UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-38829

Shockwave Medical, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**27-0494101**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5403 Betsy Ross Drive Santa Clara, CA	**95054**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 279-4262

Securities registered pursuant to Section 12(b) of the Act:

Title of each class of securities	Trading symbol(s)	Name of each national exchange and principal U.S. market for the securities
Shockwave Medical, Inc., common stock, par value $0.001 per share	SWAV	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2023, the aggregate market value of shares held by non-affiliates of the Registrant (based upon the closing sale prices of such shares on the Nasdaq Global Select Market on June 30, 2023) was approximately $7.7 billion. For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company, or unless they hold 10% or more of our outstanding common stock. These assumptions should not be deemed to constitute an admission that all executive officers, directors and 5% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company. Further information concerning the security holdings of our officers, directors and principal stockholders is included or incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

The number of shares of Registrant's common stock outstanding as of February 21, 2024 was 37,396,816.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the Registrant's fiscal year ended December 31, 2023. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains statements relating to our expectations, projections, beliefs, and prospects, which are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "might," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they may relate to future expectations around growth, strategy, and anticipated trends in our business, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements are only predictions based on our current expectations, estimates, assumptions, and projections about future events and are applicable only as of the dates of such statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and refractory angina as well as carotid disease, aortic stenosis and mitral stenosis;
- our ability to successfully execute our commercialization strategy for our approved or cleared products;
- the timing of, and our ability to, obtain regulatory approval for and commercialize our planned products as well as expand approved or cleared products to additional indications;
- our expected future growth, including growth in international operations and sales;
- the size and growth potential of the markets for our products and planned products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- the impact of government laws and regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines;
- our ability to scale our organizational culture of cooperative product development and commercial execution;
- our ability to satisfy our payment obligations and remain in compliance with covenants under our debt agreements, including our convertible debt, or to refinance our indebtedness;
- potential dilution from equity awards, convertible indebtedness and potential future convertible debt and stock issuances;
- the expected benefits of our acquisition of Neovasc Inc. ("Neovasc") in April 2023, a corporation existing under the Canada Business Corporations Act;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our estimates regarding expenses, future financial performance and capital requirements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others; and
- the impact of global business, political and macroeconomic conditions, including inflation, rising interest rates, uncertainty with respect to the federal budget, instability in the global banking system, volatile market conditions, supply chain disruptions, cybersecurity events, and global events, including regional conflicts around the world, on our operations, financial results, liquidity and capital resources, sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions and other factors that could cause our actual results, level of activity, performance, or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those described in the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors”. There may also be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this Annual Report on Form 10-K to conform our prior statements to actual results or revised expectations.

RISK FACTOR SUMMARY

The following is a summary of the principal risks to which our business is subject. This summary is not complete, and the risks summarized below are not the only risks we face. You should review and carefully consider the risks and uncertainties described in more detail in the section titled "Risk Factors" of this Annual Report on Form 10-K, which includes a more complete discussion of the risks summarized below as well as a discussion of other risks related to our business and an investment in our common stock.

- 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 products, making us vulnerable to supply problems and price fluctuations.
- 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 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 including managing risks related to excess or constrained capacity at our existing facilities. If we are unable to manage the anticipated growth of our business, our future revenue and results of operations may be adversely affected.
- 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.
- Our long-term growth depends on our ability to enhance our products 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.
- If our products are not approved for planned or new indications, our commercial opportunity will be limited.
- If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.
- 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.
- 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.
- If we are unable to successfully market and sell our products, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- 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.
- 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.
- In the future our products may become obsolete, which would negatively affect operations and financial condition.
- 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.
- 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.

- 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.
- 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.
- Our products may be subject to recalls after receiving U.S. Food and Drug Administration ("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.
- 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.
- Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.
- 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.
- 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.
- We have been 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.
- Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness.
- We may be unable to raise the funds necessary to repurchase the convertible senior notes (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.

PART I

Item 1. Business.

Company Overview

We are a medical device company focused on developing and commercializing novel technologies that transform the care of patients with cardiovascular disease. We aim to establish a new standard of care for the treatment of calcified cardiovascular disease ("atherosclerosis") through our differentiated and proprietary local delivery of sonic pressure waves, which we refer to as intravascular lithotripsy ("IVL"). Our IVL system (our "IVL System"), which leverages our IVL technology (our "IVL Technology"), is a minimally invasive, easy-to-use, and safe way to improve outcomes for patients with calcified cardiovascular disease. Additionally, we aim to transform the standard of care for patients suffering from refractory angina with our coronary sinus reducer (the "Reducer") technology, an innovative technology that creates a permanent, controlled narrowing of the coronary sinus.

Our Products

Our differentiated range of IVL catheters enables delivery of IVL therapy to diseased vasculature throughout the body for calcium modification. Our currently approved IVL catheters that treat peripheral artery disease ("PAD") and coronary artery disease ("CAD") resemble a standard balloon angioplasty catheter, the device most commonly used by interventional cardiologists. This familiarity makes our IVL System easy for healthcare providers to learn, adopt and use on a day-to-day basis. The Reducer is also a catheter-based device and is implanted in the coronary sinus, which is a major coronary vein located on the left side of the heart. It was developed to deliver this coronary sinus reduction therapy in a safe, simple and effective manner via a minimally invasive catheter that is consistent with contemporary medical practice. The Reducer is implanted using conventional catheter-based interventional techniques and reduces the diameter of the coronary sinus, which redistributes blood into the ischemic myocardium to help reduce angina symptoms. The implant procedure requires minimal training for experienced interventionalists.

Our commercial products are cleared or approved for use in a number of countries and development programs are underway to expand indications and geographies. We are currently selling the following products in countries where we have applicable regulatory approvals:

Product	Description	Major Market Regulatory Authorization	Initial Regulatory Authoriz Date
Shockwave M^5 IVL catheter ("M^5 catheter")	Five-emitter catheter for use in our IVL System in medium-diameter vessels for the treatment of PAD.	European Union (CE-Marked)	April 2018
		United States (FDA[1])	July 2018
		China (NMPA[2])	May 2022
Shockwave M^{5+} IVL catheter ("M^{5+} catheter")	Five-emitter catheter for use in our IVL System in medium-diameter vessels for the treatment of PAD, twice as fast as the M^5 catheter.	European Union (CE-Marked)	November 2020
		United States (FDA)	April 2021
Shockwave S^4 IVL catheter ("S^4 catheter")	Four-emitter catheter for use in our IVL System in small-diameter vessels for the treatment of PAD.	European Union (CE-Marked)	April 2018, second version ac May 2020
		United States (FDA)	August 2019
		China (NMPA)	May 2022
Shockwave L^6 IVL catheter ("L^6 catheter")	Six-emitter catheter for use in our IVL System in large diameter vessels for the treatment of PAD.	United States (FDA)	August 2022
Shockwave C^2 IVL catheter ("C^2 catheter")	Two-emitter catheter for use in our IVL System for the treatment of CAD.	European Union (CE-Marked)	June 2018
		United States (FDA)	February 2021
		Japan (MHLW[3])	March 2022
		China (NMPA)	May 2022

Shockwave C^{2+} IVL catheter ("C^{2+} catheter")	Two-emitter catheter for use in our IVL System for the treatment of CAD but with additional pulses compared to the C^2 catheter.	European Union (CE-Marked)	August 2022
		United States (FDA)	December 2022
The Reducer	Hourglass-shaped, balloon-expandable, stainless steel, bare metal device used to treat refractory angina.	European Union (CE-Marked)	November 2011

1 U.S. Food and Drug Administration
2 National Medical Products Administration of China
3 Ministry of Health, Labour, and Welfare of Japan

Our Pipeline

Our product pipeline includes products that target underserved patient populations and is intended to generate a steady cadence of new products that will maximize penetration into their respective markets. We continue to target the coronary and peripheral markets with next generation products that make our IVL Technology more deliverable. We are also working to complete the COSIRA-II trial to support FDA approval of our Reducer in the United States. Additionally, we plan to develop IVL catheters to treat carotid disease, aortic stenosis ("AS") and mitral stenosis ("MS"). We also will consider enhancing our pipeline through the acquisition of additional technologies. Our current product pipeline includes the following:

Coronary

- Shockwave C^2 Aero ("Aero"): Our next-generation coronary IVL catheter designed to be twice as deliverable through complex anatomy as our C^{2+} catheter.
- Shockwave Javelin Coronary: Our novel non-balloon-based catheter platform intended to treat tight, difficult-to-cross coronary lesions.

Peripheral

- Shockwave L^6: Our L^6 catheter will be upgraded to include faster pulsing than the current L^6 catheter on the market.
- Shockwave E^8 Catheter ("E^8 catheter"): Our E^8 catheter will have a longer balloon to target challenging long peripheral artery lesions.
- Shockwave Javelin Peripheral: Our novel, non-balloon-based catheter platform intended to treat tight, difficult-to-cross peripheral lesions.

Carotid IVL

- Shockwave Carotid IVL ("Carotid IVL"): Our purpose-built IVL System intended to address calcified carotid artery lesions.

Valvular Transcatheter Lithotripsy

- Shockwave Crescendo ("Crescendo"): Our new higher-powered platform developed to treat calcified, stenotic heart valves.

Clinical Research

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our products. In addition to supporting our regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of our products across multiple therapies in existing and new market segments. Our past studies have also guided optimal procedure technique and informed the design of products in development. In addition, we have

ongoing clinical programs across several products and indications, which, if successful, could allow us to expand commercialization of our products into new geographies and indications.

During 2023, we were engaged in the following CAD clinical trials:

- EMPOWER CAD Post-Approval Study: This is a post-approval observational study in the United States and Europe to assess the real-world clinical outcomes of female subjects with calcified coronary artery disease. We began enrollment in May 2023 and enrollment is ongoing.
- Disrupt CAD DUO: This is a pre-market investigational device exemption ("IDE") study to support a premarket approval application ("PMA") for our C^{2+} 2Hz coronary IVL catheter. We began enrollment in December 2023 and enrollment is ongoing.
- Mini C Flex Early Feasibility Study: This is a pre-market, feasibility study in the United Kingdom ("UK") and Australia to assess the safety and effectiveness of the Mini C Flex IVL catheter for the treatment of heavily calcified and stenotic coronary arteries. We began enrollment in May 2023 and enrollment is ongoing.

In addition, we were engaged in the following PAD clinical trials in 2023:

- BTK II: This is a post-market, prospective, multi-center, single-arm study to assess the effectiveness of IVL for treatment of BTK PAD. We began enrollment in November 2021 and study enrollment was completed in January 2024.
- Mini S Feasibility: This is a prospective, multi-center, single-arm feasibility study to assess the safety and performance of Javelin Peripheral, known as the Shockwave Medical Mini S Peripheral IVL System, for the treatment of heavily calcified, stenotic peripheral arteries. We began enrollment in March 2022 and enrollment is ongoing.
- FORWARD PAD Study: This is a pre-market IDE study to support a 510(k) application for Javelin Peripheral, known as the Shockwave Medical Mini S Peripheral IVL System, in the study. We began enrollment in June 2023 and enrollment is ongoing.

We were also engaged in the following refractory angina clinical trial in 2023:

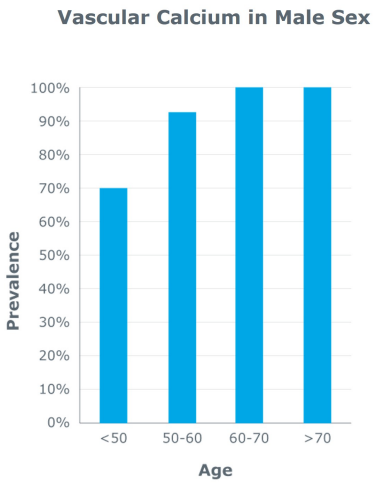
- COSIRA II Trial: This is a prospective, multi-center, randomized, double-blind, sham-controlled IDE trial to assess the safety and effectiveness of the Reducer. We began enrollment in January 2022 and enrollment is ongoing.

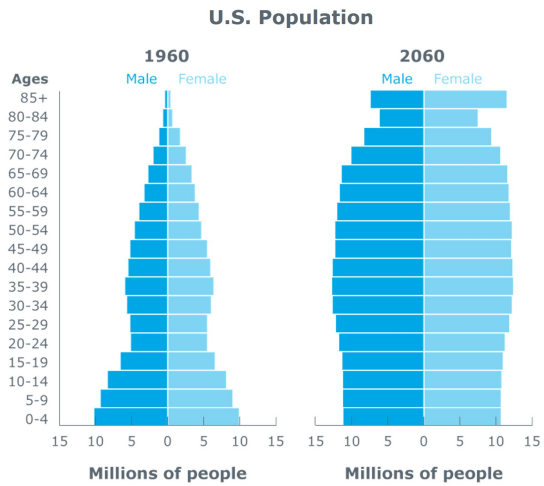
The Opportunity

We believe we are uniquely positioned to develop and commercialize a pipeline of products across multiple markets by leveraging the cumulative learning from our business. We estimate the potential global market opportunity for our portfolio to be approximately $14.5 billion. We use multiple sources and assumptions to estimate our total addressable market. While we believe them to be reasonable, these sources and assumptions may be incorrect or subject to change due to any number of factors.

The Burden and Challenges of Vascular Calcification

Vascular calcification is prevalent and growing. The factors that predispose one to vascular calcification are age, male sex, smoking, hypertension, diabetes, dyslipidemia and renal disease. Changes in population dynamics are working to increase the burden of calcification both in the United States and globally. The figure on the left below shows vascular calcification in men as identified by a computed tomography (CT) scan. By the age of 50 years the prevalence of calcification is 70% but by 60 years of age and onwards, calcification is ubiquitous. What is also significant is the distribution of the population, which is changing dramatically. The figure on the right below shows age distribution of the U.S. population in 1960 and the projected age distribution of the U.S. population in 2060. Not only is the median age of the population projected to increase, but the size of the population with advanced age is projected to dramatically increase as well. We believe the burden of vascular calcium is increasing and the challenges it poses to interventional procedures will increase in frequency and intensity, which is why we developed IVL.





The primary therapies to treat cardiovascular disease are angioplasty balloons ("balloons"), drug-coated balloons, bare metal stents, and drug-eluting stents. These devices all work by using pressurized balloons to expand the diseased blood vessels. Calcified plaque creates challenges for these therapies in achieving optimal outcomes in treating PAD and CAD because the calcified vessels fail to expand under safe pressures. This, in turn, can lead to acute failure, damage to the blood vessel, which increases the rate of restenosis (re-occlusion of the vessel following endovascular treatment) or complications requiring adjunctive tools, future re-interventions or conversion to bypass surgery. These complications are significantly increased when treating calcified cardiovascular disease and include dissections, embolization, restenosis, vessel perforations and vessel recoil.

Plaque modification devices (including atherectomy and specialty balloons) have enhanced the treatment of some moderately calcified cardiovascular lesions by improving the ability of stent and balloon therapies to effectively expand in the vessel. Atherectomy devices are designed to break or remove superficial calcium by cutting or sanding the calcium in order to improve vessel expansion. Specialty balloon devices incorporate metallic elements like wires and cutting blades onto standard balloons; these devices are intended to make discreet cuts into the calcified plaque and surrounding tissue in order to improve vessel expansion. Despite improvements in plaque modification devices, significant limitations remain, including being difficult to use and creating complications and inconsistent efficacy. Further, because medial calcium is encased in the peripheral vessel wall, and coronary arteries often feature thick layers of calcium, existing plaque modification devices are unable to impact calcium in these anatomies without damaging the vessel. Combined, these limitations decrease the utilization of plaque modification devices for treating calcified cardiovascular disease, thereby reducing the clinical benefit of angioplasty and stent therapies compared to their use in non-calcified anatomies.

Calcified iliac and femoral arteries can hinder the delivery of large endovascular devices for other catheter-based procedures, including those that treat aortic aneurysms (endovascular aneurysm repair and thoracic endovascular aneurysm repair procedures), severe AS treated with transcatheter aortic valve replacements ("TAVR"), and cardiac support devices for high-risk percutaneous coronary intervention ("PCI") (e.g., Johnson & Johnson/Abiomed's Impella). The standard practice for these procedures is to gain vascular access in the femoral artery and insert large diameter sheaths that facilitate the delivery of the treatment devices to the aorta or the heart. However, when significant calcium is present in these arteries, it can prevent delivery of the devices, and thus may require more invasive treatments, increase complications or prevent the device from being used altogether. For example, in up to 20% of patients, the transfemoral approach through the iliac and femoral arteries is not viable for TAVR delivery or creates risk of vessel trauma due to the extent of vascular calcification, according to a 2018 study in the Journal of the American College of Cardiology.

Our IVL System

For our IVL products, we have adapted the use of lithotripsy, which has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years, to the cardiovascular field with the aim of creating what we

believe is the safest, most effective means of addressing the growing challenge of cardiovascular calcification. By integrating lithotripsy into a device that resembles a standard balloon catheter, physicians can prepare, deliver, and treat calcified lesions using a familiar form factor, without disruption to their standard procedural workflow. Our differentiated IVL System works by delivering shock waves through the entire depth of the artery wall, modifying both deep wall and thick calcium, not just at the thin, superficial most intimal layer. The shock waves modify this calcium and enable the narrowed artery to expand at low pressures, thereby minimizing complications inherent to traditional balloon dilations, such as dissections or perforations. Preparing the vessel with IVL facilitates optimal outcomes with other adjacent therapies, including stents and drug-eluting technologies. Using IVL also avoids complications associated with atherectomy devices such as dissection, perforation, and embolism.

Our IVL System includes a generator, connector cable, and a variety of IVL catheters designed to treat PAD and CAD. The IVL catheter is advanced to the target lesion and the integrated balloon is inflated with fluid at a low pressure to make contact with the arterial wall. IVL is then activated through the generator with the touch of a button, creating a small bubble within the catheter balloon which rapidly expands and collapses. The rapid expansion and collapse of the bubble creates sonic pressure waves that travel through the vessel and crack the calcium, allowing the blood vessel to expand under low static pressure.

The unique benefits of our Shockwave IVL technology are that it is (1) predictable – calcium can be safely modified while significantly reducing the risk of complications to make procedures more predictable and efficient; (2) distinctly intuitive – treatment of calcium is simplified from the very first case via a unique mechanism of action on an intuitive platform; and (3) consistent – proven to achieve low residual stenosis across multiple vessel beds by disrupting superficial and deep calcium. These benefits enable more hospitals and physicians to address the challenges of calcium without compromise.

IVL Markets

Coronary and Peripheral IVL

Atherosclerosis is a common disease of aging in which arteries become narrowed (“stenotic”) and the supply of oxygenated blood to the affected organ is reduced by the progressive growth of plaque. Atherosclerotic plaque is comprised of fibrous tissue, lipids (fat) and, when it progresses, calcium. This calcium is present both deep within the walls of the artery (“deep” or “medial” calcium) and close to the inner surface of the artery (“superficial” or “intimal” calcium).

The first two indications that our IVL System addresses are PAD, the narrowing or blockage of vessels that carry blood from the heart to the extremities, and CAD, the narrowing or blockage of the arteries that supply blood to the heart muscle.

We estimate the market opportunity for use of IVL in the treatment of PAD and CAD can generally be defined as interventional procedures performed to treat those diseases where severe or moderate arterial calcium is present. In addition, IVL is utilized in so called “large bore” endovascular procedures such as TAVR and endovascular aortic aneurysm repair (“EVAR”) to treat calcified arteries along the access route, typically the common femoral or iliac arteries, where calcification can hinder the advancement of large-sized sheaths required to deliver these large-sized heart valves or endovascular grafts. The number of interventional procedures and prevalence of severe or moderate calcium vary by arterial segment, and we estimate that the aggregate addressable market for IVL in the treatment of CAD and PAD is over $8 billion.

Coronary IVL is utilized to treat patients with CAD undergoing a PCI who have severe or moderate arterial calcium that hinder a balloon angioplasty and subsequent stent expansion. According to Clarivate Plc (“Clarivate”), over six million PCI procedures were performed in 2022 in the markets we served. A study published in the American Journal of Cardiology in 2014 demonstrated that more than 30% of patients undergoing PCI have severely or moderately calcified lesions and this percentage is growing. Minimizing complications is particularly important in the coronary vessels, and alternative plaque modification devices to IVL are used somewhat sparingly in PCI procedures in patients with calcified CAD, which we believe is likely due to safety risks and the inherent challenges associated with their use. We believe the safety, ease of use and efficient impact on calcium of our IVL System has resulted in the adoption and market expansion in markets where our C^2 catheter was introduced. We believe there is an over $5 billion total addressable market opportunity for our IVL System to treat CAD.

The population of patients suffering from PAD in the United States has been estimated to be at least eight million people, according to the National Institutes of Health. Globally, Clarivate estimated that in 2022 over 1.8 million interventions were performed annually to treat symptomatic occlusive PAD. The presence of severe and moderate calcium ranges between 50% to 70% in the iliac, femoropoliteal and infrapopliteal arterial beds that are treated as part of PAD interventions. Lower extremity arteries are also treated with IVL as part of separate endovascular procedures, specifically TAVR or abdominal or thoracic EVAR ("TEVAR") procedures, where the iliac or common femoral arteries along the access vascular route are blocked by a calcified narrowing that prevents these relatively large catheters from passing from the lower extremities into the aorta to deliver their respective lifesaving therapies. Clarivate estimated that in 2022 approximately 475,000 TAVR, EVAR and TEVAR procedures were performed globally, and up to 20% of those procedures were at risk for barriers to transfemoral access due to calcium. Accordingly, we believe our IVL System to treat symptomatic occlusive PAD and iliac access for TAVR, EVAR, and TEVAR has a total addressable market opportunity of approximately $3 billion.

Carotid IVL

Disease of the carotid arteries, which are the vessels that transport blood from the heart to the brain, is the principal pathology driving the occurrence of stroke. Stroke is second only to coronary heart disease as the highest cause of death worldwide and is a major cause of morbidity and disability amongst patients. Treatment options for patients with carotid artery disease include pharmacotherapies, such as antiplatelet therapies and statins, surgical interventions with a variety of techniques, and increasingly endovascular interventions, which result in the implantation of a carotid artery stent. The majority of patients receive medical therapy, with smaller numbers of patients receiving either surgical or endovascular treatments. Endovascular intervention is the fastest growing segment, primarily driven by the increased adoption of the transcarotid artery revascularization approach by vascular surgeons. Growth of endovascular interventions is expected to continue as there are several technological advances on the horizon aimed at making interventions safer, easier to perform or the results more durable. Additionally, in the United States, the largest market for interventions, coverage has recently been expanded via a National Coverage Determination by Centers for Medicare & Medicaid Services ("CMS"), which is expected to increase the frequency of endovascular procedures utilizing both transcarotid and transfemoral approaches.

Unfortunately, patients with calcified lesions have more limited and suboptimal treatment options. Patients ordinarily suitable for endovascular procedures may instead require surgery at some risk or pharmacotherapy therapy alone. The risks posed by calcified lesions during carotid stenting include an increased risk of arterial dissection, which may cause stroke, or an under expanded stent, which leads to risk of stent fracture or renarrowing.

As has been shown in peripheral and coronary arteries, IVL technology may potentially address the risks posed by carotid artery calcification, enabling a safe and effective carotid stenting procedure. Physicians have already shown considerable enthusiasm for use of IVL in carotid interventions, but in order to capture the opportunity, we must prospectively establish both the safety and the efficacy of IVL treatment. In addition, we are developing a balloon-based IVL technology designed for the specific challenges on the carotid artery anatomy, which we believe can be seamlessly integrated into the workflow of carotid stenting procedures performed via both transcarotid and transfemal approaches.

Between surgical and endovascular interventions, we estimate that 475,000 carotid artery stenting, carotid endarterectomy and medical management procedures are performed globally. We estimate that the potential total addressable market opportunity for Carotid IVL is $750 million.

Valvular Transcatheter Lithotripsy

The global market for aortic valve replacement, the main treatment for AS, is growing rapidly, and is dominated by the emergence of TAVR devices. TAVR has rapidly developed into a multibillion-dollar market globally. According to Clarivate, the global market for TAVR is expected to grow to approximately 370,000 by 2026. We believe our IVL System may be able to improve the treatment of AS among patients for whom currently available solutions are inadequate. We are currently working to develop an IVL catheter specific for valvular transcatheter lithotripsy ("VTL") which we believe can safely and effectively treat patients with AS ("VTL System"). If successful, we believe this represents a potential total addressable market opportunity of approximately $1 billion for our VTL System to treat AS.

There are several applications where our VTL technology may improve the treatment of calcified aortic and mitral valves. On the aortic side, moderate to severe calcium can necessitate compromise in the application of current treatment options (primarily TAVR), whether that is by selecting a non-preferred valve or a sub-optimal deployment of a given

valve. By modifying the calcium, our technology may reduce compromise, maintaining a low risk of annular rupture while improving paravalvular leaks. By creating a sustained gradient reduction and increasing valve area, VTL could become a destination therapy or a bridge to TAVR for patients who need to recover from other illness, or in younger patients for whom TAVR is not yet an ideal treatment.

VTL may also have applications in addressing diseases of the mitral valve, where leaflet and mitral annular calcium ("MAC") play a role. The first consideration in the mitral valve is a destination therapy to treat degenerative MS, where modification of calcium may increase leaflet mobility and valve area. MAC poses problems in mitral regurgitation well, and therefore VTL may improve outcomes of transcatheter edge to edge repair. While still in the clinical trial phase in most of the world, transcatheter mitral valve replacement may also benefit from modification of MAC with VTL. It is generally understood that between 6% to 8% of patients with severe MAC present with MS, and that 24% of aortic stenosis patients have MS secondary to MAC.

