties,including:• we may not be able to find suitable acquisition ~~or investment~~ candidates,or ~~,~~ if we do,we may not be able to complete such acquisitions ~~or investments~~ on favorable terms ~~or at all~~ ;• the pursuit of potential acquisitions ~~or investments~~ may divert the attention of management and cause us to incur additional expenses in ~~connection with~~ identifying,investigating and pursuing suitable acquisitions ~~or investments~~ ,whether or not they are consummated;• our Credit Agreement,dated as of October 19,2022,with Wells Fargo Bank,National Association,as administrative agent,Wells Fargo Bank,National Association,as swingline lender and an issuing lender,Wells Fargo Securities,LLC and Silicon Valley Bank, ~~now a division of First Citizens Bank,~~ as joint lead arrangers and joint bookrunners,Silicon Valley Bank,as syndication agent,and the several lenders party thereto (the " Credit Agreement ") restricts our ability to pursue certain mergers,acquisitions,amalgamations or consolidations;• ~~even~~ if we do complete acquisitions ~~or investments~~ ,we may not ultimately strengthen our competitive position or achieve our goals,including increases in revenue,and any acquisitions ~~or investments~~ we complete could be viewed negatively by our customers,investors and industry analysts;• we may not be able to integrate other companies,products,employees or technologies in a successful manner;• we may have to use our existing cash to pay for acquisitions ~~or investments~~ ,which may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired;• we may have to incur debt to pay for any such acquisition ~~or investment~~ ,which would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations and which could adversely affect our financial condition or the value of our common stock;• acquisitions ~~or investments~~ may require large,one- time charges and could result in increased debt or contingent liabilities,adverse tax consequences,additional stock- based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets,any of which could negatively affect our future results of operations;and • acquisitions and investments may fail to meet our expectations and negatively affect our business,financial condition and results of operations and we may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions. **For example,in January 2023,we announced our pending acquisition of Neovasc,a company focused on the minimally invasive treatment of refractory angina,in connection with which we are exposed to the above- listed risks,among others.The completion of the acquisition is conditional upon,among other things,the requisite approval of Neovasc' s shareholders and the issuance of a final order by the Supreme Court of British Columbia.There can be no assurance that any or all such approvals will be obtained.We will not control Neovasc and its subsidiaries until completion of the acquisition,and the business and results of operations at Neovasc may be adversely affected by events that are outside of our control during the interim period.** We may enter into collaborations,in- licensing arrangements,joint ventures,strategic alliances or partnerships with third ~~-~~ parties that may not result in the development of commercially viable products or product improvements or the generation of significant future revenue.In the ordinary course of our business,we may enter into or modify collaborations,in- licensing arrangements,joint ventures,strategic alliances,partnerships or other arrangements (each,a " Collaboration ") to develop new products or product improvements and to pursue new markets.Any such Collaboration may subject us to business risks that could have a material adverse effect on our business,financial condition,and results of operations,including the following:• we may be delayed or not successful in our efforts to identify or consummate any Collaboration;• we face significant competition in seeking appropriate strategic partners,including from other companies with substantially greater financial,marketing,sales,technology or other business resources;• the negotiation process for any Collaboration may be time- consuming and complex and may distract senior management;• we may be delayed,or not be successful,in integrating ~~any~~ **such** Collaboration with our existing operations and / or in achieving the revenue or specific net income or other targets that we anticipated as a result of such Collaboration;• provisions contained in the operative documents for any Collaboration may limit our rights,control,or decision- making authority in a manner that is not in our best interest;• any delay or termination of a Collaboration related to our products could delay the development and commercialization of our products and reduce their competitiveness if they reach the market;•

counterparties in any Collaboration may have economic or business interests or goals that are,or that may become,inconsistent with our business interests or goals;• conflicts may arise with our collaborators and other business partners,such as conflicts concerning the achievement of performance milestones,or the interpretation of significant terms under any agreement,such as those related to financial obligations,termination rights or the ownership or control or other licenses of intellectual property rights,which may result in litigation or arbitration which would increase our expenses and divert the attention of our management;and • we may be required to incur non- recurring and other charges,increase our near and long- term expenditures,or issue securities that dilute our existing stockholders and disrupt our management and business.For example,in March 2021,we entered into a joint venture with Genesis ~~MedTech International Private Limited (" Genesis ")~~ to establish a long- term strategic partnership to develop,manufacture and commercialize certain of our interventional products in the **PRC** ~~People' s Republic of China,excluding the Special Administrative Regions of Hong Kong and Macau~~ .Under the joint venture agreement,Genesis Shockwave Private Ltd.was formed under the laws of Singapore to serve as a joint venture between us and Genesis for the purpose of establishing and managing such a strategic partnership.The termination of our joint venture with Genesis would disrupt our ability to commercialize our products in China.We have **limited experience operating as a commercial company.We were incorporated in 2009.We began commercializing our products in the United States and Europe in 2018,and we continue to expand our product offering.Our limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects.These factors also make it difficult for us to forecast our future financial performance and growth,and such forecasts are subject to a number of uncertainties,including our ability to:(i) successfully complete on- going clinical trials and other clinical trials we may undertake in the future,(ii) continue to successfully commercialize and expand usage of our products in the U.S.and international markets,and (iii) obtain regulatory approvals and successfully commercialize future planned products in the United States or in key international markets.If our assumptions regarding the risks and uncertainties we face,which we use to plan our business,are incorrect or change due to circumstances in our business or our markets,or if we do not address these risks successfully,our operating and financial results could differ materially from our expectations and our business could suffer.We have** a limited operating history in China and we face risks with respect to conducting business in connection with our joint venture in China due to certain legal,political,economic and social uncertainties relating to China.Our ability to monetize our joint venture in China may be limited.Our participation in the joint venture with Genesis in China is subject to general,as well as industry- specific,economic,political ~~,tax~~ and legal developments and risks in China.The Chinese government exercises significant control over the Chinese economy,including but not limited to controlling capital investments,allocating resources,setting monetary policy,controlling and monitoring foreign exchange rates,implementing and overseeing tax regulations,providing preferential treatment to certain industry segments or companies and issuing necessary licenses to conduct business.In addition,we could face additional risks resulting from changes in China' s data privacy and cybersecurity requirements ~~.Further,our operations and the sale of our products in China could be negatively impacted as a result of the recent healthcare industry- wide anti- corruption enforcement efforts by the Chinese government,which have impacted hospital and physician practices~~ .Accordingly,any adverse change in the Chinese economy,the Chinese legal system or Chinese governmental,economic or other policies could have a material adverse effect on our business and operations in China and our prospects generally. **We face** ~~Additionally -- **additional risks in** ,an escalation of recent trade tensions between the United States and~~ China **due** ~~has resulted in trade restrictions that could harm our ability to participate in Chinese markets.Sustained uncertainty about,or a worsening of,current global economic conditions and further escalation of trade tensions between the United States and China could result in a global economic slowdown and long- term changes to global trade,including retaliatory trade restrictions that could restrict our ability to operate in China.Moreover,the cardiovascular field is highly competitive,and we expect increasing competition within China from manufacturers and distributors of cardiovascular medical devices.Certain of our products may compete with products manufactured or reportedly under development by other companies in China,including companies that are large and well- capitalized,having significantly greater market share and resources within China than we do.Due~~ to China' s historically limited recognition and enforcement of contractual and intellectual property rights ~~,we~~ **.We** may experience difficulty enforcing our intellectual property rights in China ~~,including with respect to competitors or our partners~~ .Unauthorized use of our technologies and intellectual property rights by **China partners** ~~our~~ **or** competitors ~~or partners in China~~ may dilute or undermine the strength of our brands ~~.We also have received or may in the future receive claims from competitors or our partners in China that we are infringing upon their intellectual property rights.Any such claims could be costly to defend and divert management' s attention and,in the event of an adverse result,put one or more of our patents in China at risk of being invalidated or interpreted narrowly~~ .If we cannot adequately monitor the use of our technologies and products,or enforce our intellectual property rights in China or contractual restrictions relating to use of our intellectual property by Chinese companies,our revenue could be adversely affected.Our joint venture with Genesis is subject to laws and regulations applicable to foreign investment in China.There are uncertainties regarding the interpretation and enforcement of laws,regulations and policies in China.Because many of the laws,regulations and policies applicable to our operations in China are relatively new,the interpretations of such laws,regulations and policies are not always uniform.Moreover,the interpretation of statutes and regulations may be subject to government policies reflecting domestic political agendas.Enforcement of existing laws or contracts based on existing law may be uncertain and sporadic.As a result of the foregoing,it may be difficult for us to obtain swift or equitable enforcement of laws ostensibly designed to protect companies like ours,which could have a material adverse effect on our business and results of operations.Our ability to monetize our joint venture in China may also be limited. ~~Although our joint venture with Genesis is an autonomous company,it is the exclusive seller of our products in China and is therefore our public face in China.Therefore,we face reputational and brand risk as a result of any negative publicity faced by the joint venture and any such reputational and brand risk could have a material adverse effect on our business,financial condition and results of operations.~~ The terms of the Credit Agreement require us to meet certain operating and financial covenants and place restrictions

on our operating and financial flexibility.On October 19,2022, ~~we~~ **the Company** entered into the Credit Agreement.The Credit Agreement provides for a revolving credit facility in an aggregate principal amount of $ 175 ~~.0~~ million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $ 100 ~~.0~~ million or (y) ~~our~~ **the Company' s** consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.The Credit Agreement is secured by ~~substantially~~ all of ~~our~~ **the Company' s** assets, ~~including~~ **excluding** intellectual property **and certain other assets** .The Credit Agreement is subject to customary affirmative and restrictive covenants,including with respect to our ability to enter into fundamental transactions,incur additional indebtedness,grant liens,and pay any dividend or make any distributions to stockholders.If we fail to comply with the covenants or payments in connection with the Credit Agreement,it will be an event of default,which would give the lenders the right to terminate their commitments to provide additional loans and declare all borrowings outstanding,together with accrued and unpaid interest and fees,to be immediately due and payable.In addition,Wells Fargo Bank,National Association,as administrative agent,would have the right to proceed against the assets we provided as collateral pursuant to the loan.The foregoing may restrict our current and future operations,particularly our ability to respond to certain changes in our business or industry or take future actions.If we experience significant disruptions in,or breaches of,our information technology systems,our business may be adversely affected.We depend on increasingly complex information technology systems,both with our own systems and those of our cloud and third- party service providers,for the efficient functioning of our business,including the manufacture,distribution,and maintenance of our products,management of clinical trial data and employee data,as well as for accounting,data storage (including systems that store our sensitive personal,intellectual property and confidential information),compliance,purchasing and inventory management.Our information technology systems require an ongoing commitment of significant financial and human resources designed to maintain,protect and enhance those systems.However,a number of issues could impact the integrity of our systems including:• Technology risks,including failures during the process of upgrading or replacing software,databases or components thereof,upgrades,expansions or replacements of our internal systems,power outages,damage or interruption from fires or other natural disasters,hardware failures,telecommunication failures and user errors (" Technology Risks ");and • Enduring data- and cyber- security threats,including computer viruses,ransomware or other malware,crypto- jacking,cloud vulnerabilities,phishing attacks,social engineering,and attacks by computer hackers or wrongdoing from our own employees or others granted access to our information technology systems (" Cyber Risks ").We continue to work to monitor and address potential Cyber Risks and Technology Risks,including in relation to the following:• As we become more dependent on information technologies to conduct our operations,Technology Risks may become more widespread and Cyber Risks may increase in frequency and sophistication.• Due to the nature of Cyber Risks and the techniques used to obtain unauthorized access,disable or degrade service or sabotage systems that change frequently and often are not recognized until launched against a target,we and our service providers may be unable to anticipate these techniques or to implement timely adequate preventative measures.• We rely on third- party systems that could also become vulnerable to Technology Risks or Cyber Risks that could result in disruption or compromise of our systems.• A greater number of our employees working remotely as a result of the **COVID- 19 pandemic** ~~increased prevalence of hybrid and remote working arrangements~~ and changing remote work expectations ~~in recent years~~ has exposed us,and may continue to expose us,to increased Technology Risks and Cyber Risks.• ~~In 2023,we~~ **We are in the process of** ~~implemented~~ **implementing** a new company- wide enterprise resource planning (" ERP ") system to upgrade certain existing business,operational,and financial processes.The new ERP system ~~may~~ **could** be impacted by Technology Risks,the occurrence of which could adversely impact our business processes,internal controls and operating results,including if the ERP system **,once implemented,** does not function as intended or is not sufficient to meet our operating requirements,or if any subsequently planned upgrades or expansions to the ERP system adversely impact existing processes.While we have made investments,we will likely continue to need to expend significant resources and to make significant capital investment in efforts designed to protect against Cyber Risks and Technology Risks or to mitigate the impact of any actual events.We realize that Technology Risks and Cyber Risks are a threat,and there can be no assurance that our efforts to mitigate Technology Risks and Cyber Risks will prevent information security breaches that may result in business,legal,financial or reputational harm to us,or would have a material adverse effect on our results of operations and financial condition.While we have not experienced any material ~~system disruptions~~ **Technology Risk** or **Cyber Risk** ~~a security incident~~ to date,if a Technology Risk or Cyber Risk results in an actual system disruption or a security incident that results in an unauthorized access to personal information or other confidential information,such disruption or security incident could,among other things:• slow or delay our operations,including our ability to timely ship and track product orders,project inventory requirements,manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments;• result in the disclosure or misuse of confidential,personal,or proprietary information,including sensitive customer,vendor,employee or financial information;• compromise the confidentiality,integrity and availability of data stored on these systems;• damage our computers and information technology systems;• damage our ability to attract and retain new customers and work with existing customers;• damage our reputation and business,including with respect to both our customers and patients undergoing procedures utilizing our products;• result in litigation and governmental investigations;and • result in significant recovery or remediation costs.Currently,we carry business interruption coverage to mitigate certain potential losses,but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to Technology Risks and Cyber Risks and related business and system disruptions.We cannot be certain that such potential losses will not exceed our policy limits,insurance will continue to be available to us on economically reasonable terms,or at all,or any insurer will not deny coverage as to any future claim.In addition,we may be subject to changes in our insurance policies,including premium increases or the imposition of large deductible or co- insurance requirements.Accordingly,such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business,financial condition,and results of operations.To the extent that any disruption or security breach were to result in a loss of,or damage to,our data or applications,or