The Challenges of Refractory Angina

Refractory angina is an increasingly prevalent clinical syndrome characterized by ongoing ischemic symptoms despite optimal medical management in patients. Refractory angina may occur in patients with and without obstructive CAD. Refractory angina in patients with obstructive CAD is defined as the occurrence of frequent angina attacks uncontrolled by optimal drug therapy, significantly limiting the patients' daily activities, and with the presence of CAD rendering PCI or bypass surgery unsuitable. Refractory angina without obstructive arteries ("ANOCA") is defined as patients with angiographic evidence of ischemia but no obstructive CAD. We expect the prevalence of refractory angina in both groups will continue to increase due to the progressively longer life expectancy of patients, including those patients with complex or diffuse CAD.

Refractory angina has profound effects on the quality of life of affected patients. As a result, angina is a significant burden on healthcare systems worldwide. There is a clear association between more frequent angina and greater utilization of healthcare resources. The primary focus of treatment is on improving quality of life for patients. Angina is conventionally treated with anti-anginal drugs, PCI, and/or coronary artery bypass grafting. Despite those efforts, a significant number of patients remain symptomatic. We believe the burden of refractory angina is increasing and the challenges it poses to successfully treating patients with CAD remain unaddressed, which is why the Reducer was developed.

Our Reducer

The Reducer is targeting a patient population that has failed to gain adequate relief from their angina symptoms, despite other medical treatment options. A refractory patient, by definition, is resistant to other existing interventional cardiology therapies and is not receiving adequate relief from available drug regimens to manage their chest pain, shortness of breath and other debilitating symptoms.

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel, bare metal device, which is implanted in the coronary sinus (the main vein draining blood from the heart muscle), creating a narrowing in venous outflow from the myocardium (the muscular layer of the heart wall). This focal narrowing provides a pressure elevation in the coronary sinus which is intended to improve blood perfusion to ischemic territories of the heart muscle by redistributing blood from the less ischemic areas to the more ischemic areas. This can result in improved perfusion of the endocardium, which helps relieve ischemia and chest pain, shortness of breath and other debilitating symptoms. It is implanted using conventional catheter-based procedure interventional techniques. The Reducer is pre-loaded on a balloon catheter compatible with a 9 French delivery sheath and operates over a 0.035 inch guidewire. The implant procedure requires minimal training for experienced interventionalists. The Reducer is not currently available for sale in the United States.

Reducer Market

Refractory angina patients with obstructive coronary disease continue to experience symptoms of chest pain despite maximal medical therapy. It is estimated that refractory angina in patients with obstructive CAD affects approximately 300,000 new patients each year in the United States and Europe. According to a study published in the European Heart Journal in 2019, angina affects between 20% to 40% of patents after successful revascularization and further stated that persistent angina is associated with a significant economic burden with healthcare costs almost being two-fold higher among patients with persistent angina post-PCI versus those who become symptom-free. There is emerging interest in treating patients that have refractory angina despite patent coronary arteries. ANOCA disease results in

substantial morbidity in patients and may affect as many as 30% of patients undergoing angiography according to a study published in the New England Journal of Medicine in 2019. We estimate that there are 500,000 patients in the United States and Europe with refractory angina and ANOCA each year. Increasing interest in diagnosis and treatment of angina and microvascular dysfunction as evidenced by the 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes provides growing support for Reducer treatment. We believe there is an estimated $5 billion total addressable market opportunity for our Reducer to treat refractory angina.

Our Growth Strategy

Our mission is to provide safe, effective, and easy-to-use treatments to optimize outcomes for calcified cardiovascular disease. We believe the following strategies will advance our mission and will contribute to our future success and growth.

- Increase market penetration with new products.
- Expand the pool of treatable patients.
- Improve customer economics.
- Invest in clinical data.
- Maintain our team's high performance.
- Acquire differentiated platforms selectively.

Research and Development

We invest in research and development efforts that advance our technologies with the goal of expanding and improving upon our existing product offerings.

We believe our ability to rapidly develop innovative products is attributable to the dynamic product innovation process that we have implemented, the versatility and leveragability of our core technologies and the management philosophy behind that process. We have recruited and retained engineers and scientists with significant experience in the development of medical devices. We have a pipeline of products in various stages of development that are expected to provide additional commercial opportunities. Our research and development efforts are based in Santa Clara, California and New Brighton, Minnesota.

Manufacturing

The manufacturing of our products is principally done at our facilities in Santa Clara, California, except that a portion of demand for certain products is manufactured by a third-party contract manufacturer in Costa Rica. In July 2022, we purchased real property in the Coyol Free Trade Zone in Alajuela, Costa Rica, and began the construction of a new manufacturing facility. As of December 31, 2023, the first phase of the facility was completed and occupied and the second phase was still in process of construction.

We stock inventory of raw materials, components and finished goods at our facilities in California and finished products with our distribution warehouses and third-party logistics providers. We also stock inventory of finished products with our direct sales representatives, who travel to our hospital customers' locations as part of their sales efforts. In addition, our contract manufacturer holds an inventory of raw materials, components, and finished goods at its manufacturing facility in Costa Rica as necessary to support our catheter production requirements.

Our electronics (i.e., our generators and connector cables) are produced by original equipment manufacturing partners using our design specifications. We rely on a single or limited number of suppliers for certain raw materials and components, and we generally have no long-term supply arrangements with our suppliers, as we order on a purchase order basis. Under our contract manufacturing arrangements with our catheter contract manufacturer, however, we make binding one-year purchase commitments, subject to certain adjustment mechanisms specified in the contract manufacturing agreement.

We generally ship our products from our Santa Clara site to either our third-party logistics providers, who then ship the products directly to hospital customers or distributors, or directly to hospital customers or distributors. We also sell our products directly to our hospital customers through our direct sales representatives. We have offered consignment sales

arrangements to certain customers, including some customers in Germany, Austria, Andorra, Switzerland, France, Italy, Portugal, Spain and the UK who we ship to on a consignment basis from our third-party logistics provider located in the Netherlands. Our catheter contract manufacturer generally ships all products to our facility in Santa Clara, where the products are held in inventory until ready to be shipped to U.S. or international customers.

Our rigorous quality control management programs have earned us a number of quality-related manufacturing designations. Our Santa Clara facility is compliant with International Organization for Standardization ("ISO") 13485:2016 and the environmental management system at our Santa Clara site is certified to ISO 14001. In 2014, we achieved compliance with the European Union's (the "EU") Medical Device Directive (93/42/EEC) (the "MDD"). In January 2021, our quality system was successfully audited and deemed compliant with the EU's new Medical Devices Regulation (Regulation 2017/745) (the "MDR"), and we received our first device approval under the MDR for our C^{2+} catheter in August 2022. We received device approval under the MDR for the M^{5+} catheter and S^{4} catheter in October 2023. We use regular internal audits to help ensure strong quality control practices. An internal, on-going staff training, and education program contributes to our quality assurance program and training is documented and considered part of the employee evaluation process. We are also subject to periodic audits by regulatory agencies. We maintain a Medical Device Single Audit Program ("MDSAP") certification, which certifies that we meet the regulatory requirements of multiple geographies (Australia, Brazil, Canada, Japan and the United States) and bundles the surveillance of our quality management system into a single, annual audit conducted by our notified body.

Sales and Marketing

We market our products to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD, CAD and refractory angina. We have dedicated meaningful resources to establish direct sales capability in the United States, Germany, Austria, Switzerland, France, Ireland, Japan, the UK, Spain, Portugal, Canada and Italy, which we have complemented with distributors actively selling in over 55 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. We are continuing to add new U.S. sales territories and are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel and expanded direct sales territories.

Our sales representatives and sales managers generally have substantial and applicable medical device experience, specifically in the vascular space and market our products directly to interventional cardiologists, vascular surgeons and interventional radiologists. We are focused on developing strong relationships with our physician and hospital customers in order to educate them on the use and benefits of our products. Similarly, our marketing team has a significant amount of domain expertise and a strong track record of success.

In the United States, our IVL generators and connector cables may be sold, rented or loaned to hospital customers, while our disposable IVL catheters are sold to hospital customers or may be provided, in limited circumstances, on a consignment basis whereby title to such catheters passes to the hospital once they are used in a clinical procedure. In the consignment model, following such use, we charge the hospital a predetermined set fee for each IVL catheter, which fee may be determined based on the hospital's overall use of our IVL catheters. Internationally, in our direct markets where we sell both our IVL catheters and the Reducer, we maintain dedicated sales teams in those jurisdictions.

In addition to our direct sales organizations, we sell to distributors in certain geographies outside the United States where we have determined that selling through third party distributors is the best way to optimize our opportunities and resources. We select distribution partners who have deep experience in our markets, have strong customer relationships and have a demonstrated track record of launching innovative products.

Reimbursement

In the United States, our products are generally purchased by hospitals, which in turn normally bill various third-party payors, including government programs, such as Medicare and Medicaid, and private health insurance plans, for the healthcare services required to treat each patient. The applicable third-party payors determine whether to provide coverage for a particular procedure or product, and, if so, the amount for which the provider will be reimbursed for treatment. In the United States, there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product or service may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product or service once coverage is approved. Payors may limit coverage to specific products or services on an approved list, or formulary, which might not include all of the FDA-approved or -cleared products for a particular indication.

In the United States, Medicare has established dedicated coding and payment for peripheral IVL procedures performed in the hospital inpatient, hospital outpatient and ambulatory surgical settings of care. Physician coding and payment is under development led by the specialty medical societies that perform peripheral procedures in coordination with the CPT Editorial Panel, American Medical Association and CMS. Coronary IVL is an FDA-designated Breakthrough Device with coding and payment originally established under the New Technology Add-On Payment ("NTAP") and Transitional Pass-Through Payment ("TPT") programs for procedures performed in the hospital inpatient and hospital outpatient settings respectively. Upon the conclusion of the NTAP in September 2023, Medicare created new Medicare Severity Diagnosis Related Groups for coronary IVL performed in a hospital inpatient setting. The TPT program for hospital outpatient procedures is still in effect. A Category I CPT add-on code has been established effective January 1, 2024 that will remunerate physicians when coronary IVL is performed.

Outside the United States, reimbursement levels vary significantly by country, and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both.

Competition

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 with manufacturers and distributors of cardiovascular medical devices. The industry in which we operate is highly competitive, and our products may compete with products manufactured or reportedly under development by other companies, including Boston Scientific Corporation, Medtronic plc, Philips N.V. and Abbott Laboratories ("Abbott"). Some of these competitors are large, well-capitalized companies with greater market share and resources than we have. As a consequence, they may be 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:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers, and third-party payors;
- 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 and patent prosecution.

We believe that our focus on calcified cardiovascular disease and 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 pioneering and designed to treat patients with calcified cardiovascular disease safely, easily and effectively, with improved outcomes. Our continued success depends on our ability to:

- develop innovative, proprietary products that can cost-effectively address significant clinical needs in a manner that is safe and effective for patients and easy to use for physicians;
- continue to innovate and develop scientifically advanced technology;
- obtain and maintain regulatory clearances or approvals;
- demonstrate efficacy in our sponsored and third-party clinical trials and studies;
- obtain and maintain adequate reimbursement for procedures using our products;
- apply technology across product lines and markets;
- attract and retain skilled research and development and sales personnel; and
- cost-effectively manufacture and successfully market and sell products.

We believe our products fare favorably when compared with those of other companies on the basis of the factors described above.

Intellectual Property

Our success depends in part on our ability to obtain, maintain, protect and enforce our proprietary technology and intellectual property rights, in particular, defend our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect the intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position.

As of December 31, 2023, we owned 103 issued U.S. patents and 212 issued foreign patents, 47 pending U.S. non-provisional patent applications and 119 pending foreign patent applications (including ten Patent Cooperation Treaty applications). In addition, we own or have rights to trademarks and domains in the United States and select locations internationally that we use in connection with the operation of our business.

U.S. Pat. No. 8,956,371 (the "'371 patent"), which is one of our issued U.S. patents relating to our current IVL Technology, remains the subject of an inter partes review ("IPR") proceeding filed by Cardiovascular Systems, Inc. ("CSI"), which was acquired by Abbott in April 2023. On July 8, 2020, the Patent Trial and Appeal Board (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 an appeal of the PTAB rulings to the United States Court of Appeals for the Federal Circuit, and CSI has filed a cross-appeal to challenge the PTAB's decision that Claim 5 of the '371 patent is valid. Accordingly, Claim 5 and all other claims remain valid and enforceable until all appeals have been exhausted. For more information regarding these proceedings, see the section titled "*Legal Proceedings*."

Our issued patents, and any patents granted from such applications, are expected to expire between 2029 and 2042, without taking potential patent term extensions or adjustments into account. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. We aim to protect our innovation with patents, but we cannot be sure that any applications we file will issue as patents, that any patents we obtain will withstand challenge or invalidation, or that we will obtain sufficient patent protection for innovation that turns out to be more important than anticipated.

For more information regarding the risks related to our intellectual property, including the above referenced IPR proceedings, see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

Government Regulation

Our products are medical devices subject to extensive laws, rules and regulations of various U.S. federal and state, and international regulatory bodies in each of the markets in which we sell or distribute our products. These laws, rules and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, advertising, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, pricing and discounts, post-marketing surveillance and interactions with healthcare professionals. Failure to comply with applicable requirements may subject us or one or more of our products to a variety of sanctions, such as loss of product approvals/clearances/certifications, issuance of warning letters, untitled letters, civil monetary penalties and judicial sanctions, such as product seizures, injunctions or criminal prosecution.

United States

FDA's Premarket Clearance and Approval Requirements. Each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance, unless it qualifies for an exemption as outlined below, De Novo authorization, or a PMA from the FDA. Medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with the medical device and the extent of regulatory control needed to provide reasonable assurance of safety and effectiveness.

- Class I devices are deemed to be low risk and are subject to the general controls of the U.S. Federal Food, Drug and Cosmetic Act (the "FD&C Act"), such as provisions that relate to adulteration, misbranding, registration and listing, notification (including repair, replacement, or refund), records and

reports, and good manufacturing practices. Most Class I devices are classified as exempt from the premarket notification requirement under Section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA.

- Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls may include performance standards, post-market surveillance, patient registries, and guidance documents. It is typical for Class II devices to be subject to a requirement for clearance under Section 510(k) of the FD&C Act.
- Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after review of a PMA application. The FDA can also impose sales, marketing or other restrictions on Class III devices to ensure that they are used in a safe and effective manner.

510(k) Clearance Pathway. When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is "substantially equivalent" to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a premarket notification must be submitted to the FDA at least 90 days before we intend to market a device, and we must receive 510(k) clearance from the FDA before we actually market the device. The Medical Device User Fee Amendments performance goal for a traditional 510(k) clearance is 90 days. As a practical matter, however, clearance often takes longer, because the review clock is paused by the FDA to allow time to resolve any questions the FDA may have. To demonstrate substantial equivalence, we must show that the proposed device (1) has the same intended use as the predicate device, and (2) it either has (a) the same technological characteristics as the predicate device or (b) if the proposed device has different technological characteristics than the predicate device, that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class III.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance for any particular device, the FDA may retroactively require us to seek 510(k) clearance or possibly a PMA. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

De Novo Classification Pathway. If a novel device is low risk but lacks a predicate device, it may be eligible for de novo classification. In this process, the FDA by order creates a new classification regulation placing the novel device in Class I or II. This process is lengthier and more expensive than a 510(k) review. For instance, the FDA requires that the premarket notification be submitted 150 days, rather than 90 days, before the day that the device is intended to be marketed. This process is, however, quicker and less expensive than the PMA pathway described below. Once the classification regulation is established, subsequent devices in this type can use the 510(k) pathway.

Premarket Approval Pathway. A PMA application under Section 515 of the FD&C Act must be submitted to the FDA for Class III devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA application process is much more demanding than the 510(k) premarket notification process. The granting of a PMA is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s).

After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are an important factor in the FDA's overall decision-making

process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation ("QSR"). The FDA also may inspect one or more clinical sites to ensure the validity of the data and compliance with applicable FDA regulations.

Upon completion of the PMA application review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an "approvable letter" which indicates the FDA's belief that the PMA application is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a "not approvable letter" which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Some changes to an approved PMA device, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new PMA application or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMA applications.

Clinical Trials. Clinical trials are almost always required to support a PMA and are sometimes required for 510(k) clearance. In the United States, for significant risk devices, these trials require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites.

During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate insitutional review boards ("IRBs") at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of the FDA's IDE regulations and be approved by an IRB at the clinical trials sites. We, the FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Sponsors of clinical trials of devices are required to register with clinicaltrials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is made public as part of the registration.

Ongoing Regulation by the FDA. Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements will apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health; and

- post market surveillance regulations, which apply to certain Class II and Class III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

In addition, the FDA's medical device reporting laws and regulations require us to provide information to the FDA when we receive or otherwise become aware of information that reasonably suggests that one of our devices may have caused or contributed to a death or serious injury, or information that reasonably suggests a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. Our approach has been to file such reports with the FDA even in cases where reporting might not otherwise be required out of an abundance of caution.

The FDA also prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, the California Department of Health Services ("CDHS") requires us to register as a medical device manufacturer within the state. Because of this, the FDA and the CDHS inspect us on a routine basis for compliance with the QSR. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. We have undergone and expect to continue to undergo regular QSR inspections in connection with the manufacture of our products at our facilities. Further, the FDA requires us to comply with various FDA regulations regarding labeling. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA, CDHS or other state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals/clearances that have already been granted; and
- criminal prosecution.

Anti-Kickback Statute. The U.S. federal Anti-Kickback Statute (the "Anti-Kickback Statute") prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for the furnishing or arranging for a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs, such as the Medicare and Medicaid programs. The term "remuneration" expressly includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry.

There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute, however, those exceptions and safe harbors are drawn narrowly, and there may be no available exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants, or charitable donations. Practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-

Kickback Statute. Some of our practices, such as the loaning of generators or consignment of catheters, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability.

The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (the "False Claims Act"), which is discussed below. Penalties for violations of the Anti-Kickback Statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs, and the curtailment or restructuring of operations. Various states have adopted laws similar to the Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors. In addition, many foreign jurisdictions in which we operate have similar laws and regulations.

Federal Civil False Claims Act. The False Claims Act prohibits, among other things, persons, or entities from knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds or knowingly presenting or causing to be presented a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government.

Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the subject entity to the government in fines or settlement and as a result, *qui tam* cases are prevalent in the health care industry. If an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have adopted laws similar to the False Claims Act, and many of these state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government.

Federal Civil Monetary Penalties Statute. The federal Civil Monetary Penalties Statute, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knew, or should have known, was for an item or service that was not provided as claimed or is false or fraudulent.

Sunshine Act. Under the Patient Protection and Affordable Care Act (the "ACA"), the Physician Payments Sunshine Act, implemented as the Open Payments program, requires manufacturers of drugs, devices, biologics or medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the CMS, information related to payments or other "transfers of value" made to teaching hospitals, physicians and other health care providers such as physician assistants and nurse practitioners, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members, with the reported information made public on a searchable website. Similar laws have been enacted at the state level and in foreign jurisdictions, including France. The ACA has impacted existing government healthcare programs, has resulted in the development of new programs and continues to be altered by judicial challenges and Congressional modifications.

Health Insurance Portability and Accountability Act of 1996. The federal Health Insurance Portability and Accountability Act ("HIPAA") imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA and its implementing regulations impose 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 covered entities, which are healthcare providers, health plans and healthcare clearinghouses.

Other Laws, Rules and Regulations. We are also subject to a variety of other U.S. federal, state, and local laws and regulations and foreign laws, rules, and regulations, including:

- analogous state and foreign law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state and foreign laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures;
- federal, state and foreign laws governing the privacy and security of personal information in general and health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and
- federal, state, local and international laws relating to relating to safe working conditions, laboratory, and manufacturing practices.

International

Regulation of medical devices in general. In addition to the rules and regulations described above, international sales of medical devices are subject to a variety of foreign government regulations, which may vary substantially from country to country. We expect this global regulatory environment will continue to be complex and evolving, which could impact the cost, the time needed to approve, and our ability to maintain existing approvals or obtain future approvals for our products, and require extensive compliance and monitoring obligations in the countries where we sell or distribute our products.

European Union. The EU has adopted numerous regulations and standards harmonizing the requirements for the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Our products are regulated in the EU as medical devices per the MDR, which was published in May 2017 and came into application in May 2021, and which replaced, subject to certain transition provisions contained in the MDR, the MDD. Conformity with the MDD or MDR, as applicable, is indicated by the CE mark, which can be affixed by the manufacturer after a certificate of conformity is issued by the applicable Notified Body following the successful satisfaction of a variety of requirements. These requirements depend on the class of the product, but normally involve a combination of: (a) preparation of a design dossier; (b) self-assessment by the manufacturer; (c) a third-party assessment, which generally consists of an audit of the manufacturer's quality system and manufacturing site by a Notified Body; and (d) review of the design dossier, which may include safety and technical information, by the Notified Body. Our ability to affix the CE mark is contingent upon continued compliance with the applicable regulations and standards, including compliance with ISO 13485 and applicable vigilance and post-market surveillance.

The MDR, among other things, expanded and modified the pre-market and post-market obligations of manufacturers under the MDD. We are currently relying on transitional provisions for our products not yet approved under the MDR, which allow us to continue placing our products on the EU market until expiry of our current certificates of conformity issued under MDD, subject to compliance with certain conditions. 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 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. The final text of the proposal is expected to be adopted in February 2023. However, we have updated our technical documentation and other quality management system processes for compliance with the MDR requirements.

United Kingdom. We anticipate that our compliance obligations under UK law will continue to increase and change following the departure of the UK from the EU on January 31, 2020, and given that the UK Government is in the process of updating the current MDD-derived regime, the UK Medical Devices Regulations 2002 (the "UK MDR"). Revised post-market surveillance requirements are expected to apply later in 2024 with wider changes to follow in 2025.

However, based on the Government consultation in 2022, many of the changes are expected to bring the UK MDR closer to the EU MDR requirements. Currently the CE mark continues to be recognized in Great Britain and Northern Ireland. Great Britain also has an alternative UKCA mark under the UK MDR, which is currently based on MDD. 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 it needs to be supervised by a 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). We expect to commence preparations to ensure we can use the UKCA mark by the sooner of the expiry of the relevant CE certificate and June 2028 or June 2030 (as applicable to our medical devices). The UK government has already made some changes to the UK MDR, including requiring that we appoint a UK-based Responsible Person to serve as a point of contact (where previously the UK would be covered by our EU-based Authorized Representative) and register our devices with the Medicines and Healthcare products Regulatory Agency. We expect that over time the two processes will continue to diverge to some extent but note that many of the proposed changes to the UK MDR would bring the UK MDR into closer alignment with the EU MDR.

China. The country has been actively improving and updating its regulatory regime on medical devices, including innovative medical devices, addressing the entire lifecycle of medical devices, including but not limited to, research and development, clinical trials, product registration, manufacturing, distribution, import and export, packaging, labeling, advertisement, post-marketing surveillance and adverse events reporting, as well as health data and genetic data protection. Typically, medical devices in China are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device. Medical devices in different classes are subject to different marking authorization regimes: foreign Class I medical devices must be record-filed with the NMPA before importing into China for distribution; foreign Class II and Class III medical devices must be registered with the NMPA before importing into China for distribution. The Medical Device Registration Certificates for Class II and Class III medical devices are valid for five years, and an application for renewal with the NMPA is available six months prior to the expiration of the registration certificates. Any substantial changes to the design, raw materials, device specifications, device composition and structure, technical requirements, manufacturing process and manufacturing sites, application scope or instructions for use, possibly affecting the safety and efficacy of medical devices, must be updated and registered with the NMPA and, any other types of changes must be record-filed with the authority.

In China, the distribution of Class II medical devices is subject to the record-filing with the competent municipal branches of the NMPA, while that of Class III devices is subject to the approval granted by the competent municipal branches of the NMPA. In 2021, we entered into a joint venture, Genesis Shockwave Private Ltd., with Genesis MedTech International Private Limited ("Genesis"). As the distributor of our products, Genesis must strictly follow the Good Supply Practices for Medical Devices of China, including building up a quality management system and quality control measures covering the purchase, storage, sale, transportation and after-sale services of the products. Genesis must also follow correspondence requirements relating to the labels and instructions for use of medical devices by, for example, providing accurate, complete and authentic information in Chinese that is consistent with the registration with the NMPA or its competent municipal branch. Moreover, the advertising of medical devices is subject to the review and approval of the NMPA or its competent municipal branch and must be restricted within the scope registered with the NMPA.

As the marketing authorization holder of our manufactured medical devices, we are also subject to post-marketing surveillance responsibilities, including the monitoring of adverse events, handling of product defects, conduct of re-evaluation, and submitting of annual adverse event reports to the applicable authority. In the event that we were to discover that the devices are inconsistent with the registered product technical requirements or with other defects, we are required to take relevant corrective measures per company policies and regulations, and report to competent authorities.

Japan. In Japan, our products are regulated as medical devices under the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, Act No. 145 of 1960, as amended (the "PMD Act"). The PMD Act affects major areas of medical device regulations, including quality management system compliance, device registration, the regulation of medical software and third-party certifications. There are also detailed regulations prepared by the government for enforcing this law in the form of ministerial ordinances and notices, such as the Enforcement Ordinance and the Enforcement Regulations of the PMD Act, and notifications issued by the Director General of the Bureaus or the directors of the Divisions in charge in the MHLW. The Pharmaceutical and Medical Device Agency is an independent agency that works together with the MHLW to assess the safety and effectiveness of medical devices. Japan uses a risk-based classification system to categorize medical devices into four classes based on the associated risk (i.e.

Class I – lowest potential risk; Class IV – highest potential risk). We routinely monitor developments in the Japanese regulatory environment and address any new compliance obligations as new standards are adopted.

Other laws and regulations. In addition to laws regulating medical devices, our international operations, distribution and sales are subject to a variety of rules of general application: the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA") and similar anti-bribery laws in other jurisdictions including the UK Bribery Act 2010 (the "UKBA") and Chinese anti-corruption rules and regulations; U.S. and foreign export and trade control laws; U.S. and foreign tax laws; local employment, immigration and labor laws; local intellectual property laws, which may not protect intellectual property rights to the same extent as U.S. law; and privacy laws such as the European General Data Protection Regulation and the UK equivalent, the China Data Security Law, the China Cybersecurity Law, the Personal Information Protection Law of China, and the Regulations on the Administration of Human Genetic Resources of China. Some of these laws, for example the FCPA, the UKBA, and the China Cybersecurity Law, have extraterritorial effect. In countries where we sell to our customers directly, or where we sell through a joint venture, we, as well as our joint ventures, are also subject to more specific laws and codes that regulate interactions between manufacturers/distributors of medical devices and healthcare professionals. These rules also vary from country to country. For example, in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau, where we sell our products via a joint venture, such laws mainly include (i) the Criminal Law which penalizes the bribing of State functionaries or non-State functionaries (including healthcare professionals); and (ii) the Anti-Unfair Competition Law which regulates commercial bribery to parties related to specific transactions.

Regulatory Inspections

We are subject to periodic inspections by the FDA and other regulatory entities, such as our European Notified Body and the NMPA, related to the regulatory requirements that apply to medical devices designed and manufactured, and clinical trials sponsored, by us. When the FDA conducts an inspection, the investigators will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or Form FDA 483. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we would be required to respond in writing, and would be required to undertake corrective and/or preventive or other actions in order to address the FDA's or other regulators' concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

As the marketing authorization holder of our manufactured medical devices in China, our manufacturing facilities are also subject to potential on-site inspections conducted by the NMPA, with respect to authenticity, reliability and compliance during the research and manufacturing process. Failure to cooperate with the NMPA with respect to these inspections may result in a "non-compliance" decision and thus subject us to further risk control measures, including administrative orders to rectify.

Seasonality

We have experienced some seasonality during summer months, which we believe is attributable to the postponement of elective surgeries for summer vacation plans of physicians and patients. We have also experienced some seasonal slowing of demand for our products in our fourth quarters due to year-end clinical treatment patterns, such as the postponement of elective surgeries during the holiday period. We expect these seasonal factors to become more pronounced in the future as our business grows.

Human Capital Resources

As of December 31, 2023, we had 1,468 full-time and part-time employees worldwide, of which 672 were located at our headquarters in Santa Clara, California, 543 were remote and field-based employees throughout the country and 253 were located outside of the United States. Of these employees, 591 were in sales, marketing and commercial operations, 517 were in manufacturing, operations and quality, 221 were in research and development, clinical and regulatory, and 139 were in general and administration. We routinely enter into contractual agreements with our employees, which typically include confidentiality and non-competition commitments. None of our U.S. employees are represented by labor unions or collective bargaining agreements with respect to their employment by us. However, in certain countries outside of the United States in which we operate, we are subject to, and comply with, local labor law requirements which may automatically make our employees in those countries subject to industry-wide collective bargaining agreements. We have never experienced a work stoppage.

We believe that we have a good relationship with our workforce. Our employees are a key factor in transforming the way calcified cardiovascular disease is treated, and our future success largely depends upon our continued ability to attract and retain highly skilled employees. Our employee turnover for the year ended December 31, 2023 was approximately 12%. We consider the turnover rate a valuable metric to measure the effectiveness of our programs and to assist in developing new programs.

To attract, develop, and retain talent, we emphasize:

- *Compensation and Benefits*. We strive to provide a competitive mix of pay, benefits and services that help meet the needs of our employees. In addition to salaries, these programs include variable incentive compensation plans, potential annual discretionary bonuses, an employee stock purchase plan, stock awards, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. In addition to our equity incentive programs, we have used targeted equity-based grants with vesting conditions to facilitate retention of personnel.
- *Health, Safety and Wellness*. The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families.
- *Diversity, Equity and Inclusion*. We value diversity as a strength because we feel a diverse workforce leads to innovative ideas and solutions that help us change the way atherosclerosis is treated. We are an equal opportunity employer, and we maintain policies that prohibit unlawful discrimination, including based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital status and veteran status. We are investing in maintaining a work environment where our employees can feel inspired to deliver their workplace best every day by developing and expanding our equality, diversity, and inclusion initiatives across our entire workforce, led by our executive leadership and driven through diverse cross-functional teams. As of December 31, 2023, our workforce was made up of approximately 54% female employees, with approximately 38% of management positions held by female employees.
- *Communications and Engagement*. We keep our employees informed on key developments in our business and provide various forums for their voices to be heard. In addition to regular written announcements, messages and communications from members of the management team, our Chief Executive Officer leads quarterly all hands meetings to ensure our employees receive timely business updates. In these meetings, all participants have the option to anonymously ask questions, which are addressed by the executive team. We have introduced an enhanced company intranet site that highlights important business matters, profiles our employees, and provides our employees with resources that help them more efficiently do their jobs.
- *Talent Development*. We believe employees are our greatest asset and we strive to provide development and promotional opportunities in order to help our employees reach their full potential. We provide formal and informal training opportunities designed to enhance learning and development. Consistent with our employee review process, we encourage continuous manager and employee dialogue around performance and development.

We continue to assess and develop additional measures and objectives necessary to attract and retain employees including relating to talent acquisition and retention, employee engagement, employee development and training, and employee safety and wellness.

Corporate Information

We were incorporated in 2009 as a Delaware corporation under the name Shockwave Medical, Inc. Our principal executive offices are located at 5403 Betsy Ross Drive, Santa Clara, California 95054, and our telephone number is (510) 279-4262. Our website address is www.shockwavemedical.com. The information on, or that can be accessed through, our

website is not part of this Annual Report on Form 10-K. We have included our website address as an inactive textual reference only.

We use "Shockwave," "Shockwave M5," "Shockwave C2," "Shockwave S4," "Shockwave L6," and other marks as trademarks in the United States and other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our right or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the Securities and Exchange Commission (the "SEC"). Our website address is www.shockwavemedical.com. Information on our website is not part of this Annual Report on Form 10-K. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov. We use our website, as well as press releases, public conference calls, public webcasts, as means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. The information disclosed by the foregoing channels could be deemed to be material information. As such, we encourage investors, the media and others to follow the channels listed above and to review the information disclosed through such channels.

Item 1A. Risk Factors.

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

While we have reported net income in recent years, we have a history of net losses, and we may 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 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, 2021. 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. Although we achieved profitability for all four quarters of 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 losses in future periods.

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 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 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;
- 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 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 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.

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 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 build our 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, including managing risks related to excess or constrained capacity at our existing facilities. 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, 2023, we had 1,468 full-time and part-time employees worldwide, compared to 1,001 full-time employees as of December 31, 2022. 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;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and 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. In July 2022, we purchased real property in the Coyol Free Trade Zone in Alajuela, Costa Rica, and began construction of a new manufacturing facility in Costa Rica in order to improve our operational efficiency. Our ability to plan, construct and equip a new manufacturing facility is subject to significant risk and uncertainty, including risks inherent in the establishment of new manufacturing facilities, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, many of which may be out of our control. Rapid expansion in personnel may result in 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 new 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 marketing goals, which would have a material adverse effect on our business, financial condition and results of operations.

As we expand internationally, we will be increasingly exposed to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

While we currently derive a majority of our revenue from sales in the United States and maintain most of our assets in the United States, we intend to continue to pursue growth opportunities internationally, including through our new manufacturing facility in Costa Rica. As a result, we may increase our use of administrative and support functions from locations outside the United States, which could expose us to increased risks associated with international sales and operations. Additionally, our international expansion efforts may not be successful, we may experience difficulties in scaling these functions from locations outside the United States, and we may not experience the expected cost efficiencies. Our international operations are, and will continue to be, subject to a number of risks, including:

- risks relating to compliance with the laws and regulations of jurisdictions outside the United States, which may conflict from one jurisdiction to another and may change from time to time, such as tax laws, privacy and intellectual property laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- obtaining and sustaining required regulatory approvals and certifications, and maintaining regulatory compliance, where required for the sale of our products in various countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;

- logistics and regulations associated with shipping our products;
- limits on our ability to penetrate international markets, including markets in which our competitors' products or alternative procedures that do not use our products are more established;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the effect of local and regional financial pressures on demand and payment for our services, fluctuations in trade policy and tariff regulations, changes in international tax regulations applicable to our business, and exposure to foreign currency exchange rate fluctuations, which may reduce the reported value of our foreign currency denominated revenues, expenses, and cash flows;
- decreased emphasis or enforcement or intellectual property protections in some countries outside the United States in comparison to the United States;
- increased risk of litigation or administrative proceedings in connection with our relationships with international business partners, including litigation against persons whom we believe have infringed on our intellectual property, infringement litigation filed against us, litigation against a competitor, or litigation filed against us by distributors or service providers resulting from a breach of contract or other claim, as well as disputes regarding government and public tenders, any of which may result in substantial costs to us, adverse judgments, settlements, and diversion of our management's attention;
- natural disasters, political and economic instability, including 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.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), UK Bribery Act of 2010 (the "UKBA"), and comparable laws and regulations in 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 by 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 marking; 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.

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 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 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 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.

Additionally, an escalation of recent trade tensions between the United States and China 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 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 our 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 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 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 assets, including intellectual property. 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 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 implemented a new company-wide enterprise resource planning ("ERP") system to upgrade certain existing business, operational, and financial processes. The new ERP system may 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 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 or 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 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 the Health Information Technology for Economic and Clinical Health Act of 2009, 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 to take effect in many other states, including Virginia, Colorado, Connecticut, Utah, 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") 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. On the latter point, the EU GDPR (covering the EEA) as well as UK and Swiss data protection laws impose strict rules on the cross-border transfer of personal data out of the EU, UK, or Switzerland to 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 from the EU to certified companies in the United States. However, the DPF is subject to further legal challenges which could 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 concluding that the United States ensures an adequate level of protection transferred from the UK to the United States under the UK Extension to the EU-U.S. Data Privacy Framework. We anticipate a similar adequacy decision from the 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 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, 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, 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, 2023, we had net operating loss ("NOL") carryforwards of approximately $103.1 million for federal income tax purposes, $45.6 million for California income tax purposes, $31.8 million for other state income tax purposes, and $126.6 million for foreign entities. We also have research credits of $14.6 million and $14.6 million, for federal and California purposes, respectively. Unused U.S. federal NOLs 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 carryforwards is limited to 80% of taxable income. Our ability to utilize our federal NOL 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 carryforwards. We have experienced ownership changes, and although such prior ownership changes have had an immaterial impact on our utilization of affected NOL 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 carryforwards and research credits. In addition, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited. Accordingly, our ability to use our NOL 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.

Until the quarter ended December 31, 2022, we had maintained a full valuation allowance against our deferred tax assets due to our cumulative loss position and uncertainties regarding sustainable future profitability since inception. We released the valuation allowance against all of the U.S. federal deferred tax assets and other-than-California state deferred tax assets during the fourth quarter of fiscal year 2022. 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). 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 year ended December 31, 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, 2023, we had $990.6 million in cash, cash equivalents and short-term investments, and retained earnings of $110.5 million. Based on our current planned operations, 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, 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 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 terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the degree of success we experience continuing to 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; 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, imposes significant requirements on public companies, including requiring that we evaluate and determine the effectiveness of our internal control over financial reporting. Further, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") contains significant corporate governance and executive compensation related provisions, pursuant to which the SEC has adopted rules and regulations with which we must comply in areas such as "say on pay" voting and "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, these rules and regulations 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.

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 and budget and potential government shutdowns related thereto, the weakening of the global and U.S. economies, instability in the global banking sector, regional conflicts around the world, 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 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 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. Further, acts of war, terrorism, labor activism or unrest and other geopolitical unrest 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.

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, 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.

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 M^5 catheter, M^{5+} catheter and S^4 catheter for the treatment of peripheral artery disease ("PAD"), and our C^2 catheter and C^{2+} catheter for the treatment of coronary artery disease ("CAD"), each of which is available in the United States, Europe, and other international markets. We also market and sell our L^6 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 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 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.

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 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 uses. The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

Our products are approved for use in specific 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 marketing or advertising our products for any 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.

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 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 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 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 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, 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. 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 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 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 continued development of our products depends upon 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 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 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 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 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 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 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 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 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. 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 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 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.

If we are unable to successfully market and sell our products, 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. 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, 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 and our products that incorporate our technologies;
- 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, 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 technologies, but also about the diseases that our products target and the range of patient treatment choices and outcomes. We will need to convince the medical community that the additional cost and time of integrating IVL and Reducer procedures 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.

Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies are more cost effective or are received more favorably. 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 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, Medtronic plc, Philips N.V. and Abbott Laboratories ("Abbott"). 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, our focus on 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 pioneering and treat patients with 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 or that would render our technologies 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 could remain at current levels or decrease in the future. Additionally, we cannot be sure that the 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.

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 other 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 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 our products in additional targeted indications, or other planned or future products, which would affect market acceptance of these products.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. 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 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.

While we believe we have adequate product liability insurance, 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, CAD and refractory angina, and international sales comprised 20% of our revenue for the year ended December 31, 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.

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, 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, 2023, approximately 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. Although we have a program for monitoring and periodically 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 controls and import regulations could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our activities and products are subject to U.S. sanctions and export 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 regulation 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. 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 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 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, 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, 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 HIPAA, and the Physician Payments Sunshine Act, along with analogous state and foreign law equivalents, each as more fully described 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, 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 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 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 as well as a discount safe harbor. While we endeavor to structure our arrangements consistent with safe harbor requirements and industry best practices, 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, 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 C^{2+} 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 C^{2+} products we do not have prior experience in obtaining PMA approval. Our C2 catheter and C^{2+} 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 C^{2+} 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 regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, 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, 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 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 201,000 square feet. Our Santa Clara facility has been 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 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 the Patient Protection and Affordable Care Act, as amended (the "ACA"), was 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, the Budget Control Act of 2011 includes, among other things, 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 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, 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 American Taxpayer Relief Act of 2012, 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 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 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 it needs to be supervised by a 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). 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 and UK marks for our products. Adjusting to MDR and UK MDR may be costly and disruptive to 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 be prosecuted and enforced in a manner inconsistent with the best interests of our business.
- ***Patent Prosecution Process***. The patent prosecution process is expensive, time-consuming, 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 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 filing date on or after May 13, 2015) 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 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.

Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

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 petition for IPR of U.S. Pat. No. 8,956,371 (the "'371 patent"), which is one of our issued U.S. patents that relates to our current IVL technology, was filed on December 7, 2018 at the USPTO Patent Trial and Appeal Board (the "PTAB") by CSI, which was acquired by Abbott in April 2023. 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 the PTAB rulings to the United States Court of Appeals for the Federal Circuit, and CSI has filed a notice of cross-appeal to challenge the PTAB's decision that Claim 5 of the '371 patent is valid. Accordingly, Claim 5 and all other claims 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 patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 prosecuted and also impacts 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. In cases where the USPTO accepts a petition and institutes an IPR, the USPTO may cancel or significantly 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 represents a consistent source of uncertainty and 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, 2023 through December 31, 2023, the closing price of our common stock has ranged from $160.99 per share to $302.68 per share. Stock markets have experienced extreme price and volume fluctuations that have 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 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-chain disruptions, and a tightening of the global labor market; and
- other events or factors, many of which are beyond our control.

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.

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, 2023, our executive officers, directors and 5% stockholders beneficially owned approximately 33% of the outstanding shares of our common stock. As of December 31, 2023, we had 36,990,700 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, consolidations or sales of all or substantially all of our assets and other significant corporate 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 our 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 our 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, 2023, our executive officers and directors held options to purchase an aggregate of 744,607 shares of our common stock at a weighted-average exercise price of $5.70 per share and 239,019 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 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 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 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 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Our board of directors (the "Board") recognizes the critical importance of maintaining the trust and confidence of our customers, clients, business partners and employees. The Board is actively involved in oversight of our risk management program, and cybersecurity represents an important component of our overall approach to enterprise risk management ("ERM"). Our cybersecurity policies, standards, processes and practices are fully integrated into our ERM program and are based on recognized frameworks established by the National Institute of Standards and Technology Cybersecurity Framework (NIST-CSF), the International Organization for Standardization Information Security Management System Standard (ISO 27001) and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to any cybersecurity incidents.

Risk Management and Strategy

As one of the critical elements of our overall ERM approach, our cybersecurity program is focused on the following key areas:

Governance: The Board's oversight of cybersecurity risk management is supported by the Audit Committee of the Board (the "Audit Committee"), which regularly interacts with our ERM function, our Chief Information Security Officer ("CISO"), our Chief Digital & Information Officer ("CDIO") and other members of management involved in cybersecurity risk management.

Collaborative Approach: We have implemented a comprehensive, cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

Safeguards: We deploy technical and non-technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence. We operate a security operations center which monitors our environment in a continuous manner.

Incident Response and Recovery Planning: We have established and maintain business continuity and technical recovery plans of critical systems and resources in the event of a cybersecurity incident that fully address our response to a cybersecurity incident, and such plans are tested and evaluated on a regular basis. We also maintain a cybersecurity insurance policy, though the costs related to cybersecurity threats or disruptions may not be fully insured.

Third-Party Risk Management: We maintain a third-party cyber risk management program to identify and oversee cybersecurity risks presented by third party providers, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems. In the event we identify a risk, we communicate the risk to the third party and monitor the remediation. In the event of a critical risk that may cause imminent or material damage to us or our customers, our policy provides that we cease operating with such third party until the risk is remediated.

Education and Awareness: We provide regular, mandatory training, including ongoing end-user security awareness training and attack simulation assessments, for personnel regarding cybersecurity threats to equip our personnel with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices.

We engage in the periodic assessment and testing of our policies, standards, processes and practices that are designed to address cybersecurity threats and incidents, including through a formal annual risk assessment. These efforts include a wide range of activities, including external audits, assessments, tabletop exercises, threat modeling, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. We regularly engage third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits, endpoint reduction response, security operation centers, vulnerability and patch management programs and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to the Audit Committee and the Board, and we adjust our

cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

We have not identified risks from known cybersecurity threats that we believe have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, operating results, or financial condition. We will continue to monitor and assess our cybersecurity risk management program as well as invest in and seek to improve such systems and processes as appropriate. If we were to experience a material cybersecurity incident in the future, such incident may have a material effect, including on our operations, business strategy, operating results, or financial condition. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Governance

The Board, in coordination with the Audit Committee, oversees our ERM process, including the management of risks arising from cybersecurity threats. The Audit Committee receives quarterly reports, and the Board is briefed at least once annually, on cybersecurity risks from the CISO, which address a wide range of topics including the status and specific metrics on our cybersecurity program, recent developments, evolving standards and regulations, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends, and information security considerations arising with respect to our peers and third parties. The Board and the Audit Committee would receive prompt and timely information regarding any future cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed. The Board and the Audit Committee discuss our approach to cybersecurity risk management with our CISO, CDIO and other members of management involved in cybersecurity risk management regularly.

The CISO and CDIO work collaboratively across the business to implement a program designed to protect our information systems from cybersecurity threats and to promptly respond to any future cybersecurity incidents in accordance with our incident response and recovery plans. To facilitate the success of our cybersecurity risk management program, multidisciplinary teams throughout the organization are deployed to address cybersecurity threats and to respond to cybersecurity incidents. Through ongoing communications with these teams, the CISO and CDIO are informed about, and monitor the prevention, detection, mitigation and remediation, of cybersecurity threats and incidents in real time and reports such threats and incidents to the Audit Committee when appropriate.

Our CISO has served in various leadership roles in information security, including serving as the Chief Information Security Officer at two other companies. Our CISO holds an undergraduate degree in Information Systems and a master's degree in Cybersecurity and Information Assurance and has obtained multiple professional security certifications including Certified Chief Information Security Officer. Our CDIO holds an undergraduate degree in Management Information Systems with minors in Computer Science and Economics and has served in various leadership roles in information technology, including serving as the Chief Information Officer of two public companies.

Item 2. Properties.

Our corporate offices are located in Santa Clara, California where we lease approximately 201,000 square feet of office, lab and manufacturing space under leases expiring in December 2031. In addition, we produce a significant number of our products in-house at our facilities in Santa Clara. In July 2022, we purchased real property in the Coyol Free Trade Zone in Alajuela, Costa Rica, and began the construction of a new manufacturing facility. As of December 31, 2023, the first phase of the facility was completed and occupied and the second phase was still in process of construction.

Item 3. Legal Proceedings.

A petition for inter partes review ("IPR") of U.S. Pat. No. 8,956,371 (the "'371 patent"), which is one of our issued U.S. patents that relates to our current intravascular lithotripsy technology, was filed on December 7, 2018 at the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc. ("CSI"), which was acquired by Abbott Laboratories in April 2023. The PTAB instituted IPR proceedings for this patent and held oral hearings on April 15, 2020. 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 an appeal of the PTAB rulings to the United States Court of Appeals for the Federal Circuit, and CSI has filed a cross-appeal to challenge the decision that Claim 5 of the '371 patent is valid. Accordingly, Claim 5 and all other claims 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.

For more information regarding the risks presented by such proceedings, see the section titled “*Risk Factors—Risks Related to Our Intellectual Property*.”

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We have received, and may from time to time receive, letters from third parties alleging patent infringement, violation of employment practices or trademark infringement, and we may in the future participate in litigation to defend ourselves. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us due to diversion of management time and attention as well as the financial costs related to resolving such disputes.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol SWAV.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws and will depend on then existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

Holders of Record

As of February 21, 2024, there were 16 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial owners of our common stock represented by these record holders.

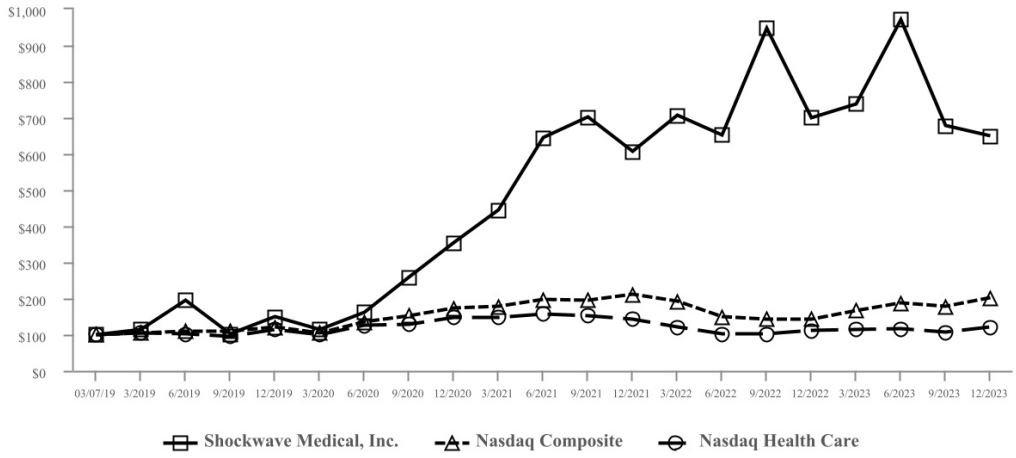
Stock Performance Graph

The following shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that Section, and shall not be deemed to be incorporated by reference into any of our other filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filing.

This chart compares the cumulative total return on our common stock with that of the Nasdaq Composite Index and the Nasdaq Health Care Index. The graph assumes $100 was invested in each of our common stock, the Nasdaq Composite Index and the Nasdaq Health Care Index, and assumes reinvestment of any dividends. Note that historic stock price performance is not necessarily indicative of future stock price performance.

COMPARISON OF CUMULATIVE TOTAL RETURN*

Among Shockwave Medical, Inc., the Nasdaq Composite Index and the Nasdaq Health Care Index



*$100 invested on 3/7/19 in stock or in index, including reinvestment of dividends. Fiscal year ending December 31.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be included in our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023, and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

None.

Issuer Purchasers of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included in Part II, Item 8 of this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains statements relating to our expectations, projections, beliefs, and prospects, which are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases you can identify these statements by forward-looking words, such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "might," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they may discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the section titled "Risk Factors," and elsewhere in this Annual Report on Form 10-K. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a medical device company focused on developing and commercializing novel technologies that transform the care of patients with cardiovascular disease. We aim to establish a new standard of care for the treatment of calcified cardiovascular disease through our differentiated and proprietary local delivery of sonic pressure waves, which we refer to as intravascular lithotripsy ("IVL"). Our IVL system (our "IVL System"), which leverages our IVL technology (our "IVL Technology"), is a minimally invasive, easy-to-use, and safe way to improve outcomes for patients with calcified cardiovascular disease. Additionally, we aim to transform the standard of care for patients suffering from refractory angina with our coronary sinus reducer (the "Reducer") technology, an effective, innovative technology that creates a permanent, controlled narrowing of the coronary sinus, the largest vein in the heart.