inappropriate disclosure of confidential,personal or proprietary information,we could incur liability and the further development and commercialization of our products could be delayed or disrupted.With the ever- changing threat landscape,and while we have implemented security measures to protect our information technology systems and infrastructure,there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. ~~Further,in July 2023,the Securities and Exchange Commission (the " SEC ") adopted new cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board' s role in overseeing cybersecurity risks,management' s role and expertise in assessing and managing cybersecurity risks,and processes for assessing,identifying and managing cybersecurity risks) in annual reports on Form 10- K.The new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents by Form 8- K,within four business days of determining that an incident is material.We are subject to such annual report disclosure requirements starting with this Annual Report on Form 10- K for the year ended December 31,2023 and we have been subject to such Form 8- K disclosure requirements since December 18,2023.Complying with these new cybersecurity disclosure obligations,or any additional new disclosure requirements that may apply to us in the future,could cause us to incur substantial costs and could increase negative publicity surrounding any incident that we are required to disclose.~~ We face risks related to our collection and use of data,which could result in investigations,inquiries,litigation,fines,legislative and regulatory action and negative press about our privacy and data protection practices.We collect and use personal information,such as name,mailing address,email addresses,mobile phone number,medical and location information,and the collection and use of this information is regulated by privacy and data protection laws,rules and regulations.We also receive personal information from third parties subject to the same legal obligations.Violations of these laws could lead to civil and criminal penalties as well as adverse publicity that could harm our ability to initiate and complete clinical trials.We also face risks inherent (i) in the collection,use,and selective disclosure of large volumes of personal and non-personal proprietary data and (ii) in the protecting of personal and sensitive information from the Cyber and Technology Risks discussed above.Any failure by us or any of our third- party service providers to follow such laws,regardless of fault,could result in significant liability or reputational harm under various state,federal and international privacy,data protection and other laws,including,the laws listed below.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 that may affect our business and increase the uncertainty of inconsistent regulator enforcement across jurisdictions that,include but not limited to:• The Federal Trade Commission (the " FTC "),who is responsible for enforcement against unfair and deceptive business practices and expects a company' s data security measures to be reasonable and appropriate.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 constitute unfair or deceptive acts or practices in violation of the **FTC** ~~Federal Trade Commission~~ Act.While we do not intend to engage in unfair or deceptive acts or practices,the FTC has the power to enforce our promises to maintain adequate security safeguards as it interprets them,and events that we cannot fully control,such as data breaches,may be result in FTC enforcement resulting in civil penalties or enforcement actions.Additionally,as may be applicable,protection of individually identifiable health information in the United States may be subject to the Health Insurance and Portability Act of 1996 (" HIPAA "),as amended ~~by~~ **,and** the Health Information Technology for Economic and Clinical Health Act of 2009 **(" HITECH ")** ,which may be enforced separately by the Health and Human Services Agency that could result in civil and criminal penalties.HIPAA imposes certain requirements relating to the privacy,security and transmission of individually identifiable health information,which are applicable to " business associates " — certain persons or entities that create,receive,maintain or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity.• California,which continues to be a critical state with respect to evolving consumer privacy laws after enacting the California Consumer Privacy Act (the " CCPA "),later amended by ballot measure through the California Privacy Rights Act (the " CPRA ").The CPRA took effect in January 2023 with enforcement beginning on July 1,2023,subject to regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency (" CPPA ").Failure to comply with the CCPA and the CPRA may result in significant civil penalties,injunctive relief,or statutory or actual damages as determined by the CPPA and California Attorney General through its investigative authority.Notably,comparable consumer privacy laws ~~have and~~ are ~~expected~~ **set** to take effect in ~~many~~ **2023 in** other states ~~,~~ including **the** Virginia **Consumer Data Protection Act (which took effect January 1** , **2023),the** Colorado ~~,~~ **Privacy Act and the** Connecticut **Data Privacy Act (both effective July 1** , **2023),and the** Utah **Consumer Privacy Act (effective December 31** , **2023)** ~~Montana,Oregon,Texas,Delaware,Iowa and Tennessee~~ .Compliance with these new privacy regulations may result in additional costs and expense of resources to maintain compliance.• The European Union (the " EU ") and United Kingdom (" UK ") **General Data Protection Regulation (" GDPR ")** ,which applies extraterritorially,and imposes several strict requirements for controllers and processors of personal information,including higher standards for obtaining consent from individuals to process their personal information,increased requirements pertaining to the processing of special categories of personal information (such as health information) and pseudonymized (i.e.,key- coded) data,and transfer of personal information from the EEA / UK / Switzerland to countries not deemed to have adequate data protections laws. **In October 2022** ~~On the latter point~~ , **President Biden issued** ~~the EU GDPR (covering the EEA) as well as UK and~~ - **an executive** ~~Swiss data protection laws impose strict rules on the cross- border~~ - **order** ~~transfer of personal data out of the EU,UK,or Switzerland~~ to **implement** ~~a " third country," including the United States.On June 4,2021,the European Commission finalized new versions of the Standard Contractual Clauses (the " SCCs ").The UK Information Commissioner' s Office of the Data Protection Authority published the UK version of the SCCs,and by March 2024,we will be required to use and honor these clauses for transfers of UK residents' personal data to a foreign country that does not have adequate data protection.Effective July 10,2023,the new~~ EU- U.S. ~~Data Privacy Framework (" DPF ") has been~~

~~recognized as adequate under EU law to allow transfers of personal~~ data **privacy safeguards** ~~from the EU to certified companies in the United States~~. **The European Commission** ~~However,the DPF~~ is ~~subject~~ **expected** to ~~further legal challenges which~~ **review the executive order and** could **propose** ~~cause the legal requirements for personal data transfers from the EU to the United States to become uncertain once again.While the DPF does not apply to the UK,on October 12,2023,the UK government adopted~~ an adequacy decision **concerning** ~~concluding that~~ the ~~United States ensures an adequate~~ level of **personal information** protection **in** ~~transferred from the UK to~~ the United States under **which personal information could flow freely** ~~the UK Extension to the EU- U.S.Data Privacy Framework.We anticipate a similar adequacy decision~~ from the **EEA** ~~Swiss government (the " Swiss DPF ").Both the UK and Swiss DPF could also be contested or otherwise affected by any challenges~~ to ~~the EU-U.S.DPF.If we cannot implement a valid compliance mechanism for cross- border data transfers,we may face increased exposure to regulatory actions,substantial fines,and injunctions against processing or transferring personal data from Europe or other~~ -- **the United States** ~~foreign jurisdictions.In the EU and other markets,potential new rules and restrictions on the flow of data across borders could increase the cost and complexity of doing business in those regions~~ .The GDPR also provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal information,including genetic data,biometric data,and health data.Companies that must comply with the GDPR face increased compliance obligations and risk,including more robust regulatory enforcement of data protection requirements and potential fines for ~~severe~~ noncompliance of up to € 20 million or 4 percent of the annual global revenues of the noncompliant company,whichever is greater.• In Japan,The Act on the Protection of Personal Information **(the " APPI ")** ,in effect since 2003 and amended several times,with the most recent amendments coming into effect in April 2022,provides a comprehensive data privacy and protection regime comparable to the GDPR to every Personal Information Controller (" PIC ") in Japan that is either a person or an entity that handles personal information in the course of their or its business.PICs have legal obligations to secure personal information and report losses to the Japanese government.Noncompliance is regulated by the Personal Information Protection Commission,which has the power to issue orders for " improvement " in response to violations of privacy law by PICs that include civil and criminal penalties.Compliance with these laws and regulations may require significant additional cost expenditures or changes in products or our business that increase competition or reduce revenue.As stated above,noncompliance ~~or any perceived noncompliance~~ could result in the imposition of fines,penalties,or orders to stop noncompliant activities, **or** withdrawal of non- compliant products from a market ~~,or other enforcement action or litigation~~ .We cannot provide assurance that (i) current or future legislation will not prevent us from generating or maintaining personal information or (ii) patients will consent to the use of their personal information (as necessary).Either of these circumstances may prevent us from undertaking or publishing essential research and development,manufacturing,and commercialization,which could have a material adverse effect on our business,results of operations,financial condition,and prospects.Federal,state,and foreign government requirements include obligations of companies to notify regulators and / or individuals of security breaches involving personal information resulting from Technology Risks or Cyber Risks experienced by us,or our vendors,contractors,or organizations with whom we had specific contractual obligations to protect our data.Further,the improper access to,use of,or disclosure of our data or a third-party' s personal information could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal,state and local regulatory entities in the United States and by international regulatory entities.Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process,and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight.In addition to government regulation,privacy advocates and industry groups have and may in the future propose self- regulatory standards from time to time.These and other industry standards may legally or contractually apply to us,or we may elect to comply with such standards.It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements,including changes in laws,regulations and standards or new interpretations or applications of existing laws,regulations and standards,we may become subject to audits,inquiries,whistleblower complaints,adverse media coverage,investigations,loss of export privileges,or severe criminal or civil sanctions,all of which may have a material adverse effect on our business,operating results,reputation,and financial condition.Any such liability,litigation,investigations and proceedings may or may not be covered by our liability insurance.and may subject us to significant penalties and negative publicity,require us to change our business practices,increase our costs,severely disrupt our business,and may result in significant reputational harm producing **a material adverse effect on our client base,patient base and revenue** Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2022~~ **2023** , we had net operating loss (" NOL ") carryforwards of approximately $ ~~239~~ **103** . ~~7~~ **1** million for federal income tax purposes, $ ~~51~~ **45** . ~~0~~ **6** million for California income tax purposes ~~and ,~~ $ ~~77~~ **31** . ~~9~~ **8** million for other state income tax purposes **, and $ 126. 6 million for foreign entities** . We also have research credits of $ ~~10~~ **14** . ~~4~~ **6** million and $ ~~10~~ **14** . ~~1~~ **6** million, for federal and California **purposes** , respectively. Unused U. S. federal **NOLs** ~~net operating losses~~ generated in tax years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal **NOL** ~~net operating loss~~ carryforwards ~~in taxable years beginning after December 31, 2020,~~ is limited to 80 % of taxable income. Our ability to utilize our federal **NOL** ~~net operating~~ carryforwards and certain credits may be limited under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended. The limitations **will** apply if we experience an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in the ownership of our equity by certain stockholders over a rolling three- year period. Similar provisions of state tax law may also apply to limit the use of our state **NOL** ~~net operating loss~~ carryforwards. We have ~~previously~~ experienced ownership changes, and although such prior ownership changes have had an immaterial impact ~~to~~ **on** our utilization of affected **NOL** ~~net operating loss~~ carryforwards **and research credits** , future changes in our stock ownership, which may be outside of our control, may trigger an ownership change that materially impacts our ability to utilize pre- change **NOL** ~~net operating loss~~ carryforwards **and research credits** . In addition, there may be periods during which the use of **NOL** ~~net operating loss~~ carryforwards is suspended

or otherwise limited. **Accordingly** ~~For example~~ , **our ability to** ~~California generally suspended the~~ use ~~of California net operating loss carryforwards to offset taxable income in tax years beginning after 2019 and before 2022. Accordingly,~~ our **NOL** ~~ability to use our net operating loss~~ carryforwards to offset taxable income may be subject to such limitations or special rules that apply at the state level, which could adversely affect our results of operations. If we cannot realize our deferred tax assets, our results of operations could be adversely affected. ~~We have~~ **Until the quarter ended December 31, 2022, we had** maintained a **full** valuation allowance **against** ~~on all~~ our ~~U. S. net~~ deferred tax assets **due to our cumulative loss position and uncertainties regarding sustainable future profitability** since ~~our~~ inception ~~as it was determined that it was more likely than not that we would not recognize the benefits of these assets~~ . We **released the** ~~continued to record a~~ valuation allowance **against all** ~~through the first nine months~~ of ~~2022. In the fourth quarter of 2022, we concluded that the valuation allowance related to~~ the U. S. federal ~~and state (excluding California)~~ deferred tax assets **and** ~~was no longer required due to the~~ **other** assessment ~~- than-~~ **California state deferred tax assets during the fourth quarter** of **fiscal year 2022** ~~our recent income / loss and forecast future taxable income~~ . Each quarter, we consider both positive and negative evidence to determine whether all or a portion of the deferred tax assets are more likely than not to be realized. If we determine that some or all of our deferred tax assets are not realizable, it could result in a material expense in the period in which this determination is made which may have a material adverse effect on our financial condition and results of operations. Changes in tax laws or regulations may have a material adverse effect on our business, cash flow, financial condition, or results of operations. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations. For example, the **Tax Cuts and Jobs Act (“** TCJA **”)** enacted many significant changes to the U. S. tax laws, including changes in corporate tax rates, the realization of net deferred tax assets relating to our U. S. operations, the taxation of foreign earnings and the deductibility of expenses. Although we are still awaiting guidance from the Internal Revenue Service on how some of the TCJA changes will impact us, beginning in 2022, the TCJA eliminated the option to immediately deduct research and development expenditures and required taxpayers to amortize domestic expenditures over five years and foreign expenditures over fifteen years. Absent a change in legislation, we expect it will continue to have an impact on cash from operating activities. In addition, many countries are implementing legislation and other guidance to align their international tax rules with the Organization for Economic Co- operation and Development’ s (“ OECD ”) Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross- border tax, transfer pricing documentation rules, and nexus- based tax incentive practices. The OECD is also continuing discussions surrounding fundamental changes in allocation of profits among tax jurisdictions in which companies do business, as well as the implementation of a global minimum tax (namely the “ Pillar One ” and “ Pillar Two ” proposals). ~~Some countries intend to implement~~ **Many non- US tax jurisdictions have enacted or begun the processing of enacting** laws based on Pillar Two proposals, which may adversely impact our provision for income taxes, net income and cash flows. These and other changes resulting from the TCJA or future tax reform legislation (domestic U. S. or international) could have a material impact on the value of our deferred tax assets, could result in significant one- time charges in the current or future taxable years, and could increase our future tax expense. We may require additional capital to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations. Although we incurred net income for the ~~fiscal~~ year ended December 31, ~~2022~~ **2023** , we may incur net losses in the future. To date, our operations have been financed primarily by net proceeds from the sale of our equity **and convertible debt** securities and our product revenue. As of December 31, ~~2022~~ **2023** , we had $ ~~304~~ **990** . ~~5~~ **6** million in cash, cash equivalents and short- term investments, and **retained earnings** ~~an accumulated deficit~~ of $ ~~36~~ **110** . ~~8~~ **5** million. Based on our current planned operations ~~, including our pending acquisition of Neovase~~ , we expect that our cash, cash equivalents and short- term investments will enable us to fund our cash requirements, including capital expenditures and working capital, for at least the next 12 months. We have based this estimate on assumptions that may prove to be incorrect ~~or different~~ , and therefore we could use our capital resources sooner than we currently expect. We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We have made and we plan to continue to make significant investments in our sales and marketing organization by increasing the number of U. S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in research and development, regulatory affairs, and clinical studies to develop future generations of our products, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and ~~Securities and Exchange Commission (the “~~ SEC ~~”)~~ compliance, investor relations and other expenses. Because of these and other factors, we may incur net losses and negative cash flows from operations in the foreseeable future. Our future capital requirements will depend on many factors, including: • the **timing, receipt and amount of sales from our current and potential products; • the cost and timing of establishing sales, marketing and distribution capabilities; • the** cost, timing and results of our clinical trials and regulatory reviews; • the ~~cost and timing of establishing sales, marketing and distribution capabilities; • the~~ terms and timing of any other collaborative, licensing and other arrangements that we may establish; • the ~~timing, receipt and amount of sales from our current and potential products; • the~~ degree of success we experience ~~in~~ **continuing to** ~~commercializing~~ **commercialize** our products; • the emergence of competing or complementary technologies; • the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; • changes in domestic and global geopolitical and macroeconomic conditions, including as a result of **regional conflicts around the world, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, the weakening of the global and U. S. economies, instability in the global banking sector,** rising interest rates, inflation, global supply- chain disruptions, and a tightening of the global labor