Our differentiated range of IVL catheters enables delivery of IVL therapy to diseased vasculature throughout the body for calcium modification. Our currently approved IVL catheters resemble a standard balloon angioplasty catheter, the device most commonly used by interventional cardiologists, to treat peripheral artery disease ("PAD") and coronary artery disease ("CAD"). This familiarity makes our IVL System easy to learn, adopt and use on a day-to-day basis. The Reducer is also a catheter-based device and is implanted in the coronary sinus, which is a major coronary vein located on the left side of the heart. It is implanted using conventional catheter-based interventional techniques and reduces the diameter of the coronary sinus, resulting in redistributed blood into the ischemic myocardium to help reduce angina symptoms. The

implant procedure requires minimal training for experienced interventionalists. The Reducer was developed to deliver this coronary sinus reduction therapy in a safe, simple and effective manner via a minimally invasive catheter that is consistent with contemporary medical practice.

Our markets

We market our products to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD, CAD and refractory angina. We have dedicated meaningful resources to establish direct sales capability in the United States, Germany, Austria, Switzerland, France, Ireland, Japan, the UK, Spain, Portugal, Canada and Italy, which we have complemented with distributors actively selling in over 55 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. We are continuing to add new U.S. sales territories and are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel and expanded direct sales territories.

Financial overview

For the years ended December 31, 2023, 2022 and 2021, we generated revenue of $730.2 million, $489.7 million and $237.1 million, respectively. For the years ended December 31, 2023, 2022 and 2021, 20%, 17% and 21%, respectively, of our product revenue was generated from customers located outside of the United States. Our sales outside of the United States are denominated principally in Euros. As a result, we have foreign exchange exposure. We have not entered into any material foreign currency hedging contracts, although we may do so in the future.

For the years ended December 31, 2023, 2022 and 2021, we had net income of $147.3 million and $216.0 million and incurred a net loss of $9.1 million, respectively. For the year ended December 31, 2022, we recognized a $99.0 million income tax benefit upon the release of a substantial portion of the valuation allowance related to our deferred tax assets.

Although we had net income for the years ended December 31, 2023 and 2022, we may incur net losses in the future which may vary significantly from period to period. We expect to continue to incur significant expenses as we (i) expand our marketing efforts to increase adoption of our products, (ii) expand existing relationships with our customers, (iii) obtain regulatory clearances or approvals for our planned or future products, (iv) conduct clinical trials on our existing and planned or future products, and (v) develop new products or add new features to our existing products. We will need to continue to generate significant revenue in order to sustain profitability as we continue to grow our business. Even if we achieve profitability for any period, we cannot be sure that we will remain profitable for any substantial period of time.

To date, our principal sources of liquidity have been the net proceeds we received through cash provided by our operating activities, sales of our equity securities, and proceeds from our debt financings. For the year ended December 31, 2023, we generated positive cash flows from operations of $196.1 million. As of December 31, 2023, we had $990.6 million in cash, cash equivalents and short-term investments and retained earnings of $110.5 million.

Convertible Debt

In August 2023, we issued $750.0 million aggregate principal amount of 1.0% convertible senior notes due 2028 (the “Notes”). In connection with the issuance of the Notes, we paid $96.4 million, including expenses, to enter into privately negotiated capped call transactions with certain initial purchasers of the Notes or their respective affiliates and certain other financial institutions (the “Capped Call Transactions”). The Capped Call Transactions are expected generally to reduce the potential dilution upon conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the Capped Call Transactions, is greater than the strike price of the Capped Call Transactions, which initially corresponds to the conversion price of the Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Notes. For additional information regarding the Notes and the Capped Call Transactions, see the section titled “Liquidity and Capital Resources.”

Impact of current business, political and macroeconomic conditions

Uncertainty in the global business, political and macroeconomic environments present significant risks to our business. We are subject to continuing risks and uncertainties, including inflation, rising interest rates, uncertainty with respect to the federal budget, instability in the global banking system, volatile market conditions, supply chain disruptions, cybersecurity events, and global events, including regional conflicts around the world. We are closely monitoring the

impact of these factors on all aspects of our business, including the impacts on our customers, patients, employees, suppliers, vendors, business partners and distribution channels.

In particular, while we have not experienced material disruptions in our supply chain to date, we have been and continue to be impacted by disruptions in the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchase of some components. In certain cases, we have incurred higher logistical expenses. We are continuing to work closely with our manufacturing partners and suppliers to source key components and maintain appropriate inventory levels to meet customer demand.

The ultimate extent of the impact of global economic conditions on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. As a result, we are subject to continuing risks and uncertainties and continue to closely monitor the impact of the current conditions on our business. For more information regarding these risks and uncertainties, see the section titled "*Risk Factors*" in Part 1, Item 1A of this Annual Report on Form 10-K.

Factors Affecting Our Business

There are a number of factors that have impacted, and we believe will continue to impact, our results of operations and growth. These factors include:

- ***Market acceptance***. The growth of our business depends on our ability to gain broader acceptance of our current products by continuing to make physicians and other hospital staff aware of the benefits of our products to generate increased demand and frequency of use, and thus increase sales to our hospital customers. Our ability to grow our business will also depend on our ability to expand our customer base in existing or new target end markets. Although we are attempting to increase the number of patients treated with procedures that use our products through our established relationships and focused sales efforts, we cannot provide assurance that our efforts will increase the use of our products.
- ***Regulatory approvals/clearances and timing and efficiency of new product introductions***. We must successfully obtain timely approvals or clearances and introduce new products that gain acceptance with physicians, ensuring adequate supply while avoiding excess inventory of older products and resulting inventory write-downs or write-offs. For our sales to grow, we will also need to obtain regulatory clearance or approval of our other pipeline products in the United States and in international markets. In addition, as we introduce new products, we expect to build our inventory of components and finished goods in advance of sales, which may cause quarterly fluctuations in our results of operations.
- ***Sales force size and effectiveness***. The rate at which we grow our sales force and the speed at which newly hired salespeople become effective can impact our revenue growth or our costs incurred in anticipation of such growth. We intend 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 hospital accounts.
- ***Competition***. Our industry is intensely competitive and, in particular, we compete with a number of large, well-capitalized companies on multiple fronts. We must continue to be successful in light of our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who use our products.
- ***Reimbursement***. The level of reimbursement from third-party payors for procedures performed using our products could have a substantial impact on the prices we are able to charge for our products and how widely our products are accepted. The level at which reimbursement is set for procedures using our products, and any increase in reimbursement for procedures using our products, will depend substantially on our ability to generate clinical evidence, to gain advocacy in the respective physician societies and to work with the Centers for Medicare & Medicaid Services and payors.
- ***Clinical results***. Publications of clinical results by us, our competitors and other third parties can have a significant influence on whether, and the degree to which, our products are used by physicians and the procedures and treatments those physicians choose to administer for a given condition.
- ***Product and geographic mix; timing***. Our financial results, including our gross margins, may fluctuate from period to period based on the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as

holidays or days of severe inclement weather in a particular geography, the mix of products sold and the geographic mix of where products are sold. In particular, our distributors for international sales receive a distribution margin on sales of our products, which affects our gross margin.

- ***Seasonality***. We have experienced some seasonality during summer months, which we believe is attributable to the postponement of elective surgeries for summer vacation plans of physicians and patients. We have also experienced some seasonal slowing of demand for our products in our fourth quarters due to year-end clinical treatment patterns, such as the postponement of elective surgeries during the holiday period. We expect these seasonal factors to become more pronounced in the future as our business grows.

In addition, we have experienced and expect to continue to experience meaningful variability in our quarterly revenue and gross margin as a result of a number of factors, including, but not limited to: inventory write-offs and write-downs; costs, benefits and timing of new product introductions; the availability and cost of components and raw materials; fluctuations in foreign currency exchange rates; inflation; and raising interest rates. Additionally, we experience quarters in which operating expenses, in particular research and development expenses, fluctuate depending on the stage and timing of product development.

While these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address.

Components of Our Results of Operations

Product revenue

Product revenue is primarily from the sale of our IVL catheters.

We sell our products to hospitals, primarily through direct sales, as well as through distributors in selected international markets. For products sold through direct sales and distributors internationally, control is transferred based on the contractual or standard shipping terms.

Cost of product revenue

Cost of product revenue consists primarily of the costs of the components for use in our products, the materials and labor that are used to produce our products, the manufacturing overhead that directly supports production and the expense relating to the equipment used in our IVL System to the extent that we loan generators to our hospital customers, without charge to facilitate the use of our IVL catheters in their procedures. We expect costs of product revenue to increase in absolute terms as our revenue grows.

Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, product mix, geographic mix, discounting practices, manufacturing costs, product yields, headcount, amortization of acquired developed technology, and cost-reduction strategies. We expect our gross margin percentage to marginally increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which, if successful, we believe will reduce costs and enable us to increase our gross margin percentage. While we expect gross margin percentage to increase over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

Research and development expenses consist of applicable personnel, consulting, materials, and clinical trial expenses. Research and development expenses include, but are not limited to:

- certain personnel-related expenses, including salaries, benefits, bonus, travel, and stock-based compensation;
- cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations, and site payments;

- materials and supplies used for internal research and development and clinical activities;
- allocated overhead including facilities and information technology expenses; and
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance.

Research and development costs are expensed as incurred. In the future, we expect research and development expenses to increase in absolute dollars as we continue to develop new products, enhance existing products and technologies, and perform activities related to obtaining additional regulatory approvals.

Sales and marketing expenses

Sales and marketing expenses consist of personnel-related expenses, including salaries, benefits, sales commissions, travel, and stock-based compensation. Other sales and marketing expenses consist of marketing and promotional activities, including trade shows and market research. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology. As a result, we expect sales and marketing expenses to increase in absolute dollars over the long term.

General and administrative expenses

General and administrative expenses consist of personnel-related expenses, including salaries, benefits, bonus, travel, and stock-based compensation. Other general and administrative expenses consist of professional services fees, including legal, audit and tax fees, insurance costs, outside consultant fees and employee recruiting and training costs. Moreover, we incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and Securities and Exchange Commission ("SEC") compliance and investor relations.

Income (loss) from equity method investment

Income (loss) from equity method investment represents our proportionate share of the underlying income or loss incurred in connection with our joint venture, Genesis Shockwave Private Ltd. (the "JV"), with Genesis MedTech International Private Limited. Also included in income (loss) from equity method investment is the portion of intra-entity profit which is eliminated to the extent the goods have not yet either been consumed by the JV for use in clinical trials, or sold through by the JV to an end customer at the end of the reporting period.

Interest expense

Interest expense consists of the interest and amortization expense related to our Credit Agreement (as defined below) and the Notes (as defined below), as well as the loss on debt extinguishment related to the repayment of the amount drawn under our Credit Agreement.

Other income (expense), net

Other income (expense), net consists of interest earned on our cash equivalents and short-term investments and the net impact of foreign exchange gains and losses.

Income tax (benefit) provision

Income tax provision consists of income taxes from the U.S. and foreign jurisdictions.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022:

	Year Ended December 31,		Change	Change
	2023	2022	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 730,230	$ 489,733	$ 240,497	49 %
Cost of revenue:				
Cost of product revenue	95,388	64,996	30,392	47 %
Gross profit	634,842	424,737	210,105	49 %
Operating expenses:				
Research and development	145,647	81,679	63,968	78 %
Sales and marketing	234,837	161,995	72,842	45 %
General and administrative	95,265	56,929	38,336	67 %
Total operating expenses	475,749	300,603	175,146	58 %
Income from operations	159,093	124,134	34,959	28 %
Loss from equity method investment	(1,869)	(2,475)	606	(24 %)
Interest expense	(6,905)	(1,886)	(5,019)	266 %
Other income, net	23,962	1,055	22,907	2,171 %
Net income before taxes	174,281	120,828	53,453	44 %
Income tax (benefit) provision	27,003	(95,168)	122,171	(128 %)
Net income	$ 147,278	$ 215,996	$ (68,718)	(32 %)

Product revenue. Product revenue increased by $240.5 million, or 49%, from $489.7 million in 2022 to $730.2 million in 2023, driven primarily by coronary catheter revenues, and secondarily by peripheral catheter revenues, as further described below.

The following table represents our product revenue based on product line:

	Year Ended December 31,		Change	Change
	2023	2022	$	%
	(in thousands, except percentages)			
Coronary	$ 528,845	$ 353,859	$ 174,986	49 %
Peripheral	194,346	132,284	62,062	47 %
Reducer	4,368	—	4,368	100 %
Other	2,671	3,590	(919)	(26 %)
Product revenue	$ 730,230	$ 489,733	$ 240,497	49 %

Coronary product revenue increased by $175.0 million, or 49%, from $353.9 million in 2022 to $528.8 million in 2023. In February 2021, we received U.S. Food and Drug Administration ("FDA") approval for our C^2 catheter. The increase in coronary product revenue was due an increase in the purchase volume of our C^2 catheters and C^{2+} catheters in the United States and increased adoption of our products internationally.

Peripheral product revenue increased by $62.1 million, or 47%, from $132.3 million in 2022 to $194.3 million in 2023. The change was due to an increase in the purchase volume of our M^{5+} catheter, S^4 catheter, and L^6 catheter within the United States and internationally driven by increased adoption of our products.

Revenue from our Reducer product, which was acquired through the acquisition of Neovasc Inc. ("Neovasc") was $4.4 million for the year ended December 31, 2023.

Other product revenue decreased by $0.9 million, or 26%, from $3.6 million in 2022 to $2.7 million in 2023. The change was due to a decrease in the purchase volume of our IVL generators and other accessories internationally.

Product revenue, classified by the major geographic areas in which our products are shipped, was $581.5 million or 80% within the United States and $148.7 million or 20% for all other countries in 2023 compared to $407.4 million or 83% within the United States and $82.3 million or 17% for all other countries in 2022.

Cost of product revenue, gross profit, and gross margin percentage. Cost of product revenue increased by $30.4 million, or 47%, from $65.0 million in 2022 to $95.4 million in 2023. The increase was driven by higher product sales volume compared to the prior year.

Gross margin percentage was 87% in 2023, consistent with 87% in 2022.

Research and development expenses. The following table summarizes our research and development expenses incurred during the periods presented:

	Year Ended December 31,		Change	Change
	2023	2022	$	%
	(in thousands, except percentages)			
Compensation and personnel-related costs	$ 69,319	$ 47,634	$ 21,685	46 %
Facilities and other allocated costs	30,277	11,115	19,162	172 %
Clinical-related costs	21,584	8,860	12,724	144 %
Other research and development costs	5,949	1,787	4,162	233 %
Materials and supplies	12,404	8,611	3,793	44 %
Outside consultants	6,114	3,672	2,442	67 %
Total research and development expenses	$ 145,647	$ 81,679	$ 63,968	78 %

Research and development expenses increased by $64.0 million, or 78%, from $81.7 million in 2022 to $145.6 million in 2023. The increase was primarily due to a $21.7 million increase in compensation and personnel-related costs due to an increase in head-count. There was also a $19.2 million increase due to increased information technology, rent and building expenditures, a $12.7 million increase in clinical-related costs, a $4.2 million increase in other research and development costs, a $3.8 million increase in materials and supplies, and a $2.4 million increase for outside consultants. Included in other research and development costs are $3.0 million in software license expenses related to research and development.

Sales and marketing expenses. Sales and marketing expenses increased by $72.8 million, or 45%, from $162.0 million in 2022 to $234.8 million in 2023. The increase was primarily due to a $43.1 million increase in compensation and personnel-related costs, resulting from increased headcount and commissions driven by increased sales of our products in 2023. There was also an $11.7 million increase due to travel-related costs, a $7.0 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, a $5.6 million increase in marketing and promotional expenses to support the continued commercialization of our products, a $1.9 million increase due to consulting and professional services, a $1.6 million increase in materials and supplies, a $1.0 million increase in general corporate costs, and a $0.9 million increase due to recruiting and training fees.

General and administrative expenses. General and administrative expenses increased by $38.3 million, or 67%, from $56.9 million in 2022 to $95.3 million in 2023. The change was primarily due to a $19.7 million increase in compensation and personnel-related costs due to an increase in head-count, a $13.0 million increase in consulting and professional services, a $3.0 million increase in general corporate costs, a $1.3 million increase in facilities and other allocated costs, a $0.8 million increase due to travel-related costs, and a $0.5 million increase in recruiting and training.

Loss from equity method investment. Loss from equity method investment decreased by $0.6 million, or 24%, from $2.5 million in 2022 to $1.9 million in 2023. The decrease in loss from equity method investment was due to in-process research and development costs that were expensed in 2022, partially offset by increased sales in 2023 by the JV to

end customers following the National Medical Products Administration approval of products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau, and the elimination of intra-entity profit for goods sold by us to the JV that have not yet been sold through by the JV to an end customer at the end of the reporting period.

Interest expense. Interest expense increased by $5.0 million or 266% from $1.9 million in 2022 to $6.9 million in 2023. The increase in interest expense was related to the $80.0 million drawn under the Credit Agreement in March 2023 until its repayment in April 2023, the $25.0 million drawn under the Credit Agreement in October 2022 until its repayment in August 2023, which resulted in a loss on debt extinguishment of $0.7 million during the three months ended September 30, 2023, and the Notes issued in the private offering in August 2023.

Other income, net. Other income, net increased by $22.9 million, or 2,171%, from $1.1 million in 2022 to $24.0 million in 2023. The increase in other income was primarily due to an increase in interest income from increased interest rates, partially offset by an increase in foreign exchange losses.

Income tax (benefit) provision. Income tax provision of $27.0 million for the year ended December 31, 2023 primarily consisted of U.S. (federal and state) and foreign income taxes. Income tax benefit of $95.2 million for the year ended December 31, 2022 primarily consisted of the release of a substantial portion of our valuation allowance on our deferred tax assets. See Note 12, "Income Taxes" in our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Comparison of the Years Ended December 31, 2022 and 2021

For a discussion regarding our financial condition and our results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021, see the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 27, 2023.

Liquidity and Capital Resources

Sources of liquidity

To date, our principal sources of liquidity have been the net proceeds of $750.0 million that we received through the issuance of our Notes, $280.0 million that we received through the sale of our common stock in our public offerings, $10.0 million from a private placement of our equity securities, payments received from customers using our products, and access to funds under our Credit Agreement.

On February 11, 2020, we entered into the First Amendment to the Loan and Security Agreement with Silicon Valley Bank (the "Amended SVB Credit Agreement") to refinance our existing term loan, which was accounted for as a modification. The Amended SVB Credit Agreement provided us with a supplemental term loan in the amount of $16.5 million. We received net proceeds of $3.3 million, which reflects an additional $4.3 million in principal as of the date of the modification less the final balloon payment fee of $1.0 million. The supplemental term loan's maturity was December 1, 2023. The Amended SVB Credit Agreement provided an interest-only payment through June 30, 2022.

On October 19, 2022, we entered into the Credit Agreement 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, as joint lead arrangers and joint bookrunners, Silicon Valley Bank, as syndication agent, and the several lenders party thereto (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 consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into the Credit Agreement, we drew down $25.0 million and prepaid in full all outstanding amounts and related expenses under the Amended SVB Credit Agreement, totaling $14.6 million, and terminated the credit facility thereunder. We repaid the $25.0 million drawn under the Credit Agreement on August 29, 2023.

On March 16, 2023, we drew down an additional $80.0 million under the Credit Agreement. We repaid the $80.0 million drawn under the Credit Agreement on April 26, 2023.

On August 15, 2023, we issued $750.0 million aggregate principal amount of the Notes. The Notes mature on August 15, 2028 unless repurchased, redeemed, or converted in accordance with their terms prior to such date. The Notes were not convertible as of December 31, 2023. On August 10, 2023, in connection with the pricing of the Notes and the initial purchasers' exercise of their option to purchase additional Notes, we entered into privately negotiated Capped Call Transactions for a cost of $96.4 million.

We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials as well as additional clinical trials designed to provide clinical evidence of the safety and efficacy of our existing products. We intend 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 and physicians 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 products based on 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 SEC compliance, investor relations and other expenses. Because of these and other factors, although we had net income and generated cash flows from operations for the year ended December 31, 2023, we may incur net losses and have negative cash flows from operations in the future.

As of December 31, 2023, we have $990.6 million in cash, cash equivalents and short-term investments and retained earnings of $110.5 million.

In the short term, we believe that our cash, cash equivalents and short-term investments will be sufficient for at least the next 12 months to meet our requirements and plans for cash, including supporting working capital, capital expenditure requirements, investments, acquisitions and repayments of indebtedness. In the long term, our ability to support our working capital and capital expenditure requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost of our research and development activities for new and modified products;
- 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 including any contract manufacturing arrangements;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- the impact of global business, political and macroeconomic conditions, including inflation, rising interest rates, uncertainty with respect to the federal budget, instability in the global banking system, volatile market conditions, supply chain disruptions, cybersecurity events, and global events, including regional conflicts around the world;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

To the extent that current and anticipated future sources of liquidity are insufficient to fund our future business activities and cash and other requirements, we may be required to seek additional equity or debt financing. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of additional debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. In the event that additional financing is required from outside sources, there is a possibility we may not be able to raise it on terms acceptable 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 we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Our material cash requirements include the following contractual and other obligations:

Debt, Principal, and Interest

As of December 31, 2023, our debt, principal and interest commitments consist of our debt obligations under the Credit Agreement and the Notes.

As discussed above, on October 19, 2022, we entered into the Credit Agreement, which 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 consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into the Credit Agreement, we drew down $25.0 million and prepaid in full all outstanding amounts and related expenses under the Amended SVB Credit Agreement, totaling $14.6 million, and terminated the credit facility thereunder. We repaid the $25.0 million drawn under the Credit Agreement on August 29, 2023.

On March 16, 2023, we drew down an additional $80.0 million under the Credit Agreement. We repaid the $80.0 million drawn under the Credit Agreement on April 26, 2023.

The Credit Agreement is secured by substantially all of our assets, including intellectual property. 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.

As of December 31, 2023, there were no outstanding borrowings under the Credit Agreement.

As discussed above, on August 15, 2023, we issued $750.0 million aggregate principal amount of the Notes and on August 10, 2023 we entered into the Capped Call Transactions for a cost of $96.4 million. The net proceeds from the issuance of the Notes and the Capped Call Transactions are discussed further in 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. The Notes mature on August 15, 2028 unless repurchased, redeemed, or converted in accordance with their terms prior to such date. The Notes were not convertible as of December 31, 2023.

Manufacturing Purchase Obligations

We have engaged certain contract manufacturers to produce and supply us with certain products. We have fixed commitments of approximately $2.4 million within the next twelve months.

Operating Leases

Our operating lease commitments mostly consist of our lease obligations for our Santa Clara headquarter office spaces, leased facilities for Neovasc, and leased facilities for laboratory and manufacturing space. Our total operating lease commitments as of December 31, 2023 are approximately $47.6 million, of which $5.6 million is expected to be paid within the next twelve months.

Contingent Consideration Liabilities Related to Business Combination

Acquisition related contingent consideration liabilities consist of estimated amounts in relation to a contingent value right entitling certain holders of Neovasc common stock and eligible equity awards to receive an additional cash payment of up to $12.00 per share or per share underlying an eligible equity award contingent on the attainment of a milestone. The milestone is defined as the grant by the FDA’s final approval of the Reducer premarket approval application regarding its treatment of angina. As of December 31, 2023, the total fair value of the contingent consideration liabilities was $9.3 million.

We did not have during the periods presented, and we do not currently have, any commitments or obligations, including contingent obligations, arising from arrangements with unconsolidated entities or persons that have or are

reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ 196,053	$ 117,732	$ 15,036
Investing activities	(625,727)	(62,150)	26,416
Financing activities	600,401	12,999	(2,451)
Effect of exchange rate changes on cash and cash equivalents	797	(1,153)	—
Net increase in cash, cash equivalents and restricted cash	$ 171,524	$ 67,428	$ 39,001

Operating activities

In 2023, cash provided by operating activities was $196.1 million, attributable to a net income of $147.3 million and non-cash charges of $92.7 million offset by a net change in our net operating assets and liabilities of $43.9 million. Non-cash charges of $92.7 million primarily consisted of $73.2 million in stock-based compensation, $10.4 million in depreciation and amortization, $3.2 million in non-cash lease expense, and $0.7 million on loss on debt extinguishment. The change in our net operating assets and liabilities of $43.9 million was primarily due to a $41.5 million increase in accounts receivable due to increased sales, and a $31.0 million increase in inventory driven by an increase in raw materials, work-in-progress, and finished goods inventory. These changes were offset by a $32.9 million increase in accrued and other current liabilities.

In 2022, cash provided by operating activities was $117.7 million, attributable to a net income of $216.0 million, offset by non-cash charges of $40.3 million and a net change in our net operating assets and liabilities of $58.0 million. Non-cash charges of $40.3 million primarily consisted of $44.9 million in stock-based compensation, $4.9 million in depreciation and amortization, $3.0 million in non-cash lease expense, and $0.6 million on loss on debt extinguishment offset by a $97.3 million change in deferred tax assets primarily related to the release of valuation allowance. The change in our net operating assets and liabilities of $58.0 million was primarily due to a $33.3 million increase in accounts receivable due to an increase in sales, and a $29.7 million increase in inventory driven by an increase in raw materials and finished goods inventory. These changes were offset by a $11.9 million increase in accrued and other current liabilities.

Investing activities

In 2023, cash used in investing activities was $625.7 million, attributable to the Neovasc business combination, net of cash acquired in the amount of $94.4 million, purchases of available-for-sale investments of $747.5 million, and purchases of property and equipment of $30.6 million, offset by proceeds from maturities of available-for-sale investments of $246.8 million.

In 2022, cash used in investing activities was $62.2 million, attributable to purchases of available-for-sale investments of $137.8 million and purchases of property and equipment of $25.2 million, offset by proceeds from maturities of available-for-sale investments of $100.8 million.

Financing activities

In 2023, cash provided by financing activities was $600.4 million, attributable to $730.5 million in proceeds from the issuance of the Notes, net of issuance costs, $80.0 million from a draw under the Credit Agreement, net of issuance costs, proceeds of $6.2 million from the issuance of shares under our employee stock purchase plan and proceeds of $1.3 million from stock option exercises, offset by $105.0 million in principal term loan payments under the Credit Agreement, $96.4 million in costs relating to the Capped Call Transactions, and $16.2 million in payment of an assumed warrant liability associated with the acquisition of Neovasc.

In 2022, cash provided by financing activities was $13.0 million, attributable to proceeds of $24.2 million from our Credit Agreement, proceeds of $4.5 million from the issuance of shares under our employee stock purchase plan and proceeds of $2.5 million from stock option exercises, offset by $18.2 million in principal term loan payments under the Amended SVB Credit Agreement.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in the Note 2 "Summary of Significant Accounting Policies" to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Goodwill and Intangible Assets

When we acquire a business, the assets acquired and liabilities assumed are recorded at their respective fair values at the acquisition date. Goodwill is the excess of the purchase price over the estimated fair value of net assets of acquired businesses. Intangible assets primarily include customer relationships, developed technology, and in-process research and development. Determining the fair value of intangible assets acquired as part of a business combination requires us to make significant estimates. These estimates include the amount and timing of projected future cash flows, the discount rate used to discount those cash flows to present value, and the assessment of the asset's life cycle. The estimates could be impacted by legal, technical, regulatory, economic, and competitive risks.

The test for impairment of goodwill requires us to make several estimates related to projected future cash flows to determine the fair value of the goodwill reporting units. Our estimates associated with the goodwill impairment test are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value. We perform annual impairment reviews of our goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate that the carrying amount may be impaired.

We assess the impairment of definite-lived intangible assets and indefinite-lived intangible assets during the fourth fiscal quarter or more frequently if business factors indicate the carrying amount may be impaired. If we were to have impairments to goodwill or intangible assets, it could adversely affect our operating results.

Our tests for goodwill and intangible assets are based on future cash flows that require significant judgment with respect to future revenue and expense growth rates, appropriate discount rates, asset groupings, and other assumptions and estimates. We use estimates that are consistent with the highest and best use of the assets based on a market participant's view of the assets being evaluated. Actual results may differ from our estimates due to a number of factors including, among others, changes in competitive conditions, timing of regulatory approval, results of clinical trials, and changes in worldwide economic conditions.

Contingent Consideration Liabilities Related to Business Combination

The contingent consideration liability consisted of estimated amounts in relation to a contingent value right contingent on the attainment of a milestone. The milestone is defined as the grant by the FDA's final approval of the premarket approval application for the Reducer product for the treatment of angina. The milestone achievement timeline and respective payment per share ranges from $12.00 per contingent value right ("CVR") if the milestone is achieved on or prior to June 30, 2026, $8.00 per CVR if the milestone is achieved between July 1, 2026 and December 31, 2026 and $4.00 per CVR if the milestone is achieved between January 1, 2027 and December 31, 2027.

We estimated the fair value of the contingent consideration liability using the probability-weighted discounted cash flow method based on the probability of achieving the milestone on each specified milestone date. The material factors that may impact the fair value of the contingent consideration are (i) the number of diluted shares outstanding as of the acquisition date that are eligible for the CVR, (ii) the probabilities and timing of achievement of the milestone, and (iii) discount rates, all of which are not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value which may materially impact our results of operations.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are evaluated for future realization and reduced by a valuation allowance to the extent we believe it is more likely than not that they will not be realized. We consider all available positive and negative evidence, including our past operating results, future reversals of existing taxable temporary differences, future taxable income, tax-planning strategies, carryback potential if permitted under the tax law, and results of recent operations. To the extent sufficient positive evidence becomes available, we may release all or a portion of our valuation allowance in one or more future periods. A release of the valuation allowance, if any, would result in the recognition of certain deferred tax assets and a material income tax benefit for the period in which such release is recorded.

Our ability to realize the deferred tax assets could be reduced in the future if our estimates of future forecasted income do not support the realization of our deferred tax assets. 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.

We also account for uncertain tax positions in accordance with Topic 740, Income Taxes – Accounting for Income Taxes, which requires us to adjust our financial statements to reflect only those tax positions that are more-likely-than-not to be sustained upon examination by the taxing authority based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. Significant judgment is required to evaluate uncertain tax positions. Our evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effective settlement of audit issues, and new audit activity. Changes in the recognition or measurement of uncertain tax positions could result in material increases or decreases in our income tax expense in the period in which we make the change, which could have a material impact on our effective tax rate and operating results.

Recent Accounting Pronouncements

See Note 2 “Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements in Item 8 “Financial Statements and Supplementary Data” for additional information regarding recent accounting pronouncements, including the respective expected dates of adoption and estimated effects, if any, on our Consolidated Financial Statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash, cash equivalents and short-term investments as of December 31, 2023 consist of $990.6 million in bank deposits, money market funds, U.S Treasury securities and commercial paper. Such interest-earning instruments carry a degree of interest rate risk. However, we believe that our exposure to interest rate risk is not significant as the majority of our investments are short-term in duration and due to the low risk profile of our investments, a change in market interest rates would not have a material impact on our financial statements. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure.

As of December 31, 2023, there were no outstanding borrowings under the Credit Agreement.

The revolving credit facility accrues interest, at our election, at (A) the Base Rate (as defined below) plus a margin ranging from 0% to 1% depending on our Consolidated Total Net Leverage Ratio (as defined in the Credit Agreement)

(which rate is currently 0%) or (B) the applicable secured overnight financing rate ("SOFR") plus a margin ranging from 1% to 2%, depending on our Consolidated Total Net Leverage Ratio (which rate is currently 1.8%). Base Rate means, at any time, the highest of (a) the Wells Fargo Bank, National Association's announced prime rate, (b) the federal funds rate plus 0.5% and (c) Term SOFR for a one-month tenor in effect on such day plus 1%. The Credit Agreement matures on October 19, 2027. The interest rate was 7.3% as of August 29, 2023.

Foreign currency exchange risk

As we expand internationally, our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is denominated primarily in U.S. dollars and Euros. For the years ended December 31, 2023 and 2022, approximately 9% and 8% of our revenue, respectively, was denominated in Euros. Our expenses are generally denominated in the currencies of the jurisdiction in which the respective operations are located, which are primarily in the United States. For the year ended December 31, 2023, we incurred $1.8 million in foreign exchange losses, primarily driven by Euro denominated accounts receivable and the strengthening of the U.S. Dollar relative to the Euro during the period. A hypothetical 10% change in exchange rates would have resulted in a change in fair value of $7.6 million and $4.2 million in foreign currency cash and accounts receivable as of December 31, 2023 and 2022, respectively. As our operations in countries outside of the United States grow, particularly in Costa Rica, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts, although we may do so in the future.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Shockwave Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Shockwave Medical, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2024 expressed an adverse opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue recognition

Description of the Matter

The Company recorded product revenue of $730.2 million for the year ended December 31, 2023. As disclosed in Note 2 to the consolidated financial statements, the Company records revenue when a customer obtains control of the promised goods. For products sold directly and to international distributors, control is transferred based on the contractual or standard shipping terms, or upon delivery.

Auditing the Company's revenue recognition was challenging due to the volume of transactions and the variability in certain terms and conditions within the customer arrangements that affect the timing of revenue recognition.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls that address the identified risks of material misstatement related to the Company's process used to determine the timing and measurement of product revenue.

To test product revenue, our audit procedures included, among others, performing analytical review procedures to trace revenue journal entries to accounts receivable and to cash collections. We also tested the timing of revenue recognition for a sample of revenue transactions recognized near the period end and confirmed a sample of outstanding receivable balances with customers.

Business Combination

Description of the Matter During 2023, the Company completed its acquisition of Neovasc Inc. (“Neovasc”) for consideration of $121.4 million, as disclosed in Note 5 to the consolidated financial statements. The transaction was accounted for as a business combination.

Auditing the Company’s accounting for the Neovasc acquisition was complex due to the significant estimations required by management to determine the fair value of certain identified intangible assets, principally consisting of developed technology and in-process research and development of $61.2 million and $31.4 million, respectively, which require prospective financial information. The significant estimation uncertainty was primarily due to the sensitivity of the respective fair values to underlying assumptions about the future performance of the acquired business. The Company used a multi-period excess earnings model to measure the developed technology and in-process research and development assets. The significant assumptions used in this model included revenue and discount rates. These significant assumptions are forward looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit To test the estimated fair value of the developed technology and in-process research and development assets, we performed audit procedures that included, among others, evaluating the Company's selection of the valuation methodology, evaluating the methods and significant assumptions described above that were used within the Company’s valuation calculations, and evaluating the completeness and accuracy of the underlying data supporting the significant assumptions and estimates. For example, we performed sensitivity analyses and compared the significant assumptions to current industry and economic trends and to the Company's budgets and forecasts, and Neovasc’s historical operating results. We performed audit procedures assisted by our valuation specialists that included our evaluation of the methodology used by the Company and significant assumptions included in the fair value estimates. Our valuation specialists’ procedures included, among others, developing a range of independent estimates for the discount rates used in the valuation models and comparing those to the discount rates selected by management. We also evaluated the Company’s acquisition and related purchase accounting disclosures included in Note 5 “Business Combination.”

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2016.

San Mateo, California

February 26, 2024

SHOCKWAVE MEDICAL, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 328,422	$ 156,586
Short-term investments	662,132	147,907
Accounts receivable, net	114,552	71,366
Inventory	107,587	75,112
Prepaid expenses and other current assets	12,567	8,292
Total current assets	1,225,260	459,263
Operating lease right-of-use assets	29,707	32,365
Property and equipment, net	68,923	48,152
Equity method investment	1,643	3,512
Intangible assets, net	92,857	—
Goodwill	39,568	—
Deferred tax assets	99,169	97,568
Other assets	9,436	5,229
TOTAL ASSETS	$ 1,566,563	$ 646,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 8,868	$ 6,721
Accrued liabilities	91,696	55,375
Lease liability, current portion	3,641	1,278
Total current liabilities	104,205	63,374
Lease liability, noncurrent portion	35,103	34,928
Convertible debt, noncurrent portion	731,863	—
Debt, noncurrent portion	—	24,198
Related party contract liability, noncurrent portion	12,273	12,273
Deferred tax liabilities	3,609	—
Long-term income tax liability	1,526	—
Other liabilities	9,307	—
TOTAL LIABILITIES	897,886	134,773
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized; No shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.001 par value per share; 281,274,838 shares authorized; 36,990,700 and 36,235,546 issued and outstanding as of December 31, 2023 and 2022, respectively	37	36
Additional paid-in capital	557,882	548,960
Accumulated other comprehensive income (loss)	293	(867)
Retained earnings (accumulated deficit)	110,465	(36,813)
TOTAL STOCKHOLDERS' EQUITY	668,677	511,316
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,566,563	$ 646,089

The accompanying notes are an integral part of these consolidated financial statements.

SHOCKWAVE MEDICAL, INC.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share data)

	Year Ended December 31,		
	2023	**2022**	**2021**
Revenue:			
Product revenue	$ 730,230	$ 489,733	$ 237,146
Cost of revenue:			
Cost of product revenue	95,388	64,996	41,438
Gross profit	634,842	424,737	195,708
Operating expenses:			
Research and development	145,647	81,679	50,544
Sales and marketing	234,837	161,995	111,288
General and administrative	95,265	56,929	34,747
Total operating expenses	475,749	300,603	196,579
Income (loss) from operations	159,093	124,134	(871)
Loss from equity method investment	(1,869)	(2,475)	(6,286)
Interest expense	(6,905)	(1,886)	(1,096)
Other income (expense), net	23,962	1,055	(582)
Net income (loss) before taxes	174,281	120,828	(8,835)
Income tax (benefit) provision	27,003	(95,168)	301
Net income (loss)	$ 147,278	$ 215,996	$ (9,136)
Unrealized gain (loss) on available-for-sale securities, net of tax	1,165	(659)	(211)
Adjustment for net gain realized and included in other income, net	(5)	(6)	—
Total comprehensive income (loss)	$ 148,438	$ 215,331	$ (9,347)
Net income (loss) per share			
Basic	$ 4.01	$ 6.02	$ (0.26)
Diluted	$ 3.85	$ 5.70	$ (0.26)
Shares used in computing net income (loss) per share			
Basic	36,706,060	35,900,738	35,098,130
Diluted	38,206,269	37,881,590	35,098,130

The accompanying notes are an integral part of these consolidated financial statements.

SHOCKWAVE MEDICAL, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2020	34,684,337	$ 35	$ 469,283	$ 9	$ (243,673)	$ 225,654
Exercise of stock options	547,155	—	3,049	—	—	3,049
Issuance of common stock under employee stock purchase plan	36,833	—	2,837	—	—	2,837
Issuance of common stock in connection with vesting of restricted stock units	239,213	—	—	—	—	—
Restricted stock units withheld in net settlement for tax	(63,066)	—	(8,337)	—	—	(8,337)
Stock-based compensation	—	—	27,974	—	—	27,974
Unrealized loss on available-for-sale securities	—	—	—	(211)	—	(211)
Net loss	—	—	—	—	(9,136)	(9,136)
Balance — December 31, 2021	35,444,472	$ 35	$ 494,806	$ (202)	$ (252,809)	$ 241,830
Exercise of stock options	401,757	1	2,561	—	—	2,562
Issuance of common stock under employee stock purchase plan	29,645	—	4,487	—	—	4,487
Issuance of common stock in connection with vesting of restricted stock units	359,774	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(102)	—	(23)	—	—	(23)
Stock-based compensation	—	—	47,129	—	—	47,129
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(659)	—	(659)
Net gain reclassified from accumulated other comprehensive loss	—	—	—	(6)	—	(6)
Net income	—	—	—	—	215,996	215,996
Balance — December 31, 2022	36,235,546	$ 36	$ 548,960	$ (867)	$ (36,813)	$ 511,316
Exercise of stock options	235,067	1	1,373	—	—	1,374
Issuance of common stock under employee stock purchase plan	38,630	—	6,230	—	—	6,230
Issuance of common stock in connection with vesting of restricted stock units	481,635	—	—	—	—	—
Taxes withheld on net settled vesting of restricted stock units	(178)	—	(43)	—	—	(43)
Stock-based compensation	—	—	73,633	—	—	73,633
Purchase of capped calls related to convertible debt, net of tax	—	—	(72,271)	—	—	(72,271)
Unrealized gain on available-for-sale securities, net of tax	—	—	—	1,165	—	1,165
Net gain reclassified from accumulated other comprehensive income	—	—	—	(5)	—	(5)
Net income	—	—	—	—	147,278	147,278
Balance — December 31, 2023	36,990,700	$ 37	$ 557,882	$ 293	$ 110,465	$ 668,677

The accompanying notes are an integral part of these consolidated financial statements.

SHOCKWAVE MEDICAL, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 147,278	$ 215,996	$ (9,136)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	10,358	4,856	3,579
Loss from equity method investment	1,869	2,475	6,286
Stock-based compensation	73,234	44,890	27,257
Non-cash lease expense	3,160	3,042	1,957
Amortization of premium and discount on available-for-sale securities	(11,956)	(68)	1,093
Loss on write down of fixed assets	271	81	7
Loss on extinguishment of debt	710	562	—
Deferred income taxes	14,760	(97,276)	—
Amortization of debt issuance costs	1,507	533	511
Foreign currency remeasurement	(1,278)	572	—
Changes in operating assets and liabilities:			
Accounts receivable	(41,535)	(33,313)	(25,746)
Inventory	(31,009)	(29,711)	(12,073)
Prepaid expenses and other current assets	(3,417)	(3,786)	(2,110)
Other assets	(4,486)	(3,243)	91
Accounts payable	112	1,945	1,870
Accrued and other current liabilities	32,923	11,941	21,637
Lease liabilities	2,026	(1,764)	(187)
Long-term income tax liability	1,526	—	—
Net cash provided by operating activities	196,053	117,732	15,036
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of available-for-sale securities	(747,471)	(137,797)	(117,245)
Proceeds from maturities of available-for-sale securities	246,750	100,773	156,100
Purchase of property and equipment	(30,595)	(25,126)	(12,439)
Business combination, net of cash acquired	(94,411)	—	—
Net cash (used in) provided by investing activities	(625,727)	(62,150)	26,416
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments of taxes withheld on net settled vesting of restricted stock units	(43)	(23)	(8,337)
Proceeds from debt financing	80,000	24,169	—
Proceeds from convertible debt, net	730,455	—	—
Purchase of capped calls related to convertible debt	(96,375)	—	—
Payment of assumed warrant liability	(16,240)	—	—
Proceeds from stock option exercises	1,374	2,562	3,049
Proceeds from issuance of common stock under employee stock purchase plan	6,230	4,487	2,837
Principal payment of debt	(105,000)	(18,196)	—
Net cash provided by (used in) financing activities	600,401	12,999	(2,451)
Effect of exchange rate changes on cash and cash equivalents	797	(1,153)	—
Net increase in cash, cash equivalents and restricted cash	171,524	67,428	39,001
Cash, cash equivalents and restricted cash at beginning of period	158,302	90,874	51,873
Cash, cash equivalents and restricted cash equivalents at end of period	$ 329,826	$ 158,302	$ 90,874
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 1,882	$ 791	$ 586
Income tax paid	$ 7,894	$ 2,162	$ 143
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Right-of-use asset obtained in exchange for lease liability	$ 195	$ 7,911	$ 21,885
Property and equipment purchases included in accounts payable and accrued liabilities	$ 3,733	$ 5,709	$ 1,923
Equity method investment obtained in exchange for related party contract liability	$ —	$ —	$ 12,273

The accompanying notes are an integral part of these consolidated financial statements.

Shockwave Medical, Inc.
Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Shockwave Medical, Inc. (the "Company") was incorporated on June 17, 2009. The Company is primarily engaged in the development and commercialization of novel technologies that transform the care of patients with cardiovascular disease. The Company is focused on its intravascular lithotripsy ("IVL") technology for the treatment of calcified plaque in patients with peripheral vascular, coronary vascular and heart valve disease. Built on a balloon catheter platform, the IVL technology uses lithotripsy to disrupt both superficial and deep vascular calcium, while minimizing soft tissue injury, and an integrated angioplasty balloon to dilate blockages at low pressures, restoring blood flow. Additionally, the Company continues to develop its coronary sinus reducer ("Reducer") technology for the treatment of refractory angina.

The Company, which is headquartered in Santa Clara, California and operates primarily in the United States, began commercial and manufacturing operations in 2016.

The consolidated financial statements include the accounts of Shockwave Medical, Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

As of December 31, 2023, the Company had cash, cash equivalents and short-term investments of $990.6 million, which are available to fund future working capital requirements, investments, acquisitions, or repayments of outstanding indebtedness. The Company believes that its cash, cash equivalents, and short-term investments as of December 31, 2023, will be sufficient for the Company to continue as a going concern for at least 12 months from the date these consolidated financial statements are filed with the Securities and Exchange Commission. The Company's future capital requirements will depend on many factors, including its growth rate, the timing and extent of its spending to support research and development activities, and the timing and cost of establishing additional sales and marketing capabilities.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to the valuation of inventory, goodwill and intangible assets, the allowance for doubtful accounts, recoverability of the Company's net deferred tax assets, and related valuation allowance amounts and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated statements of cash flows:

	December 31,	
	2023	2022
	(in thousands)	
Cash and cash equivalents	$ 328,422	$ 156,586
Restricted cash	1,404	1,716
Total cash, cash equivalents, and restricted cash	$ 329,826	$ 158,302

Restricted cash as of December 31, 2023 and 2022 relates to corporate credit card security, customer bank guarantee security, and letters of credit established for the real estate property leases relating to the Company's office buildings, and is recorded as other assets on the consolidated balance sheets.

Short-Term Investments

Short-term investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. The Company determines the appropriate classification of its investments in debt securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations. As the Company may sell its securities at any time for use in current operations even if the securities have not yet reached maturity, all marketable securities are classified as current assets in the Company's consolidated balance sheets.

The Company evaluates, on a quarterly basis, its marketable securities for potential impairment. For marketable securities in an unrealized loss position, the Company assesses whether such declines are due to credit loss based on factors such as changes to the rating of the security by a ratings agency, market conditions and supportable forecasts of economic and market conditions, among others. If credit loss exists, the Company assess whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable security before recovery of its amortized cost basis. If either condition is met, the security's amortized cost basis is written down to fair value and is recognized through other income, net. The Company has not identified any such impairment losses to date.

If neither condition is met, declines as a result of credit losses, if any, are recognized as an allowance for credit loss, limited to the amount of unrealized loss, through other income, net. Any portion of unrealized loss that is not a result of a credit loss, is recognized in other comprehensive income. Realized gains and losses, if any, on marketable securities are included in other income, net. The cost of investments sold is based on the specific-identification method. Interest on marketable securities is included in other income, net.

The Company elected to present accrued interest receivable separately from short-term and long-term investments on its consolidated balance sheets. Accrued interest receivable was recorded in prepaid expenses and other current assets as of December 31, 2023 and 2022. The Company also elected to exclude accrued interest receivable from the estimation of expected credit losses on its marketable securities and reverse accrued interest receivable through interest income (expense) when amounts are determined to be uncollectible. The Company did not write off any accrued interest receivable during the year ended December 31, 2023, 2022, and 2021.

Equity Method Investments

Entities for which the Company has significant influence over the activities of the entity, but does not control, are accounted for under the equity method of accounting in accordance with ASC 323, *Investments - Equity Method and Joint Ventures ("ASC 323")*. The Company's carrying value in the equity method investment is reported as equity method investment on the Company's consolidated balance sheets. The Company records its proportionate share of the underlying income or loss which is recognized in earnings or loss from the equity method investment. The Company eliminates a portion of intra-entity profit to the extent the goods sold by the Company have not yet been sold through by the equity method investee to an end customer at the end of the reporting period. The profit earned by the Company from the equity method investee for items not yet sold through is eliminated through equity method earnings or loss which is recognized in income (loss) from equity method investment.

The Company assesses its equity method investment for impairment when events or circumstances suggest that the carrying amount of the investment may be impaired. The Company considers all available evidence in assessing whether a decline in fair value is other than temporary. If the decline in fair value is determined to be other than temporary,

the difference between the carrying amount of the investment and estimated fair value is recognized as an impairment charge. The Company has not identified any such impairment losses to date.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, investments and trade receivables. Risks associated with cash, cash equivalents and restricted cash are mitigated by banking with creditworthy institutions and purchasing investments with investment grade ratings. The Company performs ongoing evaluations of its customers using its historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of its customers, and generally does not require collateral.

Concentration of Customers

For the years ended December 31, 2023, 2022 and 2021 no customer accounted for 10% or more of the Company's revenue. There were no customers which accounted for 10% or more of the Company's accounts receivable as of December 31, 2023 and 2022.

Fair Value of Financial Instruments

The Company's cash and cash equivalents, restricted cash, short-term investments, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at invoice value, net of any allowance for credit losses. The Company's expected loss allowance methodology for receivables is developed using its historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of its customers. Specific allowance amounts are established to record the appropriate allowance for customers that have an identified risk of default. General allowance amounts are established based upon the Company's assessment of expected credit losses for its receivables by aging category. Balances are written off when they are ultimately determined to be uncollectible.

The following table summarizes the activity in the allowance for doubtful accounts:

	For the Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Beginning balance	$ 710	$ 350	$ 380
Amounts charged (reversed) to costs and expenses	1,479	364	(12)
Write-offs	(10)	(4)	(18)
Ending balance	$ 2,179	$ 710	$ 350

Inventory

Inventory is stated at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) and net realizable value. Inventory costs include direct materials, direct labor and normal manufacturing overhead. Prior to achieving normal capacity, excess capacity costs are expensed in cost of product revenue as period costs. Finished goods that are used for research and development are expensed as consumed. Provisions for slow-moving, excess or obsolete inventories are recorded when required to reduce inventory values to their estimated net realizable values based on product life cycle, development plans, product expiration or quality issues.

Property, Plant, and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Land is carried at cost. Depreciation and amortization (other than land, which is not depreciated) is computed using the straight-line method over the estimated useful lives of the respective assets:

Asset Category	Useful Life
Equipment	3 - 5 years
Office Furniture	5 years
Software	3 years
Building	25 years
Leasehold Improvement	Lesser of useful life or remaining lease term

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheets and any resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

Revenue

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, *Revenue from Contracts with Customers ("ASC 606")*, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Product Revenue

The Company records product revenue primarily from the sale of its IVL catheters and Reducer. The Company sells its products to hospitals, primarily through direct sales, as well as through distributors in selected international markets.

Product revenue is recognized when a customer obtains control of promised goods, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods.

For products sold through direct sales and distributors internationally, control is transferred based on the contractual or standard shipping terms. The Company has elected to account for shipping and handling activities that occur after the customer has obtained control as a fulfillment activity, and not a separate performance obligation.

The Company may provide for the use of an IVL generator and connector cable under an agreement to customers at no charge to facilitate the use of the IVL catheters. These agreements generally do not contain contractually enforceable minimum commitments and are generally cancellable by either party with 30 days' notice.

License Revenue

For arrangements that contain a license of the Company's functional intellectual property with a customer, the Company considers whether the license grant is distinct from other performance obligations in the arrangement. A license grant of functional intellectual property is generally considered to be capable of being distinct if a customer can benefit from the license on its own or together with other readily available resources. License revenue for licenses of functional intellectual property is recognized at a point in time when the Company satisfies its performance obligation of transferring the license to the customer.