market ~~, the COVID- 19 pandemic and responses thereto, and the ongoing conflict between Russia and Ukraine and the responses thereto~~ ; and • the extent to which we acquire or invest in businesses, products, or technologies. As a result, we may require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings and / or debt financings. There can be no assurance that we will be successful in obtaining such additional funding at levels sufficient to fund our operations, on terms favorable to us or at all. Further, the current macroeconomic environment may make it difficult for us to raise capital on terms favorable to us or at all. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may have a material adverse effect on our business, results of operations and financial condition. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Additional capital may not be available on reasonable terms, or at all. We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the " Exchange Act "), which requires, among other things, that we file with the SEC ~~,~~ annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act of 2002, as amended (the " Sarbanes- Oxley Act "), as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market (" Nasdaq ") to implement provisions of the Sarbanes- Oxley Act, ~~impose~~ **imposes** significant requirements on public companies, including requiring that we evaluate and determine the effectiveness of our internal control over financial reporting. Further ~~, in July 2010~~ , the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") **contains** ~~, was enacted. There are~~ significant corporate governance and executive compensation related provisions **, pursuant to which** ~~in the Dodd- Frank Act that require~~ the SEC ~~to~~ **has** ~~adopt~~ **adopted** ~~additional~~ rules and regulations **with which we must comply** in areas such as " say on pay " **voting** and ~~proxy access~~ **" pay versus performance " disclosure requirements** . Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Changing laws, regulations, and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social, and governance (" ESG ") disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. Compliance with the rules and regulations applicable to public companies can be time- consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. For example, ~~we expect~~ these rules and regulations ~~to~~ **may** make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of **any** additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired. Pursuant to Section 404 of the Sarbanes- Oxley Act, we are required to furnish a report by our management on, among other things, our internal control over financial reporting. To achieve compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which process is both costly and challenging. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Moreover, Section 404 (b) of the Sarbanes- Oxley Act requires our independent registered public accounting firm to annually attest to the effectiveness of our internal control over financial reporting, which has, and will continue to, require increased costs, expenses and management resources. An independent assessment of the effectiveness of our internal controls could detect problems that our management' s assessment might not. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated, leading to financial statement restatements and requiring us to incur significant expenses associated with remediation. We are required to disclose changes made in our internal controls and procedures on a quarterly basis. **As disclosed in Item 9A of this Annual Report on Form 10- K, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023 as a result of a material weakness which resulted from design deficiencies over the level of expected control evidence that was required to substantiate the performance of management' s review over the prospective financial information that was used within the accounting for the acquisition of Neovasc. The material weakness did not result in any material misstatements in our previously issued financial statements, nor in the financial**

statements included in this Annual Report on Form 10- K. Management, with the oversight of the Audit Committee of the Board of Directors, is taking comprehensive actions to remediate this material weakness; however full remediation depends on verification of the effective operation of applicable controls in the context of a future acquisition and we cannot assure you that our remediation efforts will fully remediate the material weakness in a timely manner. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. If we identify **additional** material weaknesses in our internal control over financial reporting, if we are unable to assert that our internal control over financial reporting is effective or if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, **including as a result of failure to remediate our existing material weakness,** investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation, as well as investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies . We are highly dependent on our..... client base, patient base and revenue . Litigation and other legal proceedings may adversely affect our business. From time to time, we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and / or injunctive relief that may affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings, or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand, undermine our customers' confidence, and reduce long- term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations. Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the **U. S. Food and Drug Administration (“** FDA **”)** and other domestic and foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; (iv) data privacy laws in the United States and similar foreign laws; or (v) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations designed to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in preclinical studies or clinical trials or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics and a global anti-corruption policy, **and we have a program for monitoring and periodically auditing our distributors' compliance with various anti- corruption rules and regulations,** but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations. Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and financial markets. If the conditions in the general economy deteriorate, including as a result of changes in gross domestic product growth, recent volatility and disruptions in the capital and credit markets, rising interest rates, increasing effects of inflation, **uncertainty with respect to** the **federal debt ceiling** ~~COVID- 19 pandemic~~ and ~~the responses~~ **budget and potential government shutdowns related** thereto, the ~~ongoing~~ **weakening of the global and U. S. economies, instability in the global banking sector, regional** ~~conflict~~ **conflicts around** ~~between Russia and Ukraine and~~ the **world** ~~responses thereto~~ , global supply- chain disruptions or the tightening of the global labor market, or otherwise, our business, financial condition, and operating results could be adversely affected. **Moreover, there has been recent turmoil in the global banking system. For example, on**

March 10, 2023, Silicon Valley Bank, which was one of four lenders under the Credit Agreement, was closed by the California Department of Financial Protection & Innovation, and the Federal Deposit Insurance Corporation (the " FDIC ") was named receiver for Silicon Valley Bank. While the FDIC took steps to make depositors of Silicon Valley Bank whole and we regained access to the cash, cash equivalents and short- term and long- term investments we held at Silicon Valley Bank or under Silicon Valley Bank management, there is no assurance that similar guarantees will be made in the event of further bank closures and continued instability in the global banking system. Our ongoing cash management strategy is to maintain diversity in our deposit accounts across financial institutions, but deposits in these institutions may exceed the amount of insurance provided on such deposits and there can be no assurance that this strategy will be successful. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, then our ability to access our cash, cash equivalents and short- term and long- term investments may be threatened, which could have a material adverse effect on our business and financial condition. Moreover, events such as the closure of Silicon Valley Bank, in addition to other global macroeconomic conditions, may cause further turbulence and uncertainty in the capital markets. A severe or prolonged economic downturn ~~,~~ could result in a variety of risks to our business, including driving hospitals to tighten budgets and curtail spending, which would negatively impact our sales and business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition, and results of operations. Natural disasters, pandemics and man- made business disruptions such as war and terrorism could ~~seriously harm~~ **adversely impact** our future revenue and financial condition and increase our costs and expenses. We operate our business in regions subject to earthquakes, fires, medical epidemics, and pandemics, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, shifting climate patterns, extreme weather conditions, and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. Additionally, we rely on third- party manufacturers to produce various components that are integrated into our products, third- party distributors to distribute our products and hospitals to purchase our products, each of which is also vulnerable to such natural or man- made disasters or business interruptions. Our ability to obtain supplies of components and to distribute and sell our finished products could be disrupted if the operations of these suppliers, distributors, or hospitals were materially affected by any such natural or man-made disaster or other business interruption. Our corporate headquarters and **principal** manufacturing facilities are located in Santa Clara, California, near major earthquake faults and fire zones **. We are also expanding our manufacturing capabilities into Costa Rica, which is in an earthquake zone and may be subject to other natural disasters** . If a major earthquake, wildfire or other natural disaster were to damage our facilities or the facilities of our suppliers and service providers, or impact the ability of our employees or the employees of our suppliers and service providers to continue business operations, we may experience potential impacts ranging from production and shipping delays to lost revenues and increased costs. The occurrence of any of these natural or man- made disasters or other business disruptions could ~~seriously harm~~ **adversely impact** our operations and financial condition and increase our costs and expenses. In addition, our global operations expose us to risks associated with public health crises, such as pandemics and epidemics, which could harm our business and cause our operating results to suffer. ~~The COVID- 19 pandemic and related containment measures adversely affected our financial results and business operations during the year ended December 31, 2022 as we continued to experience disruptions in the operations of certain of our third- party suppliers. While the COVID- 19 pandemic and related containment measures may continue to adversely impact our financial results and business operations in the future, the extent to which the pandemic will continue to adversely affect us will depend on numerous evolving factors and future developments that we are not able to predict, including the duration, spread and severity of any outbreak, the availability and effectiveness of vaccines against COVID- 19, continued mutations of the virus and the impact of such mutations on transmission rates and vaccine efficacy, the nature, extent and effectiveness of containment measures, the extent and duration of the effect on the economy, and how quickly and to what extent normal economic and operating conditions can resume.~~ Further, acts of war, terrorism, labor activism or unrest and other geopolitical unrest ~~, including the ongoing conflict between Russia and Ukraine and the responses thereto,~~ could cause disruptions in our business, the businesses of our partners or the economy as a whole. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations. Regulations related to conflict minerals may cause us to incur additional expenses and could limit the supply and increase the costs of certain materials used in the manufacturing of our products. We are subject to requirements under the Dodd- Frank Act that require us to conduct due diligence on and disclose whether or not our products contain conflict minerals as defined under these provisions. The implementation of these requirements could adversely affect the sourcing, availability, and pricing of the materials used in the manufacture of components used in our products. In addition, we incur additional costs to comply with the disclosure requirements, including costs related to conducting diligence procedures to determine the sources of minerals that may be used or necessary to the production of our products and, if applicable, potential changes to products, processes, or sources of supply as a consequence of such due diligence activities. It is also possible that we may face reputational harm if we determine that certain of our products contain minerals not determined to be conflict free or if we are unable to alter our products, processes, or sources of supply to avoid such materials. ~~Investors' expectations of our performance relating to~~ ESG factors may impose additional costs and expose us to new risks. There is an increasing focus from certain investors **, regulators** , employees, customers and other stakeholders concerning corporate responsibility, specifically related to ESG matters. Some investors may use these non- financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. The growing investor demand for

measurement of non- financial performance is addressed by third- party providers of sustainability assessment and ratings on companies. The criteria by which our corporate responsibility practices are assessed may change due to the constant evolution of the sustainability landscape, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies and / or actions with respect to corporate social responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies. **In addition, we are subject to emerging climate change policies. For example, in October 2023 California adopted Assembly Bill 1305, which became effective January 1, 2024 and creates new annual disclosure requirements regarding substantiation of certain climate- related statements, and may increase our compliance costs to the extent we make any such claims. Also in October 2023, California adopted two additional climate- related bills which, starting in 2026, will require companies doing business in California that meet certain revenue thresholds to publicly disclose certain greenhouse gas emissions data and to publish climate- related financial risk reports. The SEC has also proposed new rules that, if adopted in their current form, would impose new disclosure requirements regarding, among other ESG topics, climate- related risks, greenhouse gas emissions data and any publicly set climate- related targets or goals. Efforts to comply with these or any additional new regulatory requirements, or our failure to do so, could have adverse impacts on our business, operating results and financial condition.** Furthermore, in the event that we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope, target and timelines of such initiatives or goals. If we fail to satisfy the expectations of investors, **regulators,** customers, employees and other stakeholders ~~or~~ **, if** our initiatives are not executed as planned, **or if we fail to implement sufficient oversight or accurately capture and disclose ESG matters,** our reputation and business, operating results and financial condition could be adversely impacted ~~. In addition, the SEC has also proposed a draft rule that requires climate disclosures in financial filings. To the extent the SEC proposal becomes effective for our company, we will be required to establish additional internal controls, engage additional consultants, and incur additional costs related to evaluating, managing and reporting on our environmental impact and climate- related risks and opportunities. If we fail to implement sufficient oversight or accurately capture and disclose on environmental matters, our reputation, business, operating results and financial condition may be materially adversely affected~~ . RISKS RELATED TO OUR PRODUCTS We currently manufacture and sell products that are used in a limited number of procedures and for only certain specified indications, which could negatively affect our operations and financial condition. Currently, our commercialized products consist primarily of our **intravascular lithotripsy (“** IVL **”)** system (“ IVL System ”) using **our** M5 catheter, M5 catheter and S4 catheter for the treatment of **peripheral artery disease (“** PAD **”)** , and **our** C2 catheter ~~for the treatment of CAD, each of which is available in the United States, Europe,~~ and ~~other international markets. We also market and sell our~~ C2 catheter for the treatment of **coronary artery disease (“** CAD ~~only~~ **”), each of which is available** in ~~select~~ **the United States, Europe, and other international** markets ~~in Europe~~ **. We also market** and **sell** our L6 catheter for the treatment of PAD only in the United States **and our coronary sinus reducer (“ Reducer ”) technology for the treatment of refractory angina only in select markets in Europe** . We are ~~therefore~~ dependent on widespread market adoption of these products and we will continue to be dependent on the success of these products for the foreseeable future. There can be no assurance that our products will gain a substantial degree of market acceptance among specialty physicians, patients, or healthcare providers. Our failure to successfully increase sales of these products or any other event impeding our ability to sell these products would result in a material adverse effect on our business, financial condition, and results of operations. Our long- term growth depends on our ability to enhance our products ~~, expand our indications~~ and develop and commercialize additional products in a timely manner. If we fail to identify, acquire, and develop other products, we may be unable to grow our business over the long- term. As a significant part of our growth strategy, we intend to develop and commercialize additional products through our research and development program or by licensing or acquiring additional products and technologies from third parties. The success of this strategy depends upon our ability to identify, select, **develop,** and **license or** acquire the rights to products and technologies on terms that are acceptable to us. The success of any new product offering or product enhancements **so licensed or acquired** will depend on several factors, including our ability to: • assemble sufficient resources to acquire or discover additional products; • properly identify and anticipate physician and patient needs; • develop and introduce new products and product enhancements in a timely manner; • develop intellectual property rights for our new products and continue to protect intellectual property rights for existing products; • avoid infringing upon **or misappropriating** the intellectual property rights of third ~~-~~parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials; • obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications; • be fully FDA- compliant with marketing of new devices or modified products; • produce new products in commercial quantities at an acceptable cost; • provide adequate training to potential users of our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop an effective and dedicated sales and marketing team. Proposing, negotiating, and implementing an economically viable product or technology acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of approved or cleared products **or technologies** . We may not be able to acquire or license the rights to additional approved or cleared products **or technologies** on terms that we find acceptable, or at all. If we are unable to develop **product enhancements or** suitable potential products through internal research programs or by obtaining rights from third parties, it could have a material adverse effect on our business, financial condition and results of operations. If our products are not approved for planned or new indications, our commercial opportunity will be limited. Our commercial strategy includes pursuing additional vascular indications for our products. Conducting clinical studies to obtain data for new or additional indications may require substantial additional funding. We cannot assure you that we will be able to successfully obtain clearance or approval for any of these additional product indications. Even if we obtain clearance or