Consideration received in advance of the satisfaction of a performance obligation is recognized as a contract liability. No license revenues have been recognized for the years ended December 31, 2023, 2022, and 2021.

Research and Development Costs

Research and development costs, including new product development, regulatory compliance, and clinical research are expensed as incurred.

Accrued Research and Development Costs

The Company accrues liabilities for estimated costs of research and development activities conducted by its third-party service providers, which include the conduct of preclinical and clinical studies. The estimated costs of research and development activities are recorded based upon the estimated amount of services provided but not yet invoiced, and these costs are included in accrued liabilities on the consolidated balance sheets and within research and development expense on the consolidated statements of operations and comprehensive loss.

These costs are accrued for based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with third-party service providers. Significant judgments and estimates are made in determining the accrued liabilities balance in each reporting period. Accrued liabilities are adjusted as actual costs become known. There have not been any material differences between accrued costs and actual costs incurred since the Company's inception.

Stock-Based Compensation

The Company accounts for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for stock-based compensation awards is the date of grant and the expense is recognized on a straight-line basis, over the vesting period. For share-based awards that vest upon the satisfaction of a performance target, the related compensation cost is recognized over the requisite service period based on the expected achievement of the performance target. The Company accounts for forfeitures as they occur.

Leases

The Company determines if an arrangement is or contains a lease at contract inception by assessing whether the arrangement contains an identified asset and whether the lessee has the right to control such asset. The Company is required to classify leases as either finance or operating leases and to record a right-of-use asset and a lease liability for all leases with a term greater than 12 months regardless of the lease classification. The lease classification will determine whether the lease expense is recognized based on an effective interest rate method or on a straight-line basis over the term of the lease. The Company determines the initial classification and measurement of its right-of-use assets and lease liabilities at the lease commencement date and thereafter, if modified. The Company does not have material finance leases.

For its operating leases with a lease term of 12 months or greater, the Company recognized a right-of-use asset and a lease liability on its consolidated balance sheets. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

Operating lease cost for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the consolidated statements of operations and comprehensive loss.

Lease payments may be fixed or variable; however, only fixed payments are included in the Company's lease liability calculation. Lease costs for the Company's operating leases are recognized on a straight-line basis within operating expenses over the lease term. The Company's lease agreements may contain variable non-lease components such as common area maintenance, operating expenses or other costs, which are expensed as incurred.

The Company elected the practical expedients to exclude from its balance sheets recognition of leases having a term of 12 months or less (short-term leases) and to not separate lease components and non-lease components for its long-term real estate leases.

Defined Contribution Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax basis. The Company recognized expense related to its contributions to the plan of $5.3 million, $3.7 million, and $2.5 million for the years ended December 31, 2023, 2022, and 2021, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net loss and changes in unrealized gains and losses on the Company's available-for-sale investments.

Foreign Currency

The functional currency of the Company's foreign subsidiaries is the U.S. Dollar. Accordingly, all monetary assets and liabilities of the subsidiary are remeasured at the current exchange rate at the end of the period, nonmonetary assets and liabilities are remeasured at historical rates, and revenue and expenses are remeasured at average exchange rates during the period. There were net foreign currency transaction losses of $1.8 million, $1.1 million, and $0.8 million for the years ended December 31, 2023, 2022, and 2021 respectively.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period, without consideration of potential dilutive shares of common stock. Diluted net income (loss) per share attributable to the Company's stockholders is calculated based on the weighted-average number of shares of its common stock and other dilutive securities outstanding. Where the Company was in a loss position

for any periods presented, basic net loss per share was the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

The Company uses 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 (as defined below) were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. 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, *Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity's Own Equity* ("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.

Prior to conversion of the Company's convertible debt, the Company will include, in the diluted net income per common share calculation, the effect of the additional shares that may be issued when the Company's common stock price exceeds the conversion price using the if-converted method. The Company's convertible debt has no impact on diluted net income per common share unless the average price of the Company's common stock exceeds the conversion price because the Company is required to settle the principal amount of the convertible debt in cash upon conversion.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are evaluated for future realization and reduced by a valuation allowance to the extent the Company believes it is more likely than not that they will not be realized. The Company considers all available positive and negative evidence, including future reversals of existing taxable temporary reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, carryback potential if permitted under the tax law, and results of recent operations.

The Company also accounts for uncertain tax positions in accordance with ASC 740, *Income Taxes – Accounting for Income Taxes ("ASC 740")*, which requires the Company to adjust the financial statements to reflect only those tax positions that are more-likely-than-not to be sustained upon review by federal or state examiners. The Company may recognize a tax benefit only if it is more likely than not the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined that it operates in one segment.

The Company's long-lived assets are held predominantly in the United States with the exception of the Company's long lived assets in Costa Rica and Japan which collectively encompass approximately 32% and 15%, respectively, of its consolidated net property, plant, and equipment as of December 31, 2023 and 2022. See the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K for a description of risk associated with the Company's operations located outside of the United States.

Internal-Use Software

The Company has internal-use software consisting of cloud-based hosting arrangements with service contracts. The Company capitalizes certain costs incurred to implement such software within prepaid expenses and other current assets, or within other assets. Eligible costs of internal use software and implementation costs of certain hosting

arrangements are capitalized. Once the software is ready for its intended use, the Company starts amortizing the capitalized implementation costs on a straight-line basis over the estimated service term or associated hosting arrangement, as applicable.

Business combinations

The Company applies the provisions of *ASC 805, Business Combinations ("ASC 805")*, in accounting of its acquisitions. ASC 805 requires recognition of assets acquired, liabilities assumed, and contingent consideration at their fair value on the acquisition date with subsequent changes recognized in earnings; requires acquisition-related expenses to be recognized separately from the business combination and expensed as incurred; requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset until completion or abandonment; and requires that changes in accounting for deferred tax asset valuation allowances and acquired uncertain tax positions after the measurement period be recognized as a component of provision for taxes.

When an integrated set of assets and activities does not meet the practical screen test and otherwise meets the definition of a "business" under ASC 805, the Company accounts for such acquisitions as business combinations. The purchase price of an acquisition is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date. The Company bases the estimated fair value of identifiable intangible assets acquired in an acquisition on independent third-party valuations that use information and assumptions provided by the Company's management and considers inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair values of the assets acquired and liabilities assumed is recorded as goodwill. During the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the provisional amounts of assets acquired and liabilities assumed with the corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments would be recorded in earnings.

In addition, uncertain tax positions and tax related valuation allowances assumed in a business combination are initially estimated as of the acquisition date and therefore are also provisional by nature. The Company reevaluates these items quarterly based upon facts and circumstances that existed as of the acquisition date with any adjustments to its preliminary estimates being recorded to goodwill if identified within the measurement period.

Goodwill

In accordance with *ASC 350, Intangibles-Goodwill and Other ("ASC 350")*, acquired goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. The Company performs annual impairment reviews of its goodwill balance during the fourth fiscal quarter or more frequently if business factors indicate. In testing for impairment, the Company compares the fair value of its reporting unit to its carrying value including the goodwill of that unit. If the carrying value, including goodwill, exceeds the reporting unit's fair value, the Company will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value. The loss recognized cannot exceed the total amount of goodwill allocated to that reporting unit. The Company did not incur any goodwill impairment losses during the year ended December 31, 2023.

In-process research and development

Intangible assets related to in-process research and development costs are considered indefinite-lived intangible assets until the completion or abandonment of the associated research and development efforts. If and when development is complete, the associated assets would be deemed finite-lived intangible assets and would then be amortized based on their respective estimated useful lives at that point in time. Prior to the completion or abandonment of the associated research and development efforts, the assets are not amortized but are tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the in-process research and development projects below their respective carrying amounts.

During the fourth fiscal quarter and if business factors indicate more frequently, the Company performs an assessment of the qualitative factors affecting the fair value of its in-process research and development projects. If the fair value exceeds the carrying value, there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test. The Company did not incur any impairment losses during the year ended December 31, 2023.

Intangible assets

Amortizable intangible assets include customer relationships and developed technology acquired as part of business combinations. Customer relationships and developed technology acquired through business combinations subject to amortization are amortized using the straight-line method over their estimated useful lives ranging from five to 20 years. All intangible assets subject to amortization are reviewed for impairment during the fourth fiscal quarter or more frequently if business factors indicate in accordance with *ASC 360, Property, Plant and Equipment* ("*ASC 360*"). The Company did not incur any impairment losses during the year ended December 31, 2023.

Contingent Consideration Liabilities Related to Business Combination

At each reporting period, the Company evaluates the likelihood of any expected future payments and the associated discount rate to determine the fair value of the contingent consideration. The Company remeasures the fair value of contingent consideration liabilities each reporting period, based on new developments, and records any necessary adjustments as a component of total operating expenses within the consolidated statements of operations until either the contingent consideration obligation is satisfied through payment upon the achievement of, or the obligation no longer exists due to the failure to achieve, the specified milestones. Contingent consideration liabilities are recorded within other liabilities in the consolidated balance sheets.

Convertible Debt

The Company applies the provisions of ASU 2020-06 which simplify the accounting related to convertible debt instruments by removing major separation models required under current GAAP.

Accordingly, the Company does not bifurcate the liability and equity components of the convertible debt on the consolidated balance sheets. The Company's convertible debt is reflected as a liability on the Company's consolidated balance sheets, with the initial carrying amount equal to the principal amount of the debt, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the instruments utilizing the effective interest method.

The Company accounts for its convertible debt as a single liability with no separate accounting for embedded conversion features. The remaining consideration transferred, after reducing the carrying amount of the convertible debt, is recorded as a reduction to additional paid-in capital on the Company's consolidated balance sheets.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board ("FASB") issued *ASU 2023-07, Segment Reporting ("ASC 280"): Improvements to Reportable Segment Disclosures ("ASU 2023-07")*, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company is currently in the process of evaluating the effects of this pronouncement on its related disclosures.

In December 2023, the FASB issued *ASU 2023-09, Income Taxes ("ASC 740"): Improvements to Income Tax Disclosures ("ASU 2023-09")*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on its related disclosures.

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe any accounting pronouncements issued through the date of this report will have a material impact on the Company's financial statements.

3. Financial Instruments and Fair Value Measurements

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 43,277	$ —	$ —	$ 43,277
U.S. treasury securities	109,310	—	—	109,310
Marketable securities:				
U.S. treasury securities	575,203	—	—	575,203
Commercial paper	—	46,054	—	46,054
Corporate bonds	—	20,073	—	20,073
U.S. agency securities	—	14,946	—	14,946
Asset-backed securities	—	5,856	—	5,856
Total assets	$ 727,790	$ 86,929	$ —	$ 814,719
Liabilities:				
Contingent consideration liability	$ —	$ —	$ 9,307	$ 9,307
Convertible debt	—	730,455	—	730,455
Total liabilities	$ —	$ 730,455	$ 9,307	$ 739,762

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 12,076	$ —	$ —	$ 12,076
Marketable securities:				
U.S. treasury securities	111,631	—	—	111,631
Commercial paper	—	8,039	—	8,039
Corporate bonds	—	18,808	—	18,808
U.S. agency securities	—	9,429	—	9,429
Total assets	$ 123,707	$ 36,276	$ —	$ 159,983

During the year ended December 31, 2023 and 2022 there were no transfers between Level 1, Level 2 and Level 3.

Contingent Consideration Liabilities Related to Business Combination

In connection with the Company's acquisition of Neovasc Inc. ("Neovasc"), a preliminary fair value of $9.3 million was recorded for the Neovasc contingent consideration, which consisted of estimated amounts in relation to the CVR (as defined below), on April 11, 2023, the date on which the closing conditions for the acquisition were met and the transaction was consummated. Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and Level 3 inputs and assumptions used by the Company. There were no changes in the estimated fair value of the contingent consideration liability as of December 31, 2023. See Note 5 "Business Combination" for information regarding existing contingent consideration liabilities as of December 31, 2023.

Convertible Debt

As of December 31, 2023, the fair value of the Company's convertible debt was $730.5 million. The Company measures the fair value of its convertible debt for disclosure purposes. The fair value was determined based on the quoted price of the convertible debt in an over-the-counter market on the last trading day of the reporting period and has been classified as Level 2 in the fair value hierarchy. See Note 10 "Convertible Debt" for information regarding the Company's convertible debt as of December 31, 2023.

4. Cash Equivalents and Short-Term Investments

The following is a summary of the Company's cash equivalents and short-term investments:

	December 31, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 43,277	$ —	$ —	$ 43,277
U.S. treasury securities	109,292	18	—	109,310
Marketable securities:				
U.S. treasury securities	575,008	233	(38)	575,203
Commercial paper	46,015	52	(13)	46,054
Corporate bonds	19,995	86	(8)	20,073
U.S. agency securities	14,949	16	(19)	14,946
Asset-backed securities	5,792	64	—	5,856
Total	$ 814,328	$ 469	$ (78)	$ 814,719
Reported as:				
Cash equivalents				$ 152,587
Short-term investments				662,132
Total				$ 814,719

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 12,076	$ —	$ —	$ 12,076
Marketable securities:				
U.S. treasury securities	112,719	3	(1,091)	111,631
Commercial paper	8,039	—	—	8,039
Corporate bonds	18,876	8	(76)	18,808
U.S. agency securities	9,432	4	(7)	9,429
Total	$ 161,142	$ 15	$ (1,174)	$ 159,983
Reported as:				
Cash equivalents				$ 12,076
Short-term investments				147,907
Total				$ 159,983

There were $45.9 million and $123.8 million of investments in unrealized loss positions of $0.1 million and $1.2 million as of December 31, 2023 and 2022, respectively. During the years ended December 31, 2023, 2022, and 2021 the Company did not record any other-than-temporary impairment charges on its available-for-sale securities. Based on the Company's procedures under the expected credit loss model, including an assessment of unrealized losses on the portfolio,

the Company concluded that the unrealized losses for its marketable securities were not attributable to credit and therefore an allowance for credit losses for these securities has not been recorded as of December 31, 2023 and 2022. Also, based on the scheduled maturities of the investments, the Company was more likely than not to hold these investments for a period of time sufficient for a recovery of the Company's cost basis.

For the years ended December 31, 2023 and 2022 the Company recognized $5,000 and $6,000 in realized gains on cash equivalents and short-term investments. For the year ended December 31, 2021, the Company recognized no realized gains or losses on cash equivalents and short-term investments.

The remaining contractual maturities of the Company's cash equivalents and short-term investments were as follows:

	December 31, 2023
	Fair Value
	(in thousands)
Money market funds	$ 43,277
One year or less	764,034
Greater than one year and less than two years	7,408
Total	$ 814,719

5. Business Combination

Neovasc Inc.

On January 16, 2023, the Company entered into a definitive agreement to acquire Neovasc, a company focused on the minimally invasive treatment of refractory angina. On April 11, 2023, the closing conditions were met and the transaction was consummated. Upon the closing of the transaction, the Company acquired all of Neovasc's issued and outstanding common stock equity for a cash payment of $27.25 per share. During the year ended December 31, 2023, the Company incurred $6.9 million of buyer related transaction costs related to the acquisition of Neovasc, which were recorded as general and administrative expenses.

The purchase price consideration for the acquisition totaled $121.4 million, which was comprised of cash paid of $112.1 million to the selling shareholders, and the estimated fair value of the contingent consideration liability in the amount of $9.3 million.

The contingent consideration liability consisted of estimated amounts in relation to a contingent value right (a "CVR") entitling the holders of Neovasc common stock and eligible equity awards to receive an additional cash payment of up to $12.00 per share or per share underlying an eligible equity award (equivalent to a maximum cash payment of $47.0 million) contingent on the attainment of a milestone. The milestone is defined as the final approval by the FDA of the premarket approval application for the Reducer product for the treatment of angina. The milestone achievement timeline and respective payment per share ranges from $12.00 per CVR if the milestone is achieved on or prior to June 30, 2026, $8.00 per CVR if the milestone is achieved between July 1, 2026 and December 31, 2026 and $4.00 per CVR if the milestone is achieved between January 1, 2027 and December 31, 2027. The Company estimated the fair value of the contingent consideration liability using the probability-weighted discounted cash flow method based on the probability of achieving the milestone on each specified milestone date and consequently calculated the fair value of the CVR in the amount of $9.3 million as of the acquisition date.

The material factors that may impact the fair value of the contingent consideration are (i) the number of diluted shares outstanding as of the acquisition date that are eligible for the CVR, (ii) the probabilities and timing of achievement of the milestone, and (iii) discount rates, all of which are unobservable Level 3 inputs not supported by market activity. Significant changes in any of these inputs may result in a significant change in fair value, which is estimated at each reporting date with changes reflected as general and administrative expense.

The following table summarizes the purchase price consideration for Neovasc:

Purchase Price	(in thousands)
Cash transferred	$ 112,129
Contingent consideration liability	9,307
Total	$ 121,436

Assets acquired and liabilities assumed are recorded based on valuations derived from estimated fair value assessments and Level 3 inputs and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and liabilities assumed, and the residual amount of goodwill. The following table summarizes the preliminary fair values of assets acquired and liabilities assumed through the Company's Neovasc acquisition at the acquisition date based on management's best estimates and assumptions as of the reporting date:

Purchase Price	(in thousands)
Cash and cash equivalents	$ 17,273
Accounts receivable, net	1,345
Inventory	918
Prepaid expenses and other current assets	841
Operating lease right-of-use assets	310
Property and equipment	156
Intangible assets	95,500
Other assets	502
Total identifiable assets acquired	116,845
Accounts payable	3,334
Accrued liabilities	4,082
Lease liability, current portion	253
Lease liability, noncurrent portion	64
Deferred tax liabilities	10,964
Other liabilities	16,280
Total liabilities assumed	34,977
Net identifiable assets acquired	81,868
Goodwill	39,568
Total purchase price	$ 121,436

The purchase price allocation for the acquisition is preliminary and subject to revision as additional information about fair value of assets acquired and liabilities assumed becomes available, primarily related to the Company's deferred tax liability and the related impact to goodwill. Adjustments recorded in the fourth quarter of 2023 to the amounts recorded as of the second quarter of 2023 included immaterial adjustments to the liabilities assumed. Additional information that existed as of the acquisition date but at the time was unknown to the Company may become known to the Company during the remainder of the measurement period, a period not to exceed 12 months from the acquisition date.

The Company measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible assets acquired are the developed technology related to Neovasc's Reducer, in-process research and development for its Reducer technology, and Neovasc's customer relationships in place at the time of acquisition. The fair value of the intangible assets acquired as of the acquisition date and, the method used to value these assets as well as the estimated economic lives for amortizable intangible assets were as follows (in thousands, except estimated useful life which is in years):

	Fair value	Estimated useful life	Valuation method
Customer relationships	$ 2,900	5.0 years	Avoided cost / lost profit
Developed technology	61,200	20.0 years	Multi-period excess earnings
In-process research and development	31,400	N/A	Multi-period excess earnings
Total	$ 95,500		

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired. The acquisition of Neovasc resulted in the recognition of $39.6 million of goodwill which the Company believes relates primarily to the anticipated benefits of synergies created through the acquisition and assembled workforce.

The intangible assets and goodwill created as a result of the acquisition of Neovasc are not deductible for tax purposes. As such, the Company recorded deferred tax liabilities of $11.0 million related to the intangible assets in connection with the Company's acquisition of Neovasc.

Supplemental Unaudited Pro Forma Information

The following are the supplemental consolidated financial results of the Company and Neovasc on an unaudited pro forma basis, as if the Neovasc acquisition had been consummated on January 1, 2022.

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net revenue	$731,699	$493,538
Net income	$151,339	$173,596

The unaudited pro forma financial information presented is for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved if the Neovasc acquisition was actually consummated on January 1, 2022 and is not indicative of future operating results. The pro forma results include adjustments related to purchase accounting, primarily amortization of acquisition-related intangible assets, and expense from assumed stock-based compensation awards, warrant and interest expense.

6. Goodwill and intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows:

	(in thousands)
Balance as of December 31, 2022	$ —
Goodwill acquired - Neovasc	39,568
Goodwill deductions or impairment	—
Balance as of December 31, 2023	$ 39,568

The Company performs annual impairment reviews of goodwill during the fourth fiscal quarter or more frequently if required. The Company did not incur any goodwill impairment losses during the year ended December 31, 2023.

Intangible assets

The following table presents details of the acquired intangible assets as of December 31, 2023 (in thousands, except useful life and estimated remaining useful life which are in years):

	Gross Carrying Amount	Accumulated Amortization	Impairment	Intangible Assets, Net	Useful Life	Estimated Remaining Useful Life
Customer relationships	$ 2,900	$ 421	$ —	$ 2,479	5.0 years	4.3 years
Developed technology	61,200	2,222	—	58,978	20.0 years	19.3 years
In-process research and development	31,400	—	—	31,400	N/A	N/A
Total	$ 95,500	$ 2,643	$ —	$ 92,857	19.3 years	18.6 years

Acquisition-related intangible assets included in the above table are finite-lived, other than in-process research and development which has an indefinite life, and are carried at cost less accumulated amortization. Customer relationships and developed technology are amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized. Amortization expense was $2.6 million for the year ended December 31, 2023, and was recorded to sales and marketing for customer relationships and to cost of revenue for developed technology.

The following table summarizes the estimated future amortization expense of intangible assets with finite lives as of December 31, 2023:

Years ending December 31,	(in thousands)
2024	3,640
2025	3,640
2026	3,640
2027	3,640
2028	3,219
Thereafter	43,678
Total estimated future amortization expense	$ 61,457

Actual amortization expense to be reported in future periods could differ from these estimates as a result of asset impairments, acquisitions, or other facts and circumstances. The Company performs annual impairment reviews of its intangible assets during the fourth fiscal quarter or more frequently if business factors indicate. The Company did not incur any impairment losses related to its intangible assets during the year ended December 31, 2023.

7. Balance Sheet Components

Inventory

Inventory consists of the following:

	December 31,	
	2023	2022
	(in thousands)	
Raw material	$ 25,670	$ 18,456
Work in progress	16,499	7,666
Finished goods	65,418	48,990
Total inventory	$ 107,587	$ 75,112

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2023	2022
	(in thousands)	
Equipment	$ 19,687	$ 12,784
Office furniture	1,839	1,171
Software	848	904
Building	12,166	—
Land	2,268	—
Leasehold improvements	38,168	33,703
Construction in progress	11,016	9,765
Property and equipment, gross	85,992	58,327
Less: accumulated depreciation and amortization	(17,069)	(10,175)
Total property and equipment, net	$ 68,923	$ 48,152

Depreciation and amortization expense amounted to $7.7 million, $4.9 million and $3.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

In July 2022, the Company purchased real property in the Coyol Free Trade Zone in Alajuela, Costa Rica, and began the construction of a new manufacturing facility. As of December 31, 2023, the first phase of the facility was completed and occupied and the second phase was still in process of construction.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2023	2022
	(in thousands)	
Employee compensation	$ 49,706	$ 32,885
Asset purchases	7,788	4,600
Professional services	6,269	4,044
Research and development costs	8,122	4,007
Excise, sales, income and other taxes	12,320	4,036
Sales and marketing	3,495	2,012
Other	3,996	3,791
Total accrued liabilities	$ 91,696	$ 55,375

8. Commitments and Contingencies

Operating Leases

The Company's operating leases consist of leased facilities for the Company's headquarter offices, leased facilities for Neovasc, and leased facilities for laboratory and manufacturing space. Also included in operating leases are leases for vehicles, for use by certain employees of the Company, which were not material for the periods presented.

Short-term leases are leases having a term of 12 months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases. As of December 31, 2023, the Company has no material finance leases.

In September 2021, the Company entered into an office lease agreement ("3003 Bunker Hill Lease") for the 3003 Bunker Hill facility which expires in December 2031. Concurrently, the Company entered into an Amendment to Office Lease (Net) (the "First Lease Amendment") which extended the lease terms of the 5353 Betsy Ross and 5403 Betsy Ross facilities to December 2031. The 5403 Betsy Ross lease ("5403 Lease") continued in its existing terms (and with no changes to its terms, including its base rent) until its expiration in August 2022, at which point the leased space under the 5403 Lease became subject to the terms of the First Lease Amendment. The 3003 Bunker Hill Lease and the First Lease Amendment contain options to extend the lease term at the respective facilities for up to two additional five-year terms at the then fair market rate. As of December 31, 2023, the Company is not reasonably certain it will exercise these extension options.

Additionally, included in the First Lease Amendment was an expansion option that stipulated that the Company had an option to lease the space in the adjacent building located at 5303 Betsy Ross ("5303 Lease"). The Company exercised this expansion option by entering into a Second Amendment to Office Lease (Net) (the "Second Lease Amendment") on May 26, 2023. The 5303 Lease will be accounted for as a separate lease and is expected to commence on February 1, 2024 and expire on December 31, 2031.

The Company recognizes rent expense for these operating leases on a straight-line basis over the lease period. The components of lease costs, which the Company includes in operating expenses in the consolidated statements of operations and comprehensive income, were as follows:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Operating lease cost	$ 5,110	$ 4,667	$ 2,891
Variable lease cost	1,243	1,186	496
Total lease cost	$ 6,353	$ 5,853	$ 3,387

During the years ended December 31, 2023, 2022 and 2021, the Company recorded operating lease expense of $5.1 million, $4.7 million, and $2.9 million and paid $5.5 million, $3.4 million, and $2.2 million of operating lease payments respectively related to the lease liabilities.

The Company includes operating lease payments in net cash used in operating activities in the consolidated statements of cash flows.

The weighted average remaining lease term and discount rate used to measure the Company's operating lease liabilities were 8 years and 5.2%, respectively. The Company estimated the discount rate using the incremental borrowing rate as the rate implicit in the lease was not readily determinable.