approval to market our products for additional indications in the United States or internationally, we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for new or additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations. Product clearances and approvals can often be denied or significantly delayed and material modifications to our products may require new clearances or pre- market approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained. Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510 (k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510 (k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510 (k) clearance must be supported by preclinical and clinical data. ~~Our ability to enroll patients in clinical trials has been and may continue to be impacted by the ongoing COVID- 19 pandemic.~~ The PMA process typically is more costly, lengthy, and stringent than either the 510 (k) process or the de novo classification process. Unlike a 510 (k) review, which determines " substantial equivalence, " a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries. We may be required to obtain PMAs, PMA supplements, de novo classification, or additional 510 (k) pre- market clearances to market modifications to our existing products, such as changes to the intended use or technological characteristics of our products. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether a device modification requires new approval, supplemental approval or clearance; however, the FDA can review a manufacturer' s decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. Any modification to an FDA- cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510 (k) clearance or possibly a PMA. For Class III devices, changes that affect safety and effectiveness will require the submission and approval of a PMA supplement. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA requires us to obtain PMAs, PMA supplements or pre- market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing of the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties. The FDA may not approve our current or future PMA applications or supplements or clear our 510 (k) applications for new products or modifications to, or additional indications for, our products on a timely basis or at all. 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. The FDA may also 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 products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations. **The time required to obtain a certificate of conformity from a Notified Body in the EU is also lengthy and unpredictable (the MedTech Europe industry association has recently reported a time- to- certification of 13- 18 months on average under the MDR across all device categories). The processes required in the EU before a new medical device may be marketed in the EU generally involves the conduct of clinical studies to generate sufficient clinical evidence, the preparation of technical documentation, the implementation of a quality management system and the submission to assessment and audits by a Notified Body. Similarly in China, the time required to obtain a registration certificate from the NMPA is also lengthy and unpredictable. The processes required before a new medical device may be marketed in China generally involves the conduct of clinical trials to generate sufficient Asian / Chinese population clinical evidence, the preparation of technical documentation and registration application documents, the implementation of a quality management system, and the passing of a random onsite audit by the NMPA. Other** ~~International~~ **international** regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non- U. S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non- U. S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining **any** necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations. We may expend our limited resources to pursue particular products, product candidates, indications or discovery programs and fail to capitalize on products, product candidates, indications or discovery programs that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on specific products, product candidates, indications, and discovery programs. As a result, we may forgo or delay pursuit of other opportunities that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable products. Moreover, if we do not accurately evaluate the commercial potential or target market for a particular product or product candidate, we may relinquish valuable rights to that product or product candidate through future

collaborations, licenses, and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product or product candidate. Our products are approved only **in specific countries and** for specific ~~countries and~~ uses. The use, misuse or off- label use of our products may ~~also~~ result in injuries that lead to product liability suits, which could be costly to our business. Our products are approved for use in **specific** ~~a limited number of~~ countries and for only the indications and uses specified in the applicable approval. **Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA.** This prohibits **us from** ~~our ability to market~~ **marketing** or ~~advertise~~ **advertising** our products for any ~~other~~ indication **for which they have not been approved** , which could limit our growth. Additionally, our **catheter** products are contra- indicated for use in the carotid or cerebrovascular arteries ~~. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA~~ . Use of a device outside of its cleared or approved indication is known as " off- label " use. We cannot prevent a physician from using our products for off- label uses, as the FDA ~~does~~ **and international regulatory agencies do** not restrict or regulate a physician' s choice of treatment within the practice of medicine. However, we are not allowed to actively promote or advertise our products for off- label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head- to- head comparative clinical studies, which are expensive and time-consuming. For more information regarding our regulatory risks, including those related to off- label use, see the section titled " — Risks Related to Government Regulation and Our Industry " below. We currently require limited training in the use of our products ~~incorporating our IVL technology (" IVL Technology ")~~ because we market primarily to physicians who are experienced in the interventional techniques required to use our devices. If demand for our products continues to grow, **there is a possibility that** less experienced physicians will ~~likely~~ use our products, potentially leading to more injury and an increased risk of product liability claims. The use, misuse or off- label use of our products may in the future result in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed. Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We may experience numerous unforeseen events in relation to a clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products, modifications of existing products or new indications for existing products, including: • risks relating to clinical trial approvals, including: • delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities, including in relation to the design, protocol or implementation of our clinical trials; and • delay or refusal of regulators or institutional review boards (" IRBs ") to authorize us to commence a clinical trial at a prospective trial site. • risks relating to clinical trial enrollment and trial management, including: • delays or ~~failure~~ **failures** to reach agreement on acceptable terms with prospective clinical research organizations (" CROs ") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • slower enrollment in our clinical trials than anticipated, high screen failure rates in our clinical trials, or delays in patient enrollment and variability in the number and types of patients available for clinical trials; • lower than anticipated retention rates of patients and volunteers in clinical trials or difficulty in maintaining contact with patients after treatment, resulting in incomplete data; • delays relating to adding new clinical trial sites or issues managing multiple clinical sites; • our CROs or clinical trial sites may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or deviate from the protocol or drop out of a trial; • we, the applicable IRBs, the Data Safety Monitoring Board for such trial, or the FDA or other applicable regulatory authorities may require that we or our investigators suspend or terminate our clinical trials for various reasons, including, among others **,** (i) failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA' s current GCP, regulations, or our clinical protocols, (ii) inspection of the clinical trial operations or trial site by the FDA or other applicable regulatory authority resulting in the imposition of a clinical hold, (iii) unforeseen safety issues or adverse side effects, (iv) failure to demonstrate safety and effectiveness, (v) changes in governmental regulations or administrative actions, (vi) lack of adequate funding to continue the clinical trial, (vii) exposure of participating patients to unacceptable health risks, (viii) noncompliance with regulatory requirements, ~~or~~ **and** (ix) other safety concerns; and • we may exceed our budgeted costs due to difficulty in accurately predicting costs associated with clinical trials. • risks related to clinical trial results, including: • our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials and / or preclinical testing which may be expensive and time- consuming, or we may elect to abandon projects that we expected to be promising; • reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns; • trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities; • the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans; and • the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials differently than we do. • risks related to investigation devices used in the clinical trial, including: • the quality of the investigation devices may fall below acceptable standards; • we may be unable to manufacture sufficient quantities of our products to commence or complete clinical trials; and • the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory. In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest ~~that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself~~ . Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and / or ~~and~~ stock awards in connection with such services. If these relationships and any related compensation to or ownership interest by

the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development. We do not know whether any of our future preclinical studies or clinical trials will commence as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence sales and generate associated revenue with respect to the applicable product. Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension, or revocation of expanded regulatory clearance or approval of our products. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products. From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products. From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, including GCP guidelines, the Common Rule, and FDA human subject protection regulations. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP- compliant clinical trials on our products properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant, or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for **any** other ~~reasons~~ **reason** , our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products. The ~~continuing~~ **continued** development of our products depends upon ~~our~~ **us** maintaining strong working relationships with physicians. The research, development, marketing and sale of our current products and potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon us maintaining strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and in marketing, and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, the medical device industry' s relationship with physicians is under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General (the " OIG "), the U. S. Department of Justice (the " DOJ "), state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry' s relationships with physicians or an investigation into our compliance **with such requirements** by the OIG, the DOJ, state attorney generals and other government agencies, could have a material adverse effect on our business, financial condition, and results of operations. For more information on risks relating to the laws impacting our relationships with physicians and other healthcare professionals, see the section titled " — Risks Related to Government Regulation and Our Industry " below. We have limited commercial manufacturing experience and may experience development or manufacturing problems or delays in producing our products and planned or future products that could limit our potential revenue growth or increase our losses. We are continuing to develop our expertise in commercially manufacturing our products and our ability to manufacture these products at the volume that we anticipate will be required if we achieve planned levels of commercial sales. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Our failure to obtain required components or sub- assemblies when needed and at a reasonable cost would adversely affect our business. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture our existing, planned, or future products in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design, and production standards required to market our products successfully. **Additionally, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained operators to deliver our products within the time frames our customers expect.** We may encounter unforeseen situations in the manufacturing and assembly of our products that ~~would~~ result in delays or shortfalls in our production. For example, we may be required to change our production processes and assembly methods in order to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period. We produce a significant majority of our **products** ~~IVL catheters~~ at our facility in Santa Clara, California, therefore any contamination of the controlled environment, equipment malfunction or failure to strictly follow procedures could significantly reduce our yield. A drop in yield could increase our cost to manufacture our products or, in more

severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield could require substantial time and resources. If our manufacturing activities are adversely impacted or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance ~~for~~ **of** our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations. We depend upon third- party suppliers and contract manufacturers, including single source component suppliers and a third- party contract manufacturer that produces a portion of our demand for certain ~~catheters~~ **products** , making us vulnerable to supply problems and price fluctuations. We depend on our third- party contract manufacturer located in Costa Rica to manufacture a portion of the demand for certain ~~catheters~~ **products** . If our contract manufacturers fail to deliver the required commercial quantities of finished products on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. We also rely on third- party suppliers to provide us with components used in the manufacturing of our products. Certain components of our products are provided by single source suppliers. In some cases, we purchase supplies through purchase orders and do not have long- term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers. We depend on our suppliers and contract manufacturers to provide us with materials or products in a timely manner that meet our quality, quantity, and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, including as a result of ~~the ongoing COVID- 19 pandemic and~~ ongoing global supply chain disruptions **or other factors beyond their control** , any of which could delay or impede their ability to meet our demand. For example, **during** the COVID- 19 pandemic ~~has disrupted~~ the operations of certain of our third- party suppliers **were disrupted** , resulting in increased lead- times for our purchases of some components and, in certain cases, requiring us to incur higher logistics expenses. We ~~have~~ worked closely with our manufacturing partners and suppliers **during the COVID- 19 pandemic** to enable us to source key components and maintain appropriate inventory levels to meet customer demand and have not experienced material disruptions in our supply chain to date. However, there is no assurance that we will not experience more significant disruptions in our supply chain in the future ~~, particularly if the operations of our contract manufacturing partners or any of our critical single source component providers are more severely impacted by the pandemic and associated containment measures~~ . Any supply interruption from our suppliers and contract manufacturers or failure to obtain additional suppliers or contract manufacturers for products or any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations. Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. These suppliers and contract manufacturers may cease producing the products or components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe alternate suppliers and contract manufacturers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers or contract manufacturers for any of these materials, components or services, if required, could be time- consuming, expensive and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers or contract manufacturers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay or which may not be obtained at all. If our third- party suppliers or contract manufacturers fail to deliver the required ~~commercial~~ quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or contract manufacturers capable of production at a substantially equivalent cost, volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented **, which could have material adverse effect on our business, financial condition and results of operations. A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could impact our revenues or gross margin. We are dependent on commercial freight carriers to deliver our products to our customers. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our net revenues and gross margin could materially decline. Additionally, if freight costs materially increase and we are unable to pass that increase along to our customers for any reason or otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be adversely affected** , which could have material adverse effect on our business, financial condition and results of operations. We and our third- party manufacturers and suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations. As a medical device manufacturer, we must register with the FDA and various non- U. S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain Good Manufacturing Practices (" cGMP "), including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our product and component