As of December 31, 2023, the maturities of the payments due under the Company's operating lease liabilities were as follows:

		(in thousands)
2024	$	5,555
2025		5,526
2026		5,690
2027		5,832
2028		5,960
Thereafter		18,999
Total minimum lease payments	$	47,562
Less: imputed interest		(8,818)
Total lease liability	$	38,744
Less: current portion		(3,641)
Lease liability, noncurrent portion	$	35,103

The table below summarizes the undiscounted future non-cancellable lease payments for the 5303 Lease facility under the Second Lease Amendment, which had not yet commenced as of December 31, 2023.

Years ending December 31,		**(in thousands)**
2024	$	476
2025		1,173
2026		1,207
2027		1,244
2028		1,282
Thereafter		4,077
Total undiscounted lease payments	$	9,459

Contingent Consideration Liabilities Related to Business Combination

See Note 5 "Business Combination" for information regarding existing contingent consideration liabilities as of December 31, 2023.

9. Debt

Amended SVB Credit Agreement

In February 2020, the Company entered into a First Amendment to its Loan and Security Agreement with Silicon Valley Bank (the "Amended SVB Credit Agreement") to, among other things, refinance its then-existing term loan, which is accounted for as a modification of the Loan and Security Agreement. The Amended SVB Credit Agreement provided the Company with a supplemental term loan in the amount of $16.5 million that was set to mature on December 1, 2023. The Amended SVB Credit Agreement provided an interest-only payment period through June 30, 2022.

Credit Agreement

On October 19, 2022, the Company entered into a Credit Agreement (the "Credit Agreement") 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, as joint lead arrangers and joint bookrunners, Silicon Valley Bank, as syndication agent, and the several lenders party thereto. 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) the Company's consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

Concurrent with entering into the Credit Agreement, the Company drew down $25.0 million thereunder and prepaid in full all outstanding amounts and related expenses under the Amended SVB Credit Agreement, totaling $14.6 million, and terminated the credit facility thereunder. The Company recognized a loss on debt extinguishment of $0.6 million in connection with the early repayment of its Amended SVB Credit Agreement which is included in interest expense in the consolidated statement of operations for the year ended December 31, 2022.

The Company repaid the $25.0 million drawn under the Credit Agreement on August 29, 2023. The Company recognized a loss on debt extinguishment of $0.7 million in connection with this repayment, which was included in interest expense in the consolidated statement of operations for the year ended December 31, 2023.

On March 16, 2023, the Company drew down an additional $80.0 million under the Credit Agreement. The Company repaid the $80.0 million drawn under the Credit Agreement on April 26, 2023.

The revolving credit facility accrues for interest, at the election of the Company, at (A) the Base Rate (as defined below) plus a margin ranging from 0% to 1% depending on the Company's Consolidated Total Net Leverage Ratio (as defined in the Credit Agreement) (which rate is currently 0%) or (B) the applicable secured overnight financing rate ("SOFR") plus a margin from 1% to 2%, depending on the Company's Consolidated Total Net Leverage Ratio (which rate is currently 1.8%). Base Rate means, at any time, the highest of (a) the Wells Fargo Bank, National Association's announced prime rate, (b) the federal funds rate plus 0.5% and (c) Term SOFR for a one-month tenor in effect on such day plus 1%. The Credit Agreement matures on October 19, 2027. The interest rate was 7.3% as of August 29, 2023.

The Company recorded interest expense of $2.7 million, $1.9 million and $1.1 million for the years ended December 31, 2023, 2022 and 2021, respectively.

10. Convertible Debt

On August 15, 2023, the Company issued $750.0 million in aggregate principal amount of 1.0% convertible senior notes due 2028 (the "Notes"). The issuance included the full exercise of an option granted by the Company to the initial purchasers of the Notes to purchase an additional $100.0 million in aggregate principal amount of Notes. The Notes were issued pursuant to and subject to the terms of an indenture, dated August 15, 2023, between the Company and U.S. Bank Trust Company, National Association, as trustee (the "Indenture"). The Indenture includes customary covenants and sets forth certain events of default, including certain types of bankruptcy and insolvency events, after which the Notes may be declared immediately due and payable. The Notes were offered and sold in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

The Notes are senior, unsecured obligations of the Company. The Notes will mature on August 15, 2028, unless earlier converted, redeemed, or repurchased in accordance with their terms. The Notes bear interest at a rate of 1.0% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on February 15, 2024. The Notes are convertible, in multiples of $1,000 principal amount and at the option of the noteholder, on or after May 15, 2028. Prior to May 15, 2028, holders of the Notes may convert all or a portion of their Notes, in multiples of $1,000 principal amount, only under the following circumstances: (1) during any calendar quarter commencing after December 31, 2023 (and only during such calendar quarter) if the closing price of the Company's common stock for at least 20 trading days (whether or not consecutive) in a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the then applicable conversion price for the Notes on each applicable trading day; (2) during the five business days immediately after any five consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of Notes for each day of that period was less than 98% of the product of the closing price of the Company's common stock and the then applicable conversion rate; (3) if the Company calls such Notes for redemption, at any time prior to the close of business on the

scheduled trading day immediately preceding the redemption date, but only with respect to the Notes called (or deemed called) for redemption; or (4) upon the occurrence of specific corporate events as specified in the Indenture. The Company will settle any conversions of Notes by paying or delivering, as applicable, cash up to the aggregate principal amount of the Notes to be converted and by paying or delivering, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at the election of the Company, in respect of the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount of the Notes being converted.

The conversion rate for the Notes was initially 3.4595 shares of common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of approximately $289.06 per share of common stock. The initial conversion price of the Notes represents a premium of approximately 30% over the $222.35 per share last reported sale price of common stock on August 10, 2023. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture, with a maximum conversion rate of 4.4974 shares of common stock per $1,000 principal amount of Notes.

The Company may not redeem the Notes prior to August 20, 2026. The Company may redeem, for cash equal to 100% of the principal amount of the Notes being redeemed plus accrued and unpaid interest, all or any portion of the Notes, at its option, on or after August 20, 2026, if the last reported sales price of its common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of the redemption. No sinking fund is provided for the Notes and therefore the Company is not required to redeem or retire the Notes periodically.

If the Company undergoes a fundamental change, as defined in the Indenture, then subject to certain conditions, holders may require the Company to repurchase for cash all or any portion of their Notes at a price equal to 100% of the principal amount of the Notes to be repurchased plus any accrued and unpaid interest to, but excluding, the repurchase date. In addition, under certain circumstances, holders of the Notes are entitled to an increase in the conversion rate. The conditions allowing holders of the Notes to convert were not met this quarter.

As of December 31, 2023, the Notes were classified as a long-term liability, net of issuance costs of $19.6 million, on the consolidated balance sheets. As of December 31, 2023, the net carrying amount of the Notes was $731.9 million. Interest expense recognized related to the Notes for the year ended December 31, 2023 was $4.2 million. The Notes were issued at par and costs associated with the issuance of the Notes are amortized to interest expense over the contractual term of the Notes through the application of the effective interest method. As of December 31, 2023, the effective interest rate of the Notes was 1.5%.

Capped Call Transactions

On August 10, 2023, in connection with the pricing of the Notes and the initial purchasers' exercise of their option to purchase additional Notes, the Company entered into privately negotiated capped call transactions ("Capped Call Transactions"). The Capped Call Transactions initially covered, subject to customary anti-dilution adjustments, the number of shares of common stock that underlie the Notes. The cap price of the Capped Call Transactions was initially $444.7 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock of $222.35 per share on August 10, 2023, and is subject to certain adjustments under the terms of the Capped Call Transactions. The Company used approximately $96.4 million of the proceeds from the offering of Notes to pay the cost of the Capped Call Transactions.

The Company evaluated the Capped Call Transactions and determined that they should be accounted for separately from the Notes. The cost of $96.4 million to purchase the Capped Call Transactions was recorded as a reduction to additional paid-in capital in the consolidated balance sheets as of December 31, 2023 as the Capped Call Transactions are indexed to the Company's own stock and met the criteria to be classified in stockholders' equity.

11. Stock-Based Compensation

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Cost of product revenue	$ 5,003	$ 2,193	$ 1,153
Research and development	17,160	10,354	6,240
Sales and marketing	27,945	18,387	11,043
General and administrative	23,126	13,956	8,821
Total stock-based compensation	$ 73,234	$ 44,890	$ 27,257

Stock-based compensation of $2.3 million, $2.2 million, and $0.7 million was capitalized into inventory for the years ended December 31, 2023, 2022, and 2021, respectively. Stock-based compensation capitalized into inventory is recognized as cost of product revenue when the related product is sold.

2009 Equity Incentive Plan and 2019 Equity Incentive Plan

On June 17, 2009, the Company adopted the 2009 Equity Incentive Plan (the "2009 Plan") under which the Company's board of directors (the "Board") may issue stock options to employees, directors and consultants.

In February 2019, the Company adopted the 2019 Equity Incentive Plan (the "2019 Plan"), which became effective in connection with the Company's initial public offering. As a result, effective as of March 6, 2019, the Company may not grant any additional awards under the 2009 Plan. The 2009 Plan will continue to govern outstanding equity awards granted thereunder. The Company initially reserved 2,000,430 shares of common stock for the issuance of a variety of awards under the 2019 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units ("RSUs"). In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years, which commenced on January 1, 2020, in an amount equal to 3% of the total number of shares of the Company's common stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Board. As of December 31, 2023, there were 3,516,750 shares of common stock available for issuance under the 2019 Plan.

Stock Options

Option activity under the 2009 Plan and 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Balance, December 31, 2022	1,122,009	$ 5.87	4.60	$ 224,115
Options exercised	(235,067)	5.84		
Options cancelled	(6,133)	2.41		
Balance, December 31, 2023	880,809	$ 5.90	3.60	$ 162,653
Vested and exercisable, December 31, 2023	880,809	$ 5.90	3.60	$ 162,653
Vested and expected to vest, December 31, 2023	880,809	$ 5.90	3.60	$ 162,653

There were no options granted during the years ended December 31, 2023, 2022, and 2021. The total grant date fair value of options vested was $0.1 million, $1.0 million and $1.6 million for the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023 there was no unrecognized stock-based compensation related to unvested stock options.

Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. RSUs cannot be transferred and the awards are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. RSUs generally vest over a four-year period with straight-line quarterly vesting with a one year cliff or straight-line annual vesting, provided the employee remains continuously employed with the Company. The fair value of RSUs is equal to the closing price of the Company's common stock on the grant date.

In February 2022 and 2023, the Company granted performance-based restricted stock units ("PRSUs") to certain key executives. The vesting of these PRSUs is dependent on the achievement of certain performance targets related to the Company's compound annual growth rate of revenue over a two or three year performance period, provided the executives remain employed with the Company at the time of vesting. The number of PRSUs that vest will vary from 0% to 200% of the target which will be determined based on the level of performance attained for each performance period. The fair value of these PRSUs is equal to the closing price of the Company's common stock on the grant date. Compensation cost for PRSUs is recognized over the requisite service period based on the expected achievement of performance targets.

RSU and PRSU activity under the 2019 Plan is set forth below. Grant activity for all PRSUs is disclosed at target (100%):

	Restricted Stock Units		Performance-Based Restricted Stock Units	
	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2022	1,125,991	$ 127.39	38,797	$ 165.74
RSUs and PRSUs granted	606,187	210.54	29,473	191.36
RSUs and PRSUs forfeited	(83,916)	172.66	(867)	267.54
RSUs and PRSUs vested	(481,240)	117.14	(395)	267.41
Balance, December 31, 2023	1,167,022	171.55	67,008	175.09

The total grant date fair value of RSUs vested was $56.5 million, $30.9 million, and $11.3 million, for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, there was $175.3 million of unrecognized stock-based compensation expense related to RSUs to be recognized over a weighted-average period of 2.3 years.

Employee Share Purchase Plan (ESPP)

In February 2019, the Company adopted the Employee Stock Purchase Plan ("ESPP"), which became effective as of March 6, 2019. The Company initially reserved 300,650 shares of the Company's common stock for purchase under the ESPP. In addition, the number of shares of common stock reserved for issuance under the ESPP will automatically increase on the first day of January for a period of up to ten years, which commenced on January 1, 2020, in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Board.

Each offering to the employees to purchase stock under the ESPP will begin on each September 1 and March 1 and will end on the following February 28 or 29 and August 31, respectively. On each purchase date, which falls on the last date of each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Compensation Committee of the Board, in its sole discretion.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model based on the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. The Company's historical share option exercise information is limited due to a lack of sufficient data points, and did not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

Expected Volatility—The expected volatility is measured using the historical daily changes in the market price of the Company's common stock over a period consistent with the expected term.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.

Expected Dividend Yield—The expected dividend yield is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

The Company recorded $3.3 million, $2.3 million and $1.3 million of stock-based compensation expense related to the ESPP for the years ended December 31, 2023, 2022 and 2021, respectively. At December 31, 2023, a total of 1,521,021 shares of common stock were available for issuance under the ESPP.

	Years Ended December 31,		
	2023	**2022**	**2021**
Expected term (in years)	0.5	0.5	0.5
Expected volatility	44.3%-73.8%	61.8%-73.8%	48.9%-64.8%
Risk-free interest rate	3.7%-5.5%	0.1%-3.7%	0.1%
Expected dividend yield	0%	0%	0%

12. Income Taxes

The following table presents income (loss) before income taxes for the periods presented:

	December 31,		
	2023	**2022**	**2021**
	(in thousands)		
Domestic	$ 194,406	$ 119,901	$ (9,388)
Foreign	(20,125)	927	553
Total income (loss) before income taxes	$ 174,281	$ 120,828	$ (8,835)

The income tax expense (benefit) for the periods presented consisted of the following:

	December 31,		
	2023	2022	2021
	(in thousands)		
Current provision for income taxes:			
Federal	$ 1,638	$ 403	$ —
State	5,418	1,446	84
Foreign	5,239	259	217
Total current tax provision:	12,295	2,108	301
Deferred tax provision:			
Federal	21,855	(85,618)	—
State	1,625	(11,658)	—
Foreign	(8,772)	—	—
Total deferred tax (benefit) provision	14,708	(97,276)	—
Total (benefit) provision for income taxes	$ 27,003	$ (95,168)	$ 301

The components of the deferred tax assets and liabilities are as follows:

	December 31,	
	2023	2022
	(in thousands)	
Deferred tax assets:		
Net operating loss carryovers	$ 60,636	$ 60,467
Accruals and reserves	12,856	10,876
Stock-based compensation	8,745	8,504
Research and development credits	20,736	15,250
Lease liability	9,816	9,316
Capitalized research and development	34,511	17,791
Convertible note	22,841	—
Other	92	—
Total deferred tax assets	170,233	122,204
Less valuation allowance	(57,848)	(13,371)
Gross deferred tax assets	112,385	108,833
Deferred tax liabilities:		
Fixed and intangible assets	(5,624)	(1,105)
Right-of-use-assets	(7,592)	(8,327)
In process research and development	(3,609)	—
Other	—	(1,833)
Gross deferred tax liabilities	(16,825)	(11,265)
Total net deferred tax assets	$ 95,560	$ 97,568

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Each quarter, the Company assesses its ability to use the deferred tax assets to offset its expected federal and state taxable income based on the weight of all available evidence, including such factors as the history of recent earnings and expected future taxable income on a jurisdiction by jurisdiction basis. Until the quarter ended December 31, 2022, the Company maintained a full valuation allowance against its deferred tax assets due to the Company's cumulative loss position and uncertainties regarding sustainable future profitability since inception. The Company released the valuation

allowance against all of the U.S. federal deferred tax assets and other-than-California state deferred tax assets during the fourth quarter of fiscal year 2022.

The valuation allowance increased by $44.5 million for the year ended December 31, 2023, and decreased by $91.4 million for the year ended December 31, 2022, and increased by $22.7 million for the year ended December 31, 2021. The significant increase in the valuation allowance during 2023 was primarily the result of the acquired deferred tax asset with valuation allowance from acquisition of Neovasc. The significant decrease in the valuation allowance during 2022 was the result of the Company's release of the entire valuation allowance previously established on its federal and non-California state deferred tax assets. For fiscal year 2023, the Company reported a total of $27.0 million of worldwide income tax expenses comprised of $23.5 million for U.S. federal and $7.0 million for other states, respectively. The remaining $3.5 million of income tax benefits are from foreign entities. The Company continues to maintain a full valuation allowance of $8.1 million, $16.2 million, $0.2 million, and $33.3 million on federal (Neovasc), California, other states (Neovasc), and various Neovasc foreign entities deferred tax assets, respectively, which the Company believes are not more likely than not to be realized in future periods.

As of December 31, 2023, the Company had net operating loss ("NOL") carryforwards of approximately $103.1 million for federal income tax purposes, $45.6 million for California income tax purposes, $31.8 million for other state income tax purposes, and $126.6 million for foreign entities. The federal NOL carryforwards (generated prior to 2018) of $15.2 million begin expiring in 2037 and are subject to Section 382 limitation. The federal NOL carryforwards (generated after 2018) of $87.9 million will never expire. The California NOL begin expiring in 2034 and other state NOL carryforwards begin expiring in various years, starting in 2024. The foreign NOL will begin to expire in 2026.

As of December 31, 2023, the Company had research and development credit carryforwards of $14.6 million for federal income tax purposes and $14.6 million for California state income tax purposes available to reduce future taxable income, if any. The federal research and development credit carryforwards expire beginning 2041 and California credits can be carried forward indefinitely.

Utilization of the Company's net operating losses and tax credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. The Company experienced ownership changes in 2013 and 2017 and its operating losses and tax credits generated prior to the 2017 ownership change are subject to utilization limitation.

The Company indefinitely reinvests earnings from its foreign subsidiaries and therefore no deferred tax liability has been recognized on the basis difference created by such earnings. The Company has not provided foreign withholding taxes for any undistributed earnings of its foreign subsidiaries.

Reconciliation of the statutory federal income tax to the Company's effective tax is as follows:

	December 31,		
	2023	2022	2021
	(in thousands)		
Income tax provision (benefit) at federal statutory rate	$ 36,601	$ 25,378	$ (1,856)
State and local income	5,937	(10,516)	36
Foreign tax rate differential	926	47	101
Change in valuation allowance	3,331	(87,568)	19,027
Stock-based compensation	(14,043)	(18,273)	(17,968)
Section 250 FDII deduction	(2,065)	(984)	—
Research and development credits	(6,974)	(3,937)	(808)
Section 382 limitation	—	—	575
Equity method investment	393	520	1,320
Section 162(m) limitation	2,633	—	—
Acquisition tax structuring	(2,418)	—	—
Other	2,682	165	(126)
Total current income tax (benefit) provision	$ 27,003	$ (95,168)	$ 301

The Company maintains liabilities for uncertain tax positions. The measurement of these liabilities involves considerable judgment and estimation and are continuously monitored by management based on the best information available, including changes in tax regulations, the outcome of relevant court cases, and other pertinent information.

The activity related to the gross amount of unrecognized tax benefits is as follows:

	December 31,		
	2023	2022	2021
	(in thousands)		
Beginning balance	$ 5,264	$ 5,221	$ 3,746
Additions based on tax positions related to prior years	283	—	—
Reductions based on tax positions related to prior years	—	(1,861)	(79)
Additions based on tax positions related to current years	4,418	1,904	1,554
Balance at end of year	$ 9,965	$ 5,264	$ 5,221

As of December 31, 2023, 2022 and 2021, the total amount of unrecognized tax benefits was approximately $10.0 million, $5.3 million and $5.2 million, respectively. The unrecognized tax benefit of $6.5 million would impact the effective tax rate, if recognized. A valuation allowance is maintained on the tax benefits related to California deferred tax assets and if these tax benefits were recognized it would not impact the effective tax rate. The Company had immaterial amounts of accrued interest and no accrued penalties related to unrecognized tax benefits as of December 31, 2023, 2022 and 2021. The Company does not expect its unrecognized tax benefits to change materially over the next 12 months.

While the Company believes it has adequately provided for all tax positions, amounts asserted by tax authorities could be greater or less than the recorded position. Accordingly, the Company's provisions on federal and state tax-related matters to be recorded in the future may change as revised estimates are made or the underlying matters are settled or otherwise resolved.

The Company is subject to taxation in the U.S. federal jurisdiction, various state jurisdictions, and various foreign jurisdictions. The Company is subject to examination of its income tax returns since inception by U.S. federal and state tax authorities. The foreign tax returns generally remain open to examination until three to four years after filing. The Company is not currently under audit with the Internal Revenue Service, or any material foreign, state or local jurisdiction, nor has it been notified of any other potential future income tax audit.

13. Revenue

The following table represents the Company's product revenue based on product line:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Coronary	$ 528,845	$ 353,859	$ 161,463
Peripheral	194,346	132,284	74,064
Reducer	4,368	—	—
Other	2,671	3,590	1,619
Product revenue	$ 730,230	$ 489,733	$ 237,146

Coronary product revenue encompasses sales of the Company's C^2 catheter and C^{2+} catheter. Peripheral product revenue encompasses sales of the Company's M^5 catheter, M^{5+} catheter, S^4 catheter, and L^6 catheter. Reducer revenue encompasses sales of the Company's Reducer product, resulting from the Neovasc acquisition. Other product revenue encompasses sales of the Company's generators and related accessories.

The following table represents the Company's product revenue based on the location to which the product is shipped:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
United States	$ 581,548	$ 407,425	$ 186,324
Europe	77,515	51,010	38,571
All other countries	71,167	31,298	12,251
Product revenue	$ 730,230	$ 489,733	$ 237,146

14. Equity Method Investments

Genesis Shockwave Private Limited

On March 19, 2021, the Company entered into the Joint Venture Deed (or "JV Agreement") with Genesis MedTech International Private Limited ("Genesis") to establish a long-term strategic partnership to develop, manufacture and commercialize certain of the Company's interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "PRC").

On the same date, Genesis and the Company entered into a Share Subscription Agreement pursuant to which, among other things, the JV issued (i) 54,900 ordinary shares which represents 55% of the total equity of the JV, to Genesis in exchange for a cash contribution of $15.0 million, and (ii) 45,000 ordinary shares which represents 45% of the total equity of the JV, to the Company as consideration for the Shockwave License Agreement (the "License Agreement"). Under the License Agreement, the Company has agreed to contribute to the JV an exclusive license under certain of the Company's intellectual property rights to develop, manufacture, distribute and commercialize certain products in the PRC and is entitled to receive royalties on the sales of the licensed products in the PRC. Further, the Company entered into a Distribution Agreement, pursuant to which the Company has agreed to sell certain Company-manufactured products to the JV or a PRC subsidiary of the JV for commercialization and distribution in the PRC.

As of December 31, 2023, the carrying value of the Company's investment in the JV was $1.6 million and the Company owned a 45% interest in the entity.

The Company's product revenue for products sold to the JV during the year ended December 31, 2023 and related accounts receivable from the JV as of December 31, 2023 were immaterial. Intra-entity profit, which was recorded as a reduction to equity method investment as of and for the year ended December 31, 2023, was also immaterial.

For the years ended December 31, 2023, 2022, and 2021, the Company's loss from the equity method was $1.9 million, $2.5 million, and $6.3 million, respectively.

As of December 31, 2023, the associated manufacturing technology transfer to the JV has not yet been completed. The Company maintains a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation. The Company will satisfy the outstanding performance obligation upon the completion of training provided by the Company to the JV, and successful regulatory approval for the JV manufactured product from the China National Medical Products Administration.

15. Net Income (Loss) Per Share

Basic net income per share is calculated by dividing net income by the weighted-average number of shares of common stock outstanding for the period, without consideration of potential dilutive shares of common stock. Diluted net income per share attributable to the Company's stockholders is calculated based on the weighted-average number of shares of its common stock and other dilutive securities outstanding.

Potentially dilutive common shares from employee equity incentive plans are determined by applying the treasury stock method to the assumed exercise of outstanding stock options and the assumed vesting of outstanding RSUs. Prior to conversion of the Company's convertible debt, the Company will include, in the diluted net income per common share

calculation, the effect of the additional shares that may be issued when the Company's common stock price exceeds the conversion price using the if-converted method. The Company's convertible debt has no impact on diluted net income per common share unless the average price of the Company's common stock exceeds the conversion price because the Company is required to settle the principal amount of the convertible debt in cash upon conversion.

The components of basic and diluted net income (loss) per share were as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2023	2022	2021
Numerator:			
Net income (loss)	$ 147,278	$ 215,996	$ (9,136)
Denominator:			
Basic:			
Weighted average number of common shares outstanding - basic	36,706,060	35,900,738	35,098,130
Diluted:			
Weighted average number of common shares outstanding - basic	36,706,060	35,900,738	35,098,130
Dilutive effect of outstanding common stock options	960,436	1,294,052	—
Dilutive effect of restricted stock units	535,483	684,696	—
Dilutive effect of common stock pursuant to employee stock purchase plan	4,290	2,104	—
Weighted average number of common shares outstanding - diluted	38,206,269	37,881,590	35,098,130
Net income (loss) per share:			
Basic	$ 4.01	$ 6.02	$ (0.26)
Diluted	$ 3.85	$ 5.70	$ (0.26)

All restricted shares, purchase rights under the employee stock purchase plan, and capped call options for the year ended December 31, 2023, 2022, and 2021 have been excluded from the calculation of the diluted net income per share, because all such securities are anti-dilutive for all periods presented. The total number of potential shares excluded from the calculation of diluted net income per share are as follows:

	Year Ended December 31,		
	2023	2022	2021
Common stock options issued and outstanding	—	—	1,524,985
Restricted stock units	105,726	21,537	1,156,683
Employee stock purchase plan	—	2,122	10,028
Capped call options	333,409	—	—
Total	439,135	23,659	2,691,696

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2023. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission ("SEC") rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2023 with respect to a material weakness in internal controls over financial reporting described below. As permitted by SEC guidance for newly acquired businesses, management's assessment of our internal control over financial reporting did not include an assessment of internal control over financial reporting of Neovasc Inc. ("Neovasc"). Neovasc accounted for approximately 3% of our total assets as of December 31, 2023 and 1% of revenue and (10)% of net income for the year ended December 31, 2023.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, 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. The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report which is included in this Item 9A of this Annual Report on Form 10-K.