manufacturers and suppliers are also required to meet certain standards applicable to their manufacturing processes. We cannot assure you that we, our products, our component suppliers or our contract manufacturers comply or will continue to comply with all regulatory requirements. The failure by us or one of our suppliers or contract manufacturers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, until a new supplier or contract manufacturer has been identified and evaluated. Our or any product or component supplier' s or contract manufacturer ~~'~~ **'** s failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers or contract manufacturers to satisfy our business requirements, we can locate ~~new~~ **such** suppliers or contract manufacturers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations. In the EU, we must maintain certain International Organization for Standardization certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution (" BSI "), to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations. ~~Our success depends in large part on our IVL Technology.~~ If we are unable to successfully market and sell ~~products incorporating~~ our **products** ~~IVL Technology~~ , our business prospects will be significantly harmed, and we may be unable to achieve revenue growth. Our future financial success will depend substantially on our ability to effectively and profitably market and sell our products ~~incorporating our IVL Technology~~ . The commercial success of our products and any of our planned or future products will depend on a number of factors, including: • the actual and perceived effectiveness and reliability of our products, especially relative to alternative products; • the prevalence and severity of any adverse patient events involving our products; • the results of clinical trials relating to the use of our products; • our ability to sustain meaningful clinical benefits for our patients; • our ability to obtain regulatory approval to market our planned or future products for use in treating PAD, CAD **,** ~~and aortic stenosis (" AS ")~~ **and refractory angina** in the United States **and in international markets** ; • the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products; • the degree to which treatments using our products are covered and receive adequate reimbursement from third- party payors, including governmental and private insurers; • the degree to which physicians adopt our products; • our ability to obtain, maintain, protect and enforce our intellectual property rights in and to our **technologies** ~~IVL Technology~~ and our products that incorporate our **technologies** ~~IVL Technology~~ ; • our ability to treat medial calcium and sustain a meaningful clinical benefit better than our competitors and alternative treatments or therapies; • our ability to achieve and maintain compliance with all regulatory requirements applicable to our products; • the extent to which we are successful in educating physicians about PAD, CAD ~~and~~ **,** AS **and refractory angina** in general, and the benefits of our products in treating such conditions; • the strength of our marketing and distribution infrastructure; • the effectiveness of our and our distributors' marketing and sales efforts outside the United States and our own efforts to build and manage our internal sales team; • the level of education and awareness among physicians and hospitals concerning our products; • our reputation among physicians and hospitals; • our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current cGMP and the Quality System Regulation (" QSR "); and • whether the FDA or comparable non- U. S. regulatory authorities require us to conduct additional clinical trials for future or current indications. If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition, and results of operations. Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our products and any new product or product indications that we introduce, which will, in turn, depend in part on our success in growing our customer base and driving increased use of our products. New products or product indications will also need to be approved or cleared by the FDA and comparable non- U. S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition, and results of operations. The commercial success of our products will depend upon attaining significant brand awareness and market acceptance of our products among physicians, healthcare payors and the medical community. Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to providers, cost effective. To accomplish this, we need to continue to educate the medical community about the safety, efficacy, necessity, and efficiency of our products. This will require educating them not only about the benefits of our ~~technology~~ **technologies** , but also about the ~~impact~~ **diseases that our products target and the range** of **patient** ~~calcified plaque on~~ treatment choices and outcomes. We ~~believe that focusing on calcified plaque is a paradigm shift in the treatment of atherosclerotic cardiovascular diseases because other interventions have not specifically focused on this source of atherosclerosis. Additionally, we~~ will need to convince the medical community that the additional cost and time of integrating ~~the~~ IVL **and Reducer** ~~procedure~~ **procedures** ~~, designed to prepare the vessel for the subsequent stenting or angioplasty procedure,~~ is worth the increased efficacy of the overall procedure and improvement in patient outcomes. The failure of our clinical, marketing, and executive teams to drive this shift in thinking among physicians, patients, practitioners, third- party payors ~~,~~ and regulators could adversely affect our ability to grow our business. We cannot predict how quickly, if at all, physicians will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop, may never gain broad market acceptance among physicians and the medical community for some or all of our targeted indications. The degree of market acceptance of any of our products will depend on a number of factors, including: • whether physicians and others in the medical community consider our products to be safe and cost- effective treatment methods; • the potential and perceived advantages of our products over alternative treatment methods; • the prevalence and severity of any side effects associated with using our products; • product labeling or product insert

requirements by the FDA or other regulatory authorities; • limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities; • the cost of treatment in relation to alternative treatments methods; • the convenience and ease of use of our products relative to alternative treatment methods; • pricing pressure, including from group purchasing organizations (" GPOs "), seeking to obtain discounts on our products based on the collective buying power of the GPO members; • a substantial shift in the number of PAD procedures that are performed in office- based labs (" OBLs ") compared to those performed in a hospital as OBLs tend to have higher price sensitivity than hospitals; • the availability of coverage and adequate reimbursement for procedures using our products from third- party payors, including government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage and adequate reimbursement by third- party payors, including government authorities; • our ability to provide incremental clinical and economic data that show the safety, clinical efficacy and cost effectiveness of, and patient benefits from, our products; and • the effectiveness of our sales and marketing efforts for our products. ~~If we do not educate physicians about PAD and the existence of our products, our products may not gain market acceptance since many physicians do not routinely screen for PAD while screening for CAD.~~ Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies ~~, which~~ are more cost effective or **are** received more favorably ~~, are introduced~~. Failure to achieve or maintain market acceptance and / or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations. In addition, we believe that developing and maintaining awareness of our brand in a cost- effective manner is critical to achieving broad acceptance of our products and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and ~~,~~ even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand- building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our products. We manufacture and sell products that are used in a limited number of procedures and there is a limited total addressable market for our products. The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate. Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third- party estimates, including, without limitation, the number of patients with calcified cardiovascular disease and **refractory angina and** the assumed prices at which we can sell our products for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. In addition, our estimates of the sizes of the **relevant** ~~PAD and CAD~~ patient populations **for our products** include patients who are asymptomatic or in the early stages of disease; these patients might never progress to more advanced disease stages and, accordingly, might never be likely candidates for treatment with our products. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition ~~,~~ and results of operations. The market in which we participate is highly competitive, and if we do not compete effectively, our business, operating results and financial condition could be adversely impacted. There are numerous approved products for treating vascular diseases in the indications in which we have received clearance or approval and those that we are pursuing or may pursue in the future. Many of these cleared or approved products are well- established and are widely accepted by physicians, patients, and third- party payors who may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future. The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete or plan to compete with manufacturers and distributors of cardiovascular medical devices. The cardiovascular field is highly competitive and certain of our products may compete with products manufactured or reportedly under development by other companies, including Boston Scientific Corporation, ~~Cardiovascular Systems~~ **Medtronic plc** , ~~Inc~~ **Philips N** . **V. and Abbott Laboratories** (" ~~CSI~~ **Abbott** ") ~~, Medtronic plc, Philips N. V. and Abbott Laboratories~~. Many of these competitors are large, well- capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We may also compete with smaller medical device companies that have single products or a limited range of products. Some of our competitors have: • more established reputations and significantly greater name recognition within the medical community; • greater ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets; • broader or deeper relations with healthcare professionals, customers, regulatory agencies and third- party payors; • larger and more established distribution networks; • additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage; • greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and • greater financial and human resources for product development, sales and marketing, clinical resources and patent litigation. We believe that our proprietary **technologies** ~~IVL Technology~~, our focus on ~~calcified~~ cardiovascular disease, and our organizational culture and strategy, will be important factors in our future success. In response to attempts by companies to claim their products are competitive, we emphasize that our products are ~~unique~~ **pioneering** and treat patients with ~~calcified~~ cardiovascular disease safely and effectively, with improved outcomes and procedural cost savings. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business. Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry

consolidates, competition to provide products and services to industry participants, as well as competition for materials and supplies for our products, will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, results of operations or financial condition. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our products, which would have a material adverse effect on our business, financial condition, and results of operations. In the future our products may become obsolete, which would negatively affect operations and financial condition. The medical device industry is characterized by extensive research and rapid and significant technological change. There can be no assurance that other companies will not succeed in developing or marketing devices and products that are more effective than our **technologies** ~~IVL System~~ or that would render our **technologies** ~~IVL System~~ obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend, in part, on our ability to anticipate technological advancements and competitive innovations and introduce new products to adapt to these advancements and innovations. There can be no assurance that (i) our new product development efforts will result in any commercially successful products, (ii) we will be able to respond more quickly than our competitors, many of whom have greater financial, marketing, product development, and other resources, to new or emerging technologies or a changing clinical landscape, or (iii) we will be more successful in attracting potential customers and strategic partners than our competitors. Given these factors, we cannot assure you that we will be able to sustain or increase our level of success. Our failure to introduce new and innovative products in a timely manner, and our inability to maintain or grow the market acceptance of our existing products, could have a material and adverse effect on our business, results of operations, financial condition, and cash flows. Adequate reimbursement may not be available for the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably. In both U. S. and non- U. S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third- party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third- party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Third- party payors in the United States generally do not provide direct reimbursement for our products. Rather, we expect certain components of our IVL System to continue to be purchased by hospitals and other providers who will then seek reimbursement from third- party payors for the procedures performed using our products. While third- party payors generally cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third- party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, to permit hospitals and physicians to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. Third- party payors are increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Furthermore, although we believe there is potential to improve on the current reimbursement profile for our devices in the future, the overall amount of reimbursement available ~~for PAD and CAD procedures~~ could remain at current levels or decrease in the future. Additionally, we cannot be sure that the ~~PAD and CAD procedure~~ reimbursement amounts will not reduce or otherwise negatively affect the demand for our marketed products. Failure by hospitals and other users of our products to obtain coverage and adequate reimbursement for the procedures using our products would cause our business to suffer. Third- party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third- party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre- approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such marketed products. ~~We~~ **Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. For example, Aetna announced it will require prior authorization for peripheral vascular interventions effective September 1, 2023. While we** have **not seen any** ~~established safety and effectiveness data in specific patient populations in the~~ **other** ~~treatment of PAD~~ **payors announce similar policies thus far, we can give no assurance that other third- party payors will not implement similar prior authorization requirements in the future. The clinical trial process is lengthy** and ~~CAD~~ **expensive with uncertain outcomes** . Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for ~~such~~ **our** products ~~and~~ **in additional targeted indications, or** other planned or future products, which would affect market acceptance of these products. **Clinical testing** ~~Because our IVL Technology~~ is **difficult to design** ~~relatively new in the treatment of CAD~~ and ~~PAD~~ **implement** , **can take many** ~~we have performed clinical trials only with limited patient populations. The long- term, one- year~~ **years , can be expensive,** ~~results of coronary IVL has been studied within stable coronary disease. Short- term~~ and **carries uncertain** ~~long- term results in this patient population are not predictive~~

~~for other coronary indications including acute coronary syndromes. Short- term results of peripheral IVL in the treatment of PAD have been studied across a variety of peripheral vessel beds and severity of PAD. The long- term effects of peripheral IVL in a large number of patients have not been released yet and the results of short- term clinical~~ outcomes ~~do not necessarily predict long- term clinical benefits or reveal long- term adverse effects~~ . The results of preclinical studies and clinical trials of our products conducted to date may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our ~~interpretation~~ **interpretations** of data and results from our clinical trials **conducted to date** do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier, feasibility clinical trials have nonetheless failed to replicate results in later, pivotal clinical trials and subsequently failed to obtain marketing approval. Products in later, pivotal stages of clinical trials may fail to show the desired safety and effectiveness despite having progressed through nonclinical studies and earlier, feasibility clinical trials. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products. The medical device industry has historically been subject to extensive litigation over product liability claims. We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing ~~,~~ or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre- existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub- assemblies. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our products; • injury to our reputation; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; and • the inability to market and sell our products. ~~We~~ **While we** believe we have adequate product liability insurance, ~~but~~ it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales. Defending a product liability suit, regardless of its merit or eventual outcome, could be costly, could divert management' s attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals. In addition, the occurrence of an adverse event relating to our products, a product recall or a product liability claim against us may cause our stock price to decline, which could result in securities class action litigation claims against us. Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage. We intend to continue to expand sales of our products internationally, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our products internationally even if approved. A variety of risks associated with marketing our products internationally could materially adversely affect our business. While the majority of our revenue to date has been in the United States, our current products are cleared in the EU and certain other international markets for the treatment of PAD ~~and ,~~ CAD **and refractory angina** , and international sales comprised ~~17~~ **20** % of our revenue for the year ended December 31, ~~2022~~ **2023** . Our future growth may depend, in part, on our ability to develop and commercialize our planned and future products in foreign markets. Sales of our products outside of the United States are and will be subject to foreign regulatory requirements governing clinical trials and marketing approval. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our planned or future products. We will incur substantial expenses in connection with our international expansion ~~. Additional risks related to operating in foreign countries include: • reliance on distributors; • differing regulatory requirements for approval of medical devices in foreign countries; • differing reimbursement, pricing and insurance regimes in foreign countries; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; • foreign~~

~~taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established; • potential liability under the U. S. Foreign Corrupt Practices Act of 1977, as amended (the " FCPA "), the U. K. Bribery Act 2010, or comparable foreign regulations; • the impact of the UK' s departure from the EU; • the existence of additional third- party patent rights of potential relevance to our business; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities domestically or abroad, including as a result of the ongoing global supply chain disruptions; • inflation and rising interest rates; • events resulting in negative impacts to, or uncertainty regarding, global trade, such as the COVID- 19 pandemic, and the reversal or renegotiation of international trade agreements and partnerships; and • business interruptions resulting from geopolitical actions, including war and terrorism, such as the ongoing conflict between Russia and Ukraine and the responses thereto, or natural disasters, including earthquakes, typhoons, floods and fires. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition and results of operations~~ . In addition, there can be no guarantee that we will receive approval to sell our products in every international market we target, nor can there be any guarantee that any sales would result even if such approval is received. Even if the FDA grants marketing approval for a product, comparable regulatory authorities of foreign countries must also approve the manufacturing or marketing of the product in those countries. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties, and costs for us and require additional trials and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could negatively affect our business, financial results, and results of operations. We face additional credit and compliance risks related to our international sales using foreign distributors. We partner with distributors for our products in select geographies outside of the United States. Specifically, as of December 31, ~~2022~~ **2023** , we have contracted with distributors who are actively selling our products in over 55 countries in North and South America, Europe, the UK, the Middle East, Asia, Africa, and Australia / New Zealand. For the year ended December 31, ~~2022~~ **2023** , approximately ~~17~~ **20** % of our sales were outside of the United States. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our results of operations. ~~In~~ **Although we have a program for monitoring and periodically** ~~addition~~ **auditing our distributors' compliance with various anti- corruption rules and regulations** , failure by our foreign distributors to comply with the FCPA or other applicable laws, rules and regulations, insurance requirements or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations. Governmental **sanctions,** export ~~or~~ **controls and** import ~~controls~~ **regulations** could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our **activities and** products **are** ~~may be~~ subject to U. S. **sanctions and** export ~~controls~~ **control and import regulations** . **The U. S. Department of the Treasury' s Office of Foreign Assets Control, the Bureau of Industry and Security at the U. S. Department of Commerce, and U. S. Customs and Border Protection administer regulations that restrict U. S. persons in conducting export and import activities and transacting business with or in certain countries, governments, entities and individuals subject to U. S. economic sanctions. Due to our operations, we are subject to such laws and regulations, which are complex and continuously changing. Such** ~~Governmental~~ **governmental** regulation ~~of~~ **on our activities and** the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding **sanctions and** the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions **may** prohibit the shipment of certain products and services to **certain** countries, governments **,** and persons **or for certain end uses** ~~targeted by U. S. sanctions~~ . If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of ~~certain~~ export privileges **, injunctions, asset seizures, debarment from government contracts and revocations or restrictions of licenses, as well as criminal fines and imprisonment** . Moreover, any new **sanctions,** export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or technologies targeted by such regulations, could **materially impact our operations and may** result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations. We are subject to numerous laws and regulations related to anti- bribery and anti- corruption, such as the FCPA and the **UKBA** ~~U. K. Bribery Act~~ and violations of these laws could result in substantial penalties and prosecution. For our sales and operations outside the United

States, we are subject to various heavily enforced anti- bribery and anti- corruption laws, such as the FCPA, **the UKBA** ~~U. K. Bribery Act 2010~~, and similar laws around the world. These laws generally prohibit offering, promising, authorizing or making improper payments, directly or indirectly, for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we or our third- party business partners and intermediaries fail to comply with the FCPA or other anti- corruption and anti- bribery laws. We leverage various third parties to conduct our business and sell our products abroad, including to government- owned universities and hospitals. We, our distributors, and our other third- party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities (such as in the context of obtaining government approvals, registrations or licenses or sales to government owned or controlled healthcare facilities, universities, institutes, clinics, etc.) and we may be held liable for the corrupt or other illegal activities of these third- party business partners and intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, representatives, contractors, business partners, intermediaries, or agents from violating or circumventing our policies and / or the law. Responding to any enforcement action or related investigation may result in a materially significant diversion of management' s attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti- bribery, anti- corruption or anti- money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U. S. government contracts, which could have a material and adverse effect on our business, financial condition and results of operations. RISKS RELATED TO GOVERNMENT REGULATION AND OUR INDUSTRY If we fail to comply with U. S. federal and state and international fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business operations and financial condition could be adversely affected. Healthcare providers and third- party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have obtained or may in the future obtain marketing clearance ~~or~~ **,** approval **, registration or certification** . Through our arrangements with principal investigators, healthcare professionals, third- party payors, and customers, we are exposed to broadly applicable anti- fraud and abuse, anti- kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations. In the United States, we are subject to various state and federal anti- fraud and abuse laws, including, without limitation, the U. S. federal Anti- Kickback Statute (the " Anti- Kickback Statute ") and the federal civil False Claims Act (the " False Claims Act "). Our relationships and our distributors' relationships with physicians, other health care professionals and hospitals are subject to scrutiny under various state and federal anti- kickback laws. There are similar laws in other countries. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include the Anti- Kickback Statute, the False Claims Act, federal Civil Monetary Penalties Statute, the federal ~~Health Insurance Portability and Accountability Act (" HIPAA ")~~, and the Physician Payments Sunshine Act, along with analogous state and foreign law equivalents, each as more fully described ~~in~~ in the sections titled " Business — Government Regulation — United States " and " Business — Government Regulation — International. " State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies recently have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti- Kickback Statute, False Claims Act and HIPAA' s healthcare fraud and privacy provisions. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including certain sales and marketing practices of our marketed **products** ~~IVL System~~, and financial arrangements with physicians, other healthcare providers, and other customers, could be subject to challenge under one or more such laws. For example, in the United States and certain foreign countries, we may ~~loan for free~~ **place at no charge** to customers both the reusable IVL generator and connector cable so long as the customer is purchasing our single- use catheters. Customers also have the option to purchase the IVL generator and connector cable either at the initiation of the relationship or following the consignment period. Additionally, we may consign catheters to our customers ~~, free of charge,~~ until a catheter is used at which time the customer is billed for the catheter. The Anti- Kickback Statute includes, among others, space and equipment rental safe harbors ~~. These~~ **as well as a discount** safe ~~harbors~~ **harbor. While we endeavor to structure our arrangements** ~~require, among other things, that the aggregate payment between the parties is set in advance and~~ consistent with **safe harbor requirements** ~~fair market value. As the IVL generator~~ and **industry best practices** ~~connector cable are provided for free, and no payment is made for storage of our catheters at customers' facilities~~, these arrangements may not satisfy these or other safe harbors or statutory exceptions. Therefore, if these arrangements were investigated, they would be subject to a facts and circumstances analysis to determine whether they include prohibited remuneration under the Anti- Kickback Statute **or other equivalent foreign laws** . If an arrangement were deemed to violate the Anti- Kickback Statute **or other equivalent foreign laws** , it may also subject us to violations under other fraud and abuse laws

such as the False Claims Act and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws. Achieving and sustaining compliance with applicable federal and state anti- fraud and abuse laws **, and the equivalent laws in foreign countries,** may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses, and could divert our management' s attention from the operation of our business. Companies settling False Claims Act, Anti- Kickback Statute or civil monetary penalties law cases also may be required to enter into a corporate integrity agreement with the OIG in order to avoid exclusion from participation (i. e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate integrity agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time- consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition, and results of operations. **Our operations outside the United States are governed by complex laws and regulations, and third- party partners who fail to comply with these laws during the performance of their obligations for us can create legal and other risks. Our international operations are subject to various laws, rules and regulations related to the distribution and sale of our medical devices. The failure of our company or our suppliers, vendors, joint venture partners or other third parties to operate in compliance with these laws and regulations could have a material adverse impact on our operations and results. For example, if a joint venture partner violates certain laws or regulations, such as the FCPA, the UKBA, Chinese anti- corruption rules and regulations, or other applicable laws during the performance of their obligations for us, it is possible that we could suffer adverse legal, financial and reputational consequences. These anti- corruption laws generally prohibit companies and their intermediaries from making improper payments to non- U. S. government officials and (in the case of the UKBA) private sector decision makers for the purpose of obtaining or retaining business. The reliance on third parties to operate in international markets and predominance of government administered healthcare systems presents increased corruption- related risks, and defending against an alleged violation of law could result in financial loss, significant time and resources and reputational damage, and may have a material adverse effect on our business, financial condition, and results of operations.** Regulatory compliance is expensive, complex, and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business. The FDA and similar foreign agencies regulate our products as medical devices. Complying with these regulations is costly, time- consuming, complex, and uncertain. FDA regulations and regulations of similar **foreign** agencies specific to medical devices are wide- ranging and include, among other things, oversight of: • product design, development, manufacturing (including suppliers) and testing; • laboratory, preclinical and clinical studies; • product safety and effectiveness; • product labeling; • product storage and shipping; • record keeping; • pre- market clearance ~~or~~ **,** approval **, registration or certification** ; • marketing, advertising and promotion; • product sales and distribution; • product changes; • product recalls; and • post- market surveillance and reporting of deaths or serious injuries and certain malfunctions. Our current products are subject to extensive regulation by the FDA and non- U. S. regulatory agencies. For example, our current products are regulated by the FDA and are subject to " general controls " which include: registering with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting recalls and certain device field removals and corrections to the FDA; and obtaining pre- market notification 510 (k) clearance for devices prior to marketing. Some devices known as " 510 (k)- exempt " devices can be marketed without prior marketing- clearance or approval from the FDA. In addition to the " general controls, " some Class II medical devices are also subject to " special controls, " including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510 (k) clearance, most Class III devices are subject to PMA. Our C2 catheter **and C2 catheter** for the treatment of CAD ~~is~~ **are** designated as ~~a~~ Class III ~~product~~ **products** and ~~will~~ **the related approvals** ~~follow~~ **followed** the PMA process. As a company, **other than our C2 and C2 products we do not have prior experience in obtaining PMA approval. Our C2 catheter and C2 catheter for the treatment of CAD are designated as Class III products and the related approvals followed the PMA process. As a company, other than our C2 and C2 products** we do not have prior experience in obtaining PMA approval. Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials and clearance or approval from the FDA and non- U. S. regulatory agencies prior to commercial sale and distribution. The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving marketing, business practices and product quality management. Failure to comply with applicable U. S. requirements **and equivalent foreign requirements** regarding, for example, promoting, manufacturing, or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, **withdrawal, suspension or limitation of certificates of conformity (in the EU) or registration certificate (in China),** injunctions, fines, civil penalties, and criminal prosecution. The FDA **and non- U. S. state agencies, such as the NMPA in China,** can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non- U. S. regulatory agencies could have a material adverse effect on our business, financial condition and results of operations. Our failure to comply with applicable regulatory requirements could result in

enforcement action by the FDA **, U. S.** or **non- U. S.** state agencies **and our Notified Body (in the EU)** , which may include any of the following actions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • stipulated judgments or other administrative remedies; • customer notifications for repair, replacement, or refunds; • recall, detention, or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance or PMA approval of new products or modified products **, as well as certificates of conformity (in the EU) and registration certificates (in China)** ; • operating restrictions; • withdrawing 510 (k) clearances or PMA approvals that have already been granted **, as well as suspension, withdrawal or limitation of certificates of conformity (in the EU) or registration certificates (in China); • suspension or withdrawal of our ISO 13485 certificate** ; • refusal to grant export approval for our products; • the requirement to enter into corporate integrity agreements; • civil proceedings and criminal prosecution; and • unanticipated expenditures to address or defend such actions, and the diversion of key personnel and management' s attention from their regular duties. If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations and may result in greater and continuing governmental scrutiny of our business in the future. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained commercial clearances and approvals to market a number of our products to date, these clearances or approvals can be revoked if safety or efficacy problems develop. The FDA **and equivalent authorities in foreign countries** also ~~regulates~~ **regulate** the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances ~~and~~ **,** approvals **, registrations and certifications** , that there are adequate and reasonable data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA **or any equivalent foreign authority** determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions **. Similar regulations exist in other foreign countries where we operate** . Although we have obtained regulatory clearance for a number of our products in the United States and / or in certain non- U. S. jurisdictions, they will remain subject to extensive regulatory scrutiny. Although a number of our products have received regulatory approval **, registration or certification** in the United States and in certain non- U. S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, effectiveness and other post- market information, including both federal and state requirements in the United States and requirements of comparable non- U. S. regulatory authorities. Our manufacturing facility is required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510 (k) or PMA application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory clearances ~~or~~ **,** approvals **, registrations or certifications** that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted, will be subject to the conditions of approval, or will contain requirements for potentially costly post- marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post- clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in cleared or approved labeling for each product. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. For certain changes, to a cleared or approved product, including certain changes to product labeling, the holder of a cleared 510 (k) or approved PMA application may be required to submit a new application and obtain clearance or approval. If a regulatory agency discovers previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured or disagrees with the promotion, marketing or labeling of our products, such regulatory agency or enforcement authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition, a regulatory agency or enforcement authority may, among other things: • subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication or correspondence; • issue warning or untitled letters that would result in adverse publicity or may require corrective advertising; • impose civil or criminal penalties; • suspend or withdraw regulatory clearances or approvals; • refuse to clear or approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our sub-assembly suppliers' facilities; • seize or detain products; or • require a product recall. In addition, violations of the U. S. federal Food, Drug and Cosmetic Act (" FD & C Act "), relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations. We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off- label

promotion of our products. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off- label use of our products. Healthcare providers may use our products, if approved, off- label, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. However, if the FDA determines that our promotional, reimbursement, or training materials for sales representatives or physicians constitute promotion of an off- label use, the FDA could request that we modify our training, promotional or reimbursement materials and / or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, and significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off- label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Although we train our sales force not to promote our products for off- label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory agency could conclude that we have engaged in off- label promotion. For example, the government may take the position that off- label promotion resulted in inappropriate reimbursement for an off- label use in violation of the False Claims Act for which it might impose significant civil fines and even pursue criminal action. If this were to occur, our reputation could be damaged, and adoption of the products by our customers would be impaired. Our products may be subject to recalls after receiving FDA or foreign approval or clearance, or may cause or contribute to a death or a serious injury or malfunction in certain ways prompting voluntary corrective actions or agency enforcement actions, which could divert managerial and financial resources, harm our reputation, and adversely affect our business. The FDA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture, or if there is a reasonable likelihood our products might cause or contribute to a death or a serious injury or malfunction. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality- related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation, and adversely affect our business. If we initiate a future correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. We are also subject to the correction and removal reporting regulations, which require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device or to remedy a violation of the FD & C Act caused by the device which may present a risk to health. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the FDA' s observations to the FDA' s satisfaction, could subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals, and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation, and have a material adverse effect on our business, financial condition and results of operations. Any adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as an inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit as a result of a corrective action, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations. If we or our suppliers fail to comply with the FDA' s QSR or any applicable state or country equivalent, our operations could be interrupted, and our potential product sales and results of operations could suffer. Our manufacturing processes and those of our third- party suppliers must comply with the FDA' s QSR, which covers the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process where we market products in non- U. S. jurisdictions. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic announced and unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we experience an unsuccessful QSR inspection, our operations could be disrupted, and our manufacturing could be interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut- down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline. We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services. The FDA has broad post- market and regulatory

enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We produce a significant majority of our **products** ~~IVL catheters~~ in- house at our facility in Santa Clara, California, which, together with our research and development, controlled environment room and office space, currently totals approximately ~~166~~ **201** , 000 square feet. Our Santa Clara facility has been ~~inspected~~ **approved** by the FDA and audited by the BSI. We have also entered into a contract manufacturing agreement with a third- party contract manufacturer to produce a portion of the demand for certain ~~catheters~~ **products** . We can provide no assurance that the FDA or other inspecting bodies will continue to find us or our suppliers to be in compliance with the QSR. If our or our contract manufacturer' s facilities are found to be in noncompliance or if we fail to take satisfactory corrective action in response to adverse QSR inspectional findings, the FDA could take legal or regulatory enforcement actions against us and / or our products, including but not limited to the cessation of sales or the recall of distributed products, which could impair our ability to manufacture our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Taking corrective action may be expensive, time- consuming and a distraction for management, and if we experience a shutdown or delay at our manufacturing facilities, we may be unable to manufacture our products, which would harm our business. Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and / or our products. We are also subject to periodic inspections by the FDA and other governmental regulatory agencies, as well as certain third- party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA' s and other comparable non- U. S. regulatory agencies' statutes, regulations or policies may change, and additional government regulation or statutes may be enacted, which could increase post- approval regulatory requirements, or delay, suspend or prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad. The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and / or agency enforcement actions. Any penalties, damages, fines or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management' s attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or pursuing the operations and activities in question, including the continued manufacturing and sale of any impacted product. Various claims, design features or performance characteristics of our medical devices that we may regard as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in our products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable. Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets. There have been and continue to be proposals by the federal government, state governments, regulators, and third- party payors to control or manage the increased costs of healthcare and, more generally, to reform the U. S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations. For example, in the United States ~~, in March 2010,~~ the Patient Protection and Affordable Care Act, as amended (the " ACA "), was ~~enacted. The ACA is~~ a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, (the latter of which since made non- enforceable), the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. The ACA has impacted existing government healthcare programs and has resulted in the development of new programs. Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to modify them or to alter their interpretation and implementation. It is possible that the ACA will be subject to further judicial challenges or Congressional modifications in the future. It is unclear how any efforts to challenge or modify the ACA or its implementing regulations, or portions thereof, or other healthcare reform measures, will impact our business. In addition, other healthcare reform legislative changes have been proposed and adopted since the ACA was enacted. For example, ~~on August 2, 2011,~~ the Budget Control Act of 2011 **includes** ~~was signed into law, which~~ , among other things, ~~includes~~ reductions to Medicare payments to providers of, on average, 2 % per fiscal year. Sequestration is currently set at 2 % and will increase to 2. 25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. Legislation affecting the implementation of certain taxes under the ACA has also been signed into law, including the TCJA, which includes a provision repealing ~~, effective January 1, 2019,~~ the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " **Subsequently** ~~On December 20,~~

~~2019~~ , the Further Consolidated Appropriations Act of 2020 repealed the medical device excise tax. Prior to the repeal, the tax was on a 4- year moratorium. **The** ~~On January 2, 2013, the~~ American Taxpayer Relief Act of 2012 ~~was signed into law~~ , which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. There likely will continue to be legislative and regulatory proposals at the federal and state levels, as well as internationally, directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm: • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; and • the availability of capital. Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations. Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained. 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 the United States in recent years, new legislation has been proposed and adopted at the federal and state levels that is effecting major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted and we may not be able to comply with the changed laws, they could increase the cost of manufacturing, marketing, or selling our product, could make approvals of pipeline products more difficult or prevent us from selling our products at all. We expect there will continue to be a number of legislative and regulatory changes to the U. S. health care system that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof and may impose additional costs or lengthen regulatory review times of planned or future products. If, as a result of legislative or regulatory healthcare reform, we cannot sell our products profitably, whether due to our own inability to comply with, or the inability of other economic operators in our supply chain to qualify under, any legislative reform, our business would be harmed. In addition, any change in the laws or regulations that govern the clearance and approval 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 or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. For example, in April 2017, the EU adopted **the** ~~a new Medical Devices Regulation (Regulation 2017 / 745) (“~~ MDR ~~”)~~ , which became effective May 26, 2021 and replaced the EU’ s Medical Devices Directive (93 / 42 / EEC) (“ MDD ”). Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The MDR is significantly more comprehensive and detailed than the MDD. Among other things, the MDR requires manufacturers to report on the composition of their products and verify the presence of any of 1, 200 substances referenced in the MDR. **On January 6, 2023, the European Commission published a proposal to amend the transitional provisions foreseen in the MDR. The proposal introduces an extension to the transitional periods established in the MDR to provide** ~~Medical~~ **medical** devices **manufacturers additional time to bring their medical devices into conformity with the MDR, subject to certain conditions. As a result of this amendment to the MDR, certificates of conformity may have additional validity until the end of 2027 or 2028, depending on the device classification. Additionally, UK Government is in the process of updating the current MDD- derived regime, the UK MDR. Revised post- market surveillance requirements are expected to apply later in 2024 with wider changes to follow in 2025. The CE mark will continue to be recognized in Northern Ireland whilst the Northern Ireland Protocol is in force, but it will only be recognized in Great Britain until the sooner of, the expiry of the applicable CE certificate, and (i) June 30, 2028 for general medical devices CE marked under the EU MDD; or (ii) June 30, 2030 for general medical devices CE marked under the EU MDR. After these dates, the UK mark is expected to become mandatory in Great Britain, and we will only be able to affix the UKCA mark on our products following completion of a conformity assessment procedure under the UK MDR, except** that ~~have~~ **it needs to be supervised by** a ~~valid CE Mark under MDD~~ **UK- based Approved Body rather than an EU- based Notified Body (unless the device is Class I and non- sterile / non- measuring meaning we** can **self- certify it)** ~~continue to be sold until May 2024 or until the CE Mark expires, whichever comes first, provided there are no significant changes to the design or intended use of the device~~ . Complying with the new requirements of **MDR and UK** MDR may cause regulatory authorization timelines for future medical device products to become extended and significantly increase

the costs of obtaining and maintaining CE ~~Marks~~ **marks and UK marks** for our products. Adjusting to **MDR and UK** MDR may be costly and disruptive to ~~our business. Broader legislative changes may also impact our operations. The UK held a referendum on June 23, 2016, in which voters approved withdrawal from the EU (commonly referred to as Brexit). On January 31, 2020, the UK withdrew from the EU and the transition period ended on December 31, 2020. The UK and EU reached agreement regarding their future relationship on December 24, 2020. As a result of Brexit, there may be greater restrictions on imports and exports into and out of the UK and EU countries and regulatory complexities that could adversely impact~~ our business. Environmental and health safety laws may result in liabilities, expenses, and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability. Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non- compliance could result in substantial liabilities, fines and penalties, personal injury and third- party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition, and results of operation. RISKS RELATED TO OUR INTELLECTUAL PROPERTY If we are unable to obtain and maintain patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be adversely affected. As with other medical device companies, our success depends in large part on our ability to maintain and solidify a proprietary position for our products, which will depend upon our success in obtaining and enforcing effective intellectual property (including patent claims) that cover the use, functionality and manufacture of such products. With respect to patents specifically, the process for filing, maintaining and enforcing rights in or obtaining licenses for patents is complex and subject to many risks and uncertainties, including the following: • Protection of Confidential Information. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. • Patentability. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. We cannot be certain that we were the first to make or file the inventions claimed in any of our patents or pending patent applications. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may ~~not~~ be prosecuted and enforced in a manner ~~consistent~~ **inconsistent** with the best interests of our business. • Patent Prosecution Process. The patent prosecution process is expensive, time- consuming, ~~and~~ complex **, and inconsistent between jurisdictions** , and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection or be subject to a third- party preissuance submission of prior art to the **U. S. Patent and Trademark Office (the "** USPTO **")** . • Filing Defects. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of material importance. In some instances, these defects will be expensive or not possible to remedy **. • Duty of Disclosure. We are required to submit information to the USPTO that we are aware of that is material to the patentability of our patent applications. Failure to do so can affect the validity or enforceability of our patents. While we endeavor to the best of our ability to submit such disclosure statements, it is possible that we will fail to identify material known information and / or fail to submit such information in a timely manner** . • Reduction in Scope of Patent. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or reduced after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. • Patent Maintenance Requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the ~~U. S. Patent and Trademark Office (the "~~ USPTO ~~")~~ and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non- U. S. government agencies require compliance with several procedural,

documentary, fee payment and other similar provisions during the patent application process. Failure to comply with such requirements may result in the abandonment of a patent application or the lapse of a patent in one or more jurisdictions. • Patent Lifespan. Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent **(having a** ~~is generally 14 years after its issue date, unless the~~ filing date ~~occurred~~ on or after May 13, 2015 **)** ~~, in which case the natural expiration of a design patent~~ is generally 15 years after its issue date. While various extensions may be available, the life of a patent, and the protection it affords, is limited. **Such extensions may be offset all or in part by delays in prosecuting the applications. Further, one or more patents may be subject to a terminal disclaimer with related patents, reducing the life of the patents to match the expiration of the related patents.** Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. • International Patent Protection. Filing, prosecuting, and defending patents on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. The laws of some foreign countries may not protect our patent rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. 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 where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents rights may not be effective or sufficient to prevent them from competing **. • European Unitary Patent & Unified Patent Court. The European Unitary Patent and European Unified Patent Court (the " UPC ") came into effect in 2023, which has changed the landscape for acquisition and enforcement of patents in Europe. With the implementation of the Unitary Patent, patents granted by the European Patent Office (the " EPO ") have the option of being validated in individual European countries, issued as a Unitary Patent, or a combination of both. Because the Unitary Patent does not have complete scope over all European countries that are members of the EPO, validation of EPO patents into certain individual jurisdictions remains necessary to secure patent rights in those countries (e. g., Great Britian, Spain, Switzerland and Ireland). As our patent applications are allowed by the EPO, we are evaluating them on a case- by- case basis to determine whether or not to obtain a Unitary Patent, patents validated in individual European countries, or a combination of both. Unitary Patents are subject to the jurisdiction of the UPC, which has minimal precedent, and thus a higher uncertainty for any litigation. Patents under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. For our European patents granted and validated in individual European countries before the UPC came into effect, we opted- out of the jurisdiction of the UPC for the transitional period (which will be at least seven years) until the UPC will hold jurisdiction over all patents granted by the EPO. Development of case law within the UPC may lead us to opt- in our earlier (non- Unitary) European patents at a later date before the end of the transitional period. We cannot predict with certainty the long- term effects of any potential changes** . • Third- Party Claims. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. For more information on the risks relating to third party claims, see " — Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. " • Third- Party Rights. Some of our patents and patent applications may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in- licenses. • Patent Licenses. Many medical device companies and academic institutions are competing with us and filing patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses from such third- party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in- license any intellectual property rights from third parties that we identify as necessary for planned or future products, for a variety of reasons, including actions of competitors and interests of the potential licensor. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products. • Changes in Patent Laws. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. For more information on the risks relating to changes in patent laws, see " — Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. " Consequently, we do not know whether our ~~IVL~~ products and technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or

products in a non- infringing manner which could materially adversely affect our business, financial condition, and results of operations. If we or any current or future licensors or licensees fail to establish, maintain, protect, or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. Any such outcome could impair our ability to prevent competition from third parties, which may have an adverse impact on our business and results of operations. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may become involved in opposition, derivation, revocation, reexamination, post- grant review, inter partes review (" IPR ") or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we may have to participate in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology or products. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. For example, **a** ~~petitions~~ **petition** for IPR of ~~U. S. Pat. No. 9, 642, 673 (the "' 673 patent "),~~ U. S. Pat. No. 8, 956, 371 (the "' 371 patent ") ~~and U. S. Pat. No. 8, 728, 091 (the "' 091 patent ")~~, which ~~are three~~ **is one** of our issued U. S. patents that ~~relate~~ **relates** to our **current** IVL ~~Technology~~ **technology** , ~~were~~ **was** filed ~~in~~ **on** December **7,** 2018 at the ~~U. S. Patent and Trademark Office' s (the "~~ USPTO ~~")~~ Patent Trial and Appeal Board (the " PTAB ") by CSI, **which was acquired by Abbott** ~~one of our competitors. The PTAB instituted IPR proceedings for all three patents and held oral hearings~~ in April ~~2020~~ **2023** ~~. On January 18, 2022, the U. S. Court of Appeals for the Federal Circuit issued two opinions affirming the previous decisions of the U. S. Patent and Trademark Office' s Patent Trial and Appeal Board, finding that the claims for the ' 673 patent and the ' 091 were invalid. Accordingly, the IPR proceedings initiated by CSI for the' 091 patent and the' 673 patent are concluded and resulted in the loss in scope of these two patents, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours~~ . On July 8, 2020, the PTAB ruled that one claim (" Claim 5 ") in the' 371 patent is valid and ruled that all other claims in the' 371 patent are invalid. **We have filed a notice of appeal of** ~~On August 27, 2020, further briefing by the parties was requested by~~ the PTAB **rulings** ~~in the' 371 patent proceeding~~ to ~~assess whether recent guidance from~~ the ~~USPTO relating~~ **United States Court of Appeals for the Federal Circuit, and CSI has filed a notice of cross- appeal** to **challenge** ~~" applicant admitted prior art " impacted~~ the PTAB' s decision ~~in the' 371 patent proceeding. In addition, the PTAB reset the time for commencement of an appeal in the' 371 patent proceeding pending the entry of a final decision after the requested briefing. The requested briefing is complete and the PTAB' s decision is pending. On March 9, 2022, the PTAB issued an order authorizing us to file a motion for additional discovery. On March 23, 2022, we filed a motion for additional discovery, relating to additional information publicized by CSI after the PTAB' s decision on the patents. On February 2, 2023, the PTAB denied the motion for additional discovery and issued a final decision, ruling again~~ that Claim 5 **of the ' 371 patent** is valid **. Accordingly, Claim 5** and ~~that~~ all other claims ~~are invalid. We will be pursuing further review and appeal of this ruling. Accordingly, Claim 5 and all other claims in the' 371 patent~~ remain valid and enforceable until all appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the' 371 patent proceedings could result in the loss or narrowing in scope of the' 371 patent, which could further limit our ability to stop others from using or commercializing products and technology similar or identical to ours. In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re- examination, post- grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Any loss or limitation of patent protection could have a material adverse effect on our business, financial condition, and results of operations. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the " America Invents Act "), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This

will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications **are** ~~will be~~ prosecuted and also **impacts** ~~may affect~~ patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post- grant review, IPR and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. ~~The number of~~ **In cases where the USPTO accepts a petition and institutes an** IPR ~~challenges filed is increasing, and in many cases~~, the USPTO ~~is~~ **may** ~~canceling~~ --- **cancel** or significantly ~~narrowing~~ --- **narrow** issued patent claims. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation ~~could increase the~~ **represents a consistent source of** ~~uncertainties~~ **uncertainty** and ~~costs~~ **cost** surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U. S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U. S. Supreme Court and the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture, and commercialization of one or more of our products. We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship **or ownership** of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition and results of operations. Third- party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products. The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we could become subject to significant intellectual property- related litigation and proceedings relating to our or third- party intellectual property and proprietary rights. Our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third- party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post- grant review, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other

parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications **with claims that we do not infringe** that may ultimately issue with claims that we **do** infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non- practicing entities (" NPEs "), which have no relevant product revenue and against whom our own patent portfolio may have no deterrent **or defensive** effect. Third parties, including NPEs, have claimed, and may in the future claim, that our products infringe or violate their patents or other intellectual property rights. In the event that any third- party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third- party patents are valid, enforceable, and infringed by our products. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden requires us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to infringe third- party patents, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and / or royalties, and the rights granted to us might be non- exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. Defense of infringement **or misappropriation** claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement **or misappropriation** against us, we may be enjoined from further developing or commercializing the infringing products and / or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees if we were found to willfully infringe such intellectual property. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Engaging in litigation to defend against third- party infringement **or misappropriation** claims is very expensive, particularly for a company of our size, and time- consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, or results of operations. We **are currently involved, and** may become involved **in the future,** in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming ~~,~~ and unsuccessful. Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also **have in the past, and** may **in the future,** become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time- consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, or results of operations. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be

misappropriated or disclosed. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our products, we also rely upon unpatented trade secrets, know- how and continuing technological innovation to develop and maintain a competitive position. We seek to protect such proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. These confidentiality and information assignment agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties. We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence of confidentiality restrictions. Confidentiality agreements may not provide meaningful protection for our trade secrets, know- how, or other proprietary information in the event the unwanted use **or disclosure** is outside the scope of the provisions of the agreements or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know- how, or other proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed or reverse engineered by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know- how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions. We also seek to preserve the integrity and confidentiality of our proprietary data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time- consuming, and the outcome is unpredictable. Further, we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known to, or be independently discovered by, competitors, and in such cases we could not assert any trade secret rights against such parties. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions, which could have a material adverse effect on our business, financial condition and results of operations. We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Many of our employees, consultants and contractors are or were previously employed at other medical device companies, including those that are our direct competitors or could potentially become our direct competitors. In some cases, those employees joined our company recently. Some of these employees, consultants and contractors, may have executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know- how of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used **, misappropriated** or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of such employee' s non- competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our business, financial condition and results of operations. We cannot guarantee that this type of litigation will not occur in the future, which may adversely affect our ability to hire the most qualified personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We rely on our trademarks and trade names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks (including domain names) and trade names may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations **. RISKS RELATED TO OUR DEBT We face risks related to our debt obligations, including our 1. 0 % convertible senior notes (the " Notes "). In August 2023, we completed an offering of $ 750. 0 million aggregate principal amount of the Notes.**

Our debt obligations under the Notes could adversely impact us. For example, these obligations could: • require us to use a substantial portion of our cash flow from operations to pay principal and interest on debt, or to repurchase the Notes when required upon the occurrence of certain events or otherwise pursuant to the terms thereof, which will reduce the amount of cash flow available to fund working capital, capital expenditures, acquisitions, and other business activities ; • require us to use cash to settle any obligations; • result in certain of our debt instruments being accelerated or being deemed to be in default if certain terms of default are triggered, such as applicable cross- payment default and / or cross-acceleration provisions ; • adversely impact our credit rating, which could increase future borrowing costs ; • limit our future ability to raise funds for capital expenditures, strategic acquisitions or business opportunities, and other general corporate requirements ; • increase our vulnerability to adverse economic and industry conditions ; and • place us at a competitive disadvantage compared to our less leveraged competitors. We also have a revolving credit facility in an aggregate principal amount of $ 175. 0 million, which is currently undrawn, under the Credit Agreement. The Credit Agreement includes customary affirmative and restrictive covenants, including covenants relating to the incurrence of additional debt or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, and mergers and acquisitions, among other customary covenants. The Credit Agreement also restricts us from paying dividends or making distributions or payments on our capital stock subject to limited exceptions. The Credit Agreement also includes customary representations and warranties, events of default and termination provisions. Failure to comply with the covenants or other restrictions could result in a default under the Credit Agreement. In addition, the revolving credit facility is secured by substantially all of our assets, including intellectual property, and requires us to satisfy certain financial covenants. Our ability to meet our payment obligations under our debt instruments depends on our ability to generate significant cash flows in the future. This, to some extent, is subject to market, economic, financial, competitive, legislative, and regulatory factors as well as other factors that are beyond our control. There can be no assurance that our business will generate cash flow from operations, or that additional capital will be available to us, in amounts sufficient to enable us to meet our debt payment obligations and to fund other liquidity needs. For example, we may utilize proceeds from the Notes for acquisitions or other investments that do not increase our enterprise value or we may otherwise be unable to generate sufficient cash flows to repay our debt obligations. See Note 9 “ Debt ” and Note 10 “ Convertible Debt ” of the Notes to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10- K for more information about the revolving credit facility and the Notes. Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, or to make cash payments in connection with any conversions of Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our existing indebtedness and any future indebtedness we may incur and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, restructuring debt or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any current or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms or at all, which could result in a default on our debt obligations. In addition, any of our future current or future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt. We may be unable to raise the funds necessary to repurchase the Notes for cash following a fundamental change (as defined in the indenture, dated August 15, 2023, between us and U. S. Bank Trust Company, National Association, as trustee (the “ Indenture ”)) or to pay any cash amounts due upon conversion, and our other indebtedness limits our ability to repurchase the Notes or pay cash upon their conversion. Noteholders may require us to repurchase their Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid special interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash up to the aggregate principal amount of the Notes to be converted and in cash, shares of common stock or a combination of cash and shares of common stock, at our election, in respect of the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Notes or pay the cash amounts due upon conversion. Our failure to repurchase Notes or to pay the cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or a fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Notes. The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results. In the event the conditional conversion feature of the Notes is triggered, holders will be entitled to convert their Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, we would be required to settle any converted principal amount of such Notes through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current, rather than long-

term, liability, which would result in a material reduction of our net working capital. Conversion of the Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock. The conversion of some or all of the Notes may dilute the ownership interests of our stockholders to the extent we deliver shares upon conversion of any of the Notes. Upon conversion of the Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock in respect of the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted. If we elect to settle the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress the price of our common stock. Capped call transactions entered into in connection with the Notes may affect the value of the Notes and our common stock. In connection with the Notes, we entered into privately negotiated capped call transactions (the " Capped Call Transactions ") with certain initial purchasers of the Notes or their respective affiliates and certain other financial institutions (the " Option Counterparties "). The Capped Call Transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Notes and / or offset any potential cash payments we are required to make in excess of the principal amount upon conversion of any Notes, with such reduction and / or offset subject to a cap. In connection with establishing their initial hedges of the Capped Call Transactions, the Option Counterparties and / or their respective affiliates purchased shares of our common stock and / or entered into various derivative transactions with respect to our common stock. This activity could have increased (or reduced the size of any decrease in) the market price of our common stock or the Notes at that time. In addition, the Option Counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock in secondary market transactions (and are likely to do so following any conversion of Notes, any repurchase of the Notes by us on any fundamental change repurchase date, any redemption date, or any other date on which the Notes are retired by us). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes. The potential effect, if any, of these transactions and activities on the market price of our common stock or the Notes will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock. We are subject to counterparty risk with respect to the Capped Call Transactions, and the Capped Call Transactions may not operate as planned. The Option Counterparties are financial institutions, and we will be subject to the risk that they might default under the Capped Call Transactions. Our exposure to the credit risk of the Option Counterparties will not be secured by any collateral. Global economic conditions have from time to time resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an Option Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under our transactions with that Option Counterparty. Our exposure will depend on many factors, but, generally, the increase in our exposure will be correlated with increases in the market price or the volatility of our common stock. In addition, upon a default by an Option Counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of any Option Counterparty. In addition, the Capped Call Transactions are complex, and they may not operate as planned. For example, the terms of the Capped Call Transactions may be subject to adjustment, modification or, in some cases, renegotiation if certain corporate or other transactions occur. Accordingly, these transactions may not operate as we intend if we are required to adjust their terms as a result of transactions in the future or upon unanticipated developments that may adversely affect the functioning of the Capped Call Transactions. The accounting method for the Notes could adversely affect our reported financial condition and results. We have adopted Accounting Standards Update 2020- 06 (" ASU 2020- 06 ") as of January 1, 2022. Accordingly, we do not bifurcate the liability and equity components of the Notes on our balance sheets, and we use the if- converted method of calculating diluted earnings per share. Under the " if- converted " method, diluted earnings per share will generally be calculated assuming that all the Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti- dilutive, which could adversely affect our diluted earnings per share. Because the principal amount of the Notes upon conversion is required to be paid in cash, and only the excess is permitted to be settled in shares, the application of the if- converted method will produce a similar result as the treasury stock method prior to the adoption of ASU 2020- 06. The effect of the treasury stock method is that the shares issuable upon conversion of such Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of such Notes exceeds their principal amount. In accordance with ASU 2020- 06, the Notes are reflected as a liability on our consolidated balance sheets, with the initial carrying amount equal to the principal amount of the Notes, net of issuance costs. The issuance costs will be treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the Notes. As a result of this amortization, the interest expense that we expect to recognize for the Notes for accounting purposes will be greater than the cash interest payments we will pay on the Notes, which will result in lower reported income. We cannot be sure whether future changes made to the current accounting standards related to the Notes will have a material effect on our reported financial results . RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK The market price of our common stock has been and may continue to be highly volatile. The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in price in

response to various factors, many of which are beyond our control. From January 1, ~~2022~~ **2023** through December 31, ~~2022~~ **2023** , the closing price of our common stock has ranged from $ ~~115~~ **160** . ~~91~~ **99** per share to $ ~~310~~ **302** . ~~53~~ **68** per share. Stock markets ~~in general and the market for medical device companies in particular~~ have experienced extreme price and volume fluctuations that have ~~often been~~ **affected and continue to affect the market prices of equity securities for many companies. Stock prices of many companies, including medical device companies in particular, have fluctuated in a manner** unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may ~~seriously harm~~ **adversely impact** the market price of our common stock, regardless of our operating performance. Price declines in our common stock could result from general market and economic conditions, many of which are beyond our control, and a variety of other factors, including any of the risk factors described in this Annual Report on Form 10- K and others that we may not have anticipated. The market price for our common stock may be influenced by many factors, including: • the volume of sales of our products; • the failure by our customers to obtain coverage and adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers; • unanticipated serious safety concerns related to the use of our products; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • announcements of technological or medical innovations for the treatment of vascular disease; • our ability to effectively manage our growth; • the size and growth of our target markets; • actual or anticipated quarterly variations in our or our competitors' results of operations; • failure to meet estimates or recommendations by securities analysts who cover our stock; • failure to meet our own financial estimates; • accusations that we have violated a law or regulation; • recalls of our products; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain, maintain, protect and enforce our patents and other intellectual property rights for our technologies and products; • significant litigation, including stockholder litigation or litigation related to intellectual property; • our cash position; • any delay in any regulatory filings for our planned or future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such products; • adverse regulatory decisions, including failure to receive regulatory approval or clearance of our planned and future products or maintain regulatory approval or clearance for our existing products; • changes in laws or regulations applicable to our products; • adverse developments concerning our suppliers or distributors; • our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices, including as a result of the ongoing global supply chain disruption; • our inability to establish and maintain collaborations if needed; • changes in the market valuations of similar companies; • overall performance of the equity markets; • sales of large blocks of our common stock, including sales by our executive officers, directors, and significant stockholders; • trading volume of our common stock; • additions or departures of key scientific or management personnel; • changes in accounting principles; • ineffectiveness of our internal controls; • actual or anticipated changes in healthcare policy and reimbursement levels; • general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors, including **regional conflicts around the world, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, the weakening of the global and U. S. economies, instability in the global banking sector,** rising interest rates, inflation, **global supply** ~~as well as the COVID - 19 pandemic~~ **chain disruptions,** and **a tightening of** the **global labor market** ~~ongoing conflict in Ukraine and the responses thereto~~ ; and • other events or factors, many of which are beyond our control. In ~~addition, in~~ recent years the trading prices for **the** common stock of other medical device companies have been highly volatile. In the past, following periods of volatility in the trading price of a company' s securities, securities class action litigation has often been brought against that company. If the market price of our common stock is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management' s attention and resources from our business. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could have an adverse effect on our business, operating results, and financial condition. ~~An active trading market for our common stock may not be sustained. Our common stock is currently listed and trades on the Nasdaq under the symbol " SWAV. " We cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our common stock when desired, or the prices that you may obtain for your shares.~~ We do not intend to pay dividends on our common stock, so any returns will be limited to increases, if any, in our stock' s value. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors and 5 % stockholders beneficially owned approximately 33 % of the outstanding shares of ~~capital~~ **our common** stock. As of December 31, ~~2022~~ **2023** , we had 36, ~~235~~ **990** , ~~546~~ **700** shares of common stock outstanding. Accordingly, these stockholders have a material influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, mergers, ~~consolidation~~ **consolidations** or ~~sale~~ **sales** of all or substantially all of our assets **and** ~~or any~~ other significant corporate ~~transaction~~ **transactions** . The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could attempt to delay or prevent a change in control of ~~the~~ **our** ~~Company~~ **company** , even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of ~~the~~ **our**

~~Company~~ **company** or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise. As of December 31, ~~2022~~ **2023** , our executive officers and directors held options to purchase an aggregate of ~~882~~ **744** , ~~481~~ **607** shares of our common stock at a weighted- average exercise price of $ 5. ~~50~~ **70** per share and ~~264~~ **239** , ~~153~~ **019** shares of common stock underlying outstanding restricted stock units (" RSUs "). We have registered all of the shares of common stock issuable upon the exercise of outstanding options, upon the vesting of outstanding RSUs and upon exercise or settlement of any other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as amended (the " Securities Act "). Accordingly, these shares may be freely sold in the public market upon issuance, subject to applicable vesting requirements and compliance by affiliates with Rule 144 of the Securities Act. Furthermore, holders of our common stock have certain rights with respect to the registration of such shares under the Securities Act. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. Our stock price and trading volume is heavily influenced by the way analysts and investors interpret our financial information and other disclosures. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over- reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own. Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. Our restated certificate of incorporation, our amended and restated bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management. Provisions of Delaware law (where we are incorporated), our restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. In addition, 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 or remove our board of directors. These provisions include: • authorizing the issuance of " blank check " preferred stock without any need for action by stockholders; • requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and amended and restated bylaws; • eliminating the ability of stockholders to call and bring business before special meetings of stockholders; • prohibiting stockholder action by written consent; • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings; • dividing our board of directors into three classes so that only one third of our directors will be up for election in any given year; and • providing that our directors may be removed by our stockholders only for cause. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which may have an anti- takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that could have resulted in a premium over the market price for shares of our common stock. These provisions apply even if a takeover offer may be considered beneficial by some stockholders, could delay or prevent an acquisition that our board of directors determines is not in our and our stockholders' best interests and could also affect the price that some investors are willing to pay for our common stock. Our **amended and** restated **bylaws** ~~certificate of incorporation provides~~ **provide** an exclusive forum provision for certain claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our **amended and** restated **bylaws** ~~certificate of incorporation provides~~ **provide** that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision will not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and our **amended and** restated **bylaws** ~~certificate of incorporation provides~~ **provide** that the federal district courts of the United States of America are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision, unless we consent in writing to the selection of an alternative forum. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities will be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our **amended and** restated **bylaws** ~~certificate of incorporation~~ to be inapplicable or unenforceable in an action, we may incur additional costs associated

with resolving such action in other jurisdictions, which could harm our business and financial condition.