Remediation Plan for Material Weaknesses

Our management is committed to maintaining a strong internal control environment. In response to the material weakness described above, management, with the oversight of the Audit Committee of the Board of Directors, is taking comprehensive actions to remediate this material weakness in internal control over financial reporting. For remediation, we are implementing additional processes to timely document and retain evidence to substantiate management's review over prospective financial information used in connection with any future acquisitions that we may undertake.

We believe that these actions will remediate the material weakness. However, full remediation depends on verification of the effective operation of applicable controls in the context of a future acquisition. Accordingly, we cannot at this time estimate the time to full remediation.

Changes in internal control over financial reporting.

Other than the single material weakness described above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange

Act that occurred during the three months ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Shockwave Medical, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Shockwave Medical, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Shockwave Medical, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. The material weakness 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 Company's accounting for its acquisition of Neovasc Inc. (Neovasc).

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Neovasc, which is included in the 2023 consolidated financial statements of the Company and constituted 3% of total assets as of December 31, 2023 and 1% and (10)% of revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Neovasc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated February 26, 2024, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California

February 26, 2024

Item 9B. Other Information.

During the quarter ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our 2024 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2023 (the "Proxy Statement").

Item 11. Executive Compensation.

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) We have filed the following documents as part of this Annual Report on Form 10-K:

1. Financial Statements: The financial statements included in "Index to Consolidated Financial Statements" in Part II, Item 8 are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules: All schedules are omitted because they are not applicable or because the required information is shown in the consolidated financial statements and notes.

3. Exhibits.

Exhibit Index

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit(s)	Filing Date
2.1	Arrangement Agreement by and between the Registrant and Neovasc Inc., dated January 16, 2023	8-K	001-38829	2.1	January 17, 2023
3.1	Restated Certificate of Incorporation	8-K	001-38829	3.3	March 12, 2019
3.2	Second Amended and Restated Bylaws	8-K	001-38829	3.1	December 23, 2022
4.1	Form of Common Stock Certificate	S-1	333-229590	4.1	February 8, 2019
4.2	Amended and Restated Investors' Rights Agreement, between the Registrant and the investors listed on Exhibit A thereto	S-1	333-229590	4.2	February 8, 2019
4.3	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-38829	4.3	February 27, 2023
4.4	Indenture dated August 15, 2023 between Shockwave Medical, Inc. and U.S. Bank Trust Company, National Association, as trustee (including the form of 1.00% Convertible Senior Notes due 2028)	8-K	001-38829	4.1	August 15, 2023
10.1	Form of Capped Call Transaction Confirmation	8-K	001-38829	99.1	August 15, 2023
10.2	Sublease Agreement by and between the Registrant and Benvenue Medical, Inc. for facilities at 5403 Betsy Ross Drive, Santa Clara, California, dated May 7, 2018	S-1	333-229590	10.1	February 8, 2019
10.3	Lease Agreement by and between the Registrant and Betsy Ross Property, LLC for facilities at 5403 and 5353 Betsy Ross Drive, Santa Clara, California, dated December 13, 2019	10-K	001-38829	10.2	March 12, 2020
10.4	Office Lease (Net), dated as of September 27, 2021, between Bunker Hill Lane Property, LLC, a Delaware limited liability company, as Landlord, and Shockwave Medical, Inc., a Delaware Corporation, as Tenant, for 3003 Bunker Hill Lane, Santa Clara, California.	8-K	001-38829	10.1	September 28, 2021
10.5	First Amendment to Office Lease (Net), dated as of September 27, 2021, by and between Betsy Ross Property, LLC, a Delaware limited liability company, and Shockwave Medical, Inc., a Delaware corporation, relating to 5353 Betsy Ross Drive, and 5403 Betsy Ross Drive, Santa Clara, California	8-K	001-38829	10.2	September 28, 2021

10.6	Second Amendment to Office Lease (Net), dated as of May 26, 2023, by and between Betsy Ross Property, LLC, a Delaware limited liability company, and Shockwave Medical, Inc., a Delaware corporation, relating to 5353 Betsy Ross Drive, and 5403 Betsy Ross Drive, Santa Clara, California	8-K	001-38829	10.1	June 1, 2023
10.7†	2009 Equity Incentive Plan, and forms of Stock Option Agreement and Early Exercise Stock Option Agreement	S-1	333-229590	10.3	February 8, 2019
10.8†	2019 Equity Incentive Plan and form of Stock Option Agreement	S-1/A	333-229590	10.4	February 25, 2019
10.9†	Form of Global Restricted Stock Unit Agreement	10-K	001-38829	10.5	February 27, 2023
10.10*†	Form of Global Performance-Based Restricted Stock Unit Award Agreement				
10.11†	Employee Stock Purchase Plan	S-1/A	333-229590	10.5	February 25, 2019
10.12†	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers	S-1	333-229590	10.6	February 8, 2019
10.13†	Offer Letter with Douglas Godshall	S-1	333-229590	10.7	February 8, 2019
10.14†	Amended and Restated Separation Pay Agreement with Douglas Godshall	10-Q	001-38829	10.1	May 9, 2022
10.15†	Offer Letter with Dan Puckett	S-1	333-229590	10.8	February 8, 2019
10.16*†	Consulting Agreement with Dan Puckett				
10.17*†	Offer Letter with Renee Gaeta				
10.18†	Offer Letter with Isaac Zacharias	S-1	333-229590	10.9	February 8, 2019
10.19†	Amended and Restated Form of Separation Pay Agreement for Executive Officers (other than CEO)	10-Q	001-38829	10.2	May 9, 2022
10.20†	Amended and Restated Non-Employee Director Compensation Policy	10-Q	001-38829	10.1	August 7, 2023
10.21	Credit Agreement by and between the Registrant and the Lenders referred to therein as Lenders, and Wells Fargo Bank, National Association, as Administrative Agent, Swingline Lender and an Issuing Lender, Wells Fargo Securities, LLC, and Silicon Valley Bank, as Joint Lead Arrangers and Joint Bookrunners, and Silicon Valley Bank, as Syndication Agent, dated October 19, 2022	8-K	001-38829	10.1	October 20, 2022
21.1*	Subsidiaries of the Registrant				
23.1*	Consent of Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (included on signature page)				
31.1*	Certification of Principal Executive Officer required under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
31.2*	Certification of Principal Financial Officer required under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				
32.1*#	Certification of Principal Executive Officer required under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				
32.2*#	Certification of Principal Financial Officer required under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				

97.1*	Amended and Restated Policy for Recoupment of Incentive Compensation
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2023 has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Shockwave Medical, Inc.

Date: February 26, 2024

By: /s/ Douglas Godshall
Douglas Godshall
President, Chief Executive Officer & Director

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Douglas Godshall and Renee Gaeta, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Douglas Godshall Douglas Godshall	President, Chief Executive Officer & Director (principal executive officer)	February 26, 2024
/s/ Renee Gaeta Renee Gaeta	Chief Financial Officer (principal financial officer)	February 26, 2024
/s/ Trinh Phung Trinh Phung	Senior Vice President of Finance (principal accounting officer)	February 26, 2024
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman & Director	February 26, 2024
/s/ Laura Francis Laura Francis	Director	February 26, 2024
/s/ Frederic Moll Frederic Moll, M.D.	Director	February 26, 2024
/s/ Antoine Papiernik Antoine Papiernik	Director	February 26, 2024
/s/ Maria Sainz Maria Sainz	Director	February 26, 2024
/s/ Sara Toyloy Sara Toyloy	Director	February 26, 2024
/s/ F.T Jay Watkins F.T. “Jay” Watkins	Director	February 26, 2024
/s/ Kevin Ballinger Kevin Ballinger	Director	February 26, 2024

Exhibit 10.10

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN

NOTICE OF PERFORMANCE-BASED RESTRICTED STOCK UNIT AWARD

Except as otherwise indicated, any capitalized term used but not defined in this Notice of Performance-Based Restricted Stock Unit Award (this "**Notice**") shall have the meaning ascribed to such term in the Shockwave Medical, Inc. 2019 Equity Incentive Plan (as it may be amended from time to time, the"**Plan**").

Name:

Address:

The undersigned Participant has been granted an Award of Performance-Based Restricted Stock Units (the "**Award**") under the Plan, subject to the terms and conditions of the Plan, this Notice and the attached Performance-Based Restricted Stock Unit Agreement, including any country-specific appendix attached hereto (the "**Agreement**").

Target Number of Performance-Based Restricted Stock Units ("Total Target PRSUs"):	
Date of Grant:	
Dividend Equivalents:	Not Included
Performance Conditions:	The actual number of Performance-Based Restricted Stock Units that may be earned will be between 0% and 200% of the Total Target PRSUs, based upon achievement of the performance conditions set forth in Annex A
Performance Measurement Period	With respect to 50% of the Total Target PRSUs, January 1, 20__ through December 31, 20__ (the "First Measurement Period") With respect to the remaining 50% of the of the Total Target PRSUs, January 1, 20__ through December 31, 20__ (the "Second Measurement Period", and together with the First Measurement Period, the "Measurement Periods")
Vesting Schedule:	The Award will vest in accordance with the schedule set forth in Annex A

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN

GLOBAL PERFORMANCE-BASED RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Plan, the Administrator of the Plan hereby grants to the Participant named in the Notice to which this Agreement is attached, an Award, subject to the terms of the Notice, this Agreement and the Plan, effective as of the Date of Grant set forth in the Notice (the "**Grant Date**"). Except as otherwise indicated, any capitalized term used but not defined in this Agreement shall have the meaning ascribed to such term in the Notice or the Plan.

1. Grant of Award. Each Award of Performance-Based Restricted Stock Units shall represent the unsecured right to receive one Share upon the vesting of such Performance-Based Restricted Stock Unit, subject to certain restrictions, as determined in accordance with and subject to the terms of this Agreement, the Plan and the Notice. The target number of Performance-Based Restricted Stock Units is set forth in the Notice.

2. Performance and Vesting Schedule. Subject to Section 1, the Award shall be eligible to become Earned PRSUs (as defined in Annex A) and vest pursuant to the terms and schedule set forth in Annex A.

3. Termination of Service. Unless otherwise provided in any employment, severance or similar contract with the Participant, in the event of Participant's Termination of Service for any reason, any Performance-Based Restricted Stock Units that have not become Earned PRSUs and vested as of the date of such Termination of Service will be forfeited and Participant will have no right to the forfeited Performance-Based Restricted Stock Units or the underlying Shares.

4. Change in Control. In the event of a "merger or Change in Control" (within the meaning of Section 15(c) of the Plan), the Performance-Based Restricted Stock Units will be treated in accordance with Section 15(c) of the Plan, subject to Section 2 of Annex A.

5. Voting Rights. Participant shall have no voting rights or any other rights as a shareholder of the Company with respect to the Performance-Based Restricted Stock Units unless and until Participant becomes the record owner of the Shares underlying the Performance-Based Restricted Stock Units.

6. Dividend Equivalents. If dividend equivalents are included in this Award, as determined by the Administrator and indicated in the Notice, and a cash dividend is declared on Shares during the period commencing on the Grant Date and ending on the date on which the Shares underlying the Performance-Based Restricted Stock Units are distributed to Participant pursuant to this Agreement, Participant shall be eligible to receive an amount in cash (a "**Dividend Equivalent**") equal to the dividend that Participant would have received had the Shares that are actually earned and issued pursuant to this Award been held by Participant as of the time at which such dividend was declared. Each Dividend Equivalent will be paid to Participant in cash as soon as reasonably practicable (and in no event later than 30 days) after the applicable vesting date of the corresponding Performance-Based Restricted Stock Units. For clarity, no Dividend Equivalent will be paid with respect to any Performance-Based Restricted Stock Units that are forfeited.

7. Distribution of Shares. Subject to the provisions of this Agreement, upon the vesting of any of the Performance-Based Restricted Stock Units, the Company shall deliver to Participant, as soon as reasonably practicable (and in no event later than 30 days) after the applicable vesting date, one Share for each vested Performance-Based Restricted Stock Unit. Upon the delivery of Shares pursuant to this Agreement, the Shares delivered shall be fully assignable, alienable, saleable and transferrable by

Participant; *provided* that any such assignment, alienation, sale, transfer or other alienation with respect to such Shares shall be in accordance with applicable securities laws and any applicable Company policy.

8. Responsibility for Taxes.

(a) Participant acknowledges that, regardless of any action taken by the Company or if different, Participant's employer (the "**Employer**"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items related to Participant's participation in the Plan and legally applicable to Participant ("**Tax-Related Items**") is and remains Participant's responsibility and may exceed the amount actually withheld by the Company or the Employer. Participant further acknowledges that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award, including, but not limited to, the grant, vesting or settlement of the Performance-Based Restricted Stock Units, the subsequent sale of Shares acquired pursuant to such settlement and the receipt of any dividends and/or any Dividend Equivalents; and (2) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate Participant's liability for Tax-Related Items or achieve any particular tax result. Further, if Participant is subject to Tax-Related Items in more than one jurisdiction, Participant acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, Participant agrees to make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items. In this regard, Participant authorizes the Company and/or the Employer, or their respective agents, at their discretion, to satisfy any applicable withholding obligations with regard to all Tax-Related Items by one or a combination of the following:

(1) withholding from Participant's wages or other cash compensation paid to Participant by the Company and/or the Employer; or

(2) withholding from proceeds of the sale of Shares acquired upon settlement of the Performance-Based Restricted Stock Units either through a voluntary sale or through a mandatory sale arranged by the Company (on Participant's behalf pursuant to this authorization without further consent); or

(3) withholding in Shares to be issued upon settlement of the Performance-Based Restricted Stock Units, provided, however, that if Participant is a Section 16 officer of the Company under the U.S. Securities and Exchange Act of 1934, as amended, then the Administrator (as constituted in accordance with Rule 16b-3 under the U.S. Securities and Exchange Act of 1934, as amended) shall establish the method of withholding from alternatives (a)-(c) herein and, if the Administrator does not exercise its discretion prior to the Tax-Related Items withholding event, then Participant shall be entitled to elect the method of withholding from the alternatives above in advance of any taxable or tax withholding event, as applicable, and in the absence of Participant's timely election, the Company will withhold in Shares upon the relevant taxable or tax withholding event, as applicable, or the Administrator (as constituted in accordance with Rule 16b-3 under the U.S. Securities and Exchange Act of 1934, as amended) may determine that a particular method be used to satisfy any obligations for Tax Related Items; or

(4) any other method of withholding determined by the Company and permitted by applicable law.

(c) Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates in the relevant Participant jurisdiction(s), in which case Participant will receive a refund of any over-withheld amount in cash and will have no entitlement to the Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax

purposes, Participant is deemed to have been issued the full number of Shares subject to the vested Performance-Based Restricted Stock Units, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items. The Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

9. Deferral of Compensation. Notwithstanding any provision of the Plan or the Agreement to the contrary, this Award is intended to be exempt from Code Section 409A; provided that the Company does not guarantee to Participant any particular tax treatment of the Performance-Based Restricted Stock Units. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on Participant by Code Section 409A or any damages for failing to comply with Code Section 409A. Notwithstanding anything in this Section 9 to the contrary, to avoid a prohibited acceleration under Code Section 409A, if Shares subject to Performance-Based Restricted Stock Units will be withheld (or sold on Participant's behalf) to satisfy any Tax Related Items arising prior to the date of settlement of the Performance-Based Restricted Stock Units for any portion of the Performance-Based Restricted Stock Units that is considered nonqualified deferred compensation subject to Code Section 409A, then the number of Shares withheld (or sold on Participant's behalf) shall not exceed the number of Shares that equals the liability for Tax-Related Items.

10. Nature of Grant. In accepting the Award, Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the Award is voluntary, exceptional and occasional and does not create any contractual or other right to receive future awards, or benefits in lieu of awards, even if awards have been granted in the past;

(c) all decisions with respect to future Award grants or other grants, if any, will be at the sole discretion of the Company;

(d) Participant is voluntarily participating in the Plan;

(e) the Performance-Based Restricted Stock Units and the Shares subject to the Performance-Based Restricted Stock Units are not intended to replace any pension rights or compensation;

(f) the Performance-Based Restricted Stock Units and the Shares subject to the Performance-Based Restricted Stock Units, and the income and value of same, are not part of normal or expected compensation or salary for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, holiday pay, pension or retirement or welfare benefits or similar mandatory payments;

(g) in the event that Participant is not an employee of the Company, the Award and Participant's participation in the Plan will not be interpreted to form an employment or service contract or relationship with the Company;

(h) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the Performance-Based Restricted Stock Units resulting from Participant's Termination of Service (for any reason whatsoever and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) and, in consideration of the grant of the Performance-Based Restricted Stock Units to which Participant is

otherwise not entitled, Participant irrevocably agrees never to institute any claim against the Company, the Employer, or any Subsidiary, waives his or her ability, if any, to bring any such claim, and releases the Company, the Employer, and any Subsidiary from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, Participant shall be deemed irrevocably to have agreed not to pursue such claim and agrees to execute any and all documents necessary to request dismissal or withdrawal of such claim;

(j) for purposes of the Performance-Based Restricted Stock Units, Participant's employment or service relationship will be considered terminated as of the date Participant is no longer actively providing services to the Company, the Employer or a Subsidiary (the "Termination Date") (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) and, unless otherwise expressly provided in the Agreement or determined by the Company, Participant's right to vest in the Performance-Based Restricted Stock Units under the Plan, if any, will terminate as of such date and will not be extended by any notice period (e.g., Participant's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any); the Administrator shall have the exclusive discretion to determine when Participant is no longer actively providing services for purposes of the Performance-Based Restricted Stock Units (including whether Participant may still be considered to be providing services while on a leave of absence); and

(k) neither the Company, the Employer, nor any Subsidiary shall be liable for any foreign exchange rate fluctuation between Participant's local currency and the United States Dollar that may affect the value of the Performance-Based Restricted Stock Units or of any amounts due to Participant pursuant to the settlement of the Performance-Based Restricted Stock Units or the subsequent sale of any Shares.

11. Data Privacy Information and Consent.

(a) Data Collection and Usage. The Company or the Employer may collect, process and use certain personal information about Participant, including, but not limited to, Participant's name, home address and telephone number, office address (including department and employing entity) and telephone number, e-mail address, date of birth, citizenship, country of residence at the time of grant, work location country, system employee ID, employee local ID, employment status (including international status code), supervisor (if applicable), job code, job title, salary, bonus target and bonuses paid (if applicable), termination date and reason, tax payer's identification number, tax equalization code, US Green Card holder status, contract type (single/dual/multi), social insurance number, passport or other identification number (e.g., resident registration number), nationality, any directorships held in the Company, any shares of stock held, details of all Performance-Based Restricted Stock Units or any other equity awards granted, canceled, forfeited, exercised, vested, unvested or outstanding with respect to Participant, estimated tax withholding rate, brokerage account number (if applicable), and brokerage fees ("Data"), for the purposes of implementing, administering and managing the Plan. The legal basis, where required, for the processing of Data is the Company's legitimate business interest of providing discretionary benefits under the Plan to Participant.

(b) Stock Plan Administration Service Providers. The Company may transfer Data to third parties, including E*Trade Corporate Financial Services, Inc. and E*Trade Securities LLC ("E*Trade"), who assists the Company with the implementation, administration and management of the Plan. The Company may select different service providers or additional service providers and share Data with such other provider serving in a similar manner. Participant may be asked to agree on separate terms and data processing practices with the service provider, with such agreement being a condition to the ability to participate in the Plan.

(c) International Data Transfers. The Company and its service providers are based in the United States. Participant's country or jurisdiction may have different data privacy laws and protections than the

United States. The Company's legal basis, where required, for the transfer of Data is the Company's legitimate business interest of providing discretionary benefits under the Plan to Participant.

(d) Data Retention. The Company will hold and use the Data only as long as is necessary to implement, administer and manage Participant's participation in the Plan, or as required to comply with legal or regulatory obligations, including under tax and securities laws.

(e) Voluntariness and Consequences of Consent Denial or Withdrawal. Participation in the Plan is voluntary and Participant is providing the accepting the Performance-Based Restricted Stock Units on a purely voluntary basis. The processing activity is pursuant to the Company's legitimate business interest of providing the benefits under the Plan to Participant. Participant may opt out of such processing, although this would mean that the Company could not grant Performance-Based Restricted Stock Units under the Plan to Participant. For questions about opting out, Participant should contact the Company's General Counsel, Haj Tada.

(f) Data Subject Rights. Participant may have a number of rights under data privacy laws in Participant's jurisdiction. Depending on where Participant is based, such rights may include the right to (i) request access or copies of Data the Company processes, (ii) rectification of incorrect Data, (iii) deletion of Data, (iv) restrictions on processing of Data, (v) portability of Data, (vi) lodge complaints with competent authorities in Participant's jurisdiction, and/or (vii) receive a list with the names and addresses of any potential recipients of Data. To receive clarification regarding these rights or to exercise these rights, Participant can contact the Company's General Counsel, Haj Tada.

(g) Electronic Acceptance. By accepting the Performance-Based Restricted Stock Units and indicating consent via the Company's acceptance procedure, Participant is declaring that Participant agrees with the data processing practices described herein and further consent to the collection, processing and use of Data by the Company and the transfer of Data to the recipients mentioned above, including recipients located in countries which do not adduce an adequate level of protection from a European (or other non-U.S.) data protection law perspective, for the purposes described above.

12. Electronic Delivery and Participation. The Company may, in its sole discretion, decide to deliver the Agreement, the Plan, account statements, Plan prospectuses and any documents related to current or future participation in the Plan by electronic means. Participant hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

13. Provisions of Plan Control. This Agreement is subject to all the terms, conditions and provisions of the Plan, including the amendment provisions thereof, and to such rules, regulations and interpretations relating to the Plan as may be adopted by the Administrator and as may be in effect from time to time. The Plan is incorporated herein by reference. If and to the extent that this Agreement conflicts or is inconsistent with the Plan, the Plan shall control, and this Agreement shall be deemed to be modified accordingly.

14. No Guarantee of Continued Service. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF THE AWARD PURSUANT TO THE VESTING SCHEDULE HEREOF IS EARNED ONLY BY CONTINUING AS A SERVICE PROVIDER AT THE WILL OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS AWARD OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) TO

TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER AT ANY TIME, WITH OR WITHOUT CAUSE.

15. Transferability. Except as may be permitted by the Administrator, neither the Award nor any right under the Award shall be sold, pledged, assigned, hypothecated, or otherwise transferred in any manner other than by will or by the laws of descent and distribution, and any attempt to sell, pledge, assign, hypothecate or otherwise transfer the Award or any right under the Award, other than as permitted by the Administrator, shall be void and of no effect. This provision shall not apply to any portion of the Award that has been fully settled, and shall not preclude forfeiture of any portion of the Award in accordance with the terms herein.

16. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant should consult with his or her own personal tax, legal and financial advisors regarding his or her participation in the Plan before taking any action related to the Plan.

17. Clawback or Recoupment. This Award shall be subject to any clawback or recoupment policies that the Company may have in place from time to time, including any such policy implemented to comply with Section 10D of the Exchange Act or any other applicable law or regulation, or implemented discretionarily by the Company. Any such clawback or recoupment policy may require the forfeiture or cancellation of all or any portion of this Award, or the repayment of any Shares (or the value thereof) previously distributed to the Participant in respect of this Award upon the occurrence of specified events.

18. Language. If Participant has received the Agreement, including a country-specific appendix thereto, or any other document related to the Award and/or the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

19. Insider Trading/Market Abuse Laws. Participant acknowledges that, depending on his or her country of residence, Participant may be subject to insider trading restrictions and/or market abuse laws, which may affect his or her ability to acquire or sell Shares or rights to Shares (e.g., the Award) under the Plan during such times as Participant is considered to have "inside information" regarding the Company (as defined by the laws in Participant's country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. Participant is solely responsible for ensuring his or her compliance with any applicable restrictions and is advised to consult his or her personal legal advisor on this matter.

20. Foreign Asset/Account Reporting Requirements. Participant acknowledges that there may be certain foreign asset and/or account reporting requirements which may affect his or her ability to acquire or hold Shares acquired under the Plan or cash received from participating in the Plan (including from any dividends paid on Shares acquired under the Plan) in a brokerage or bank account outside his or her country. Participant may be required to report such accounts, assets or transactions to the tax or other authorities in his or her country. Participant also may be required to repatriate sale proceeds or other funds received as a result of participating in the Plan to his or her country through a designated bank or broker within a certain time after receipt. Participant acknowledges that it is his or her responsibility to be compliant with such regulations, and he or she should speak to his or her personal advisor on this matter.

21. Lock-Up Agreement.

(a) Participant hereby agrees that Participant shall not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Stock (or other securities) of the Company or enter into any swap, hedging or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Common Stock (or other securities) of the Company held by Participant (other than those included in the registration) for a

period specified by the representative of the underwriters of Common Stock (or other securities) of the Company not to exceed one hundred and eighty (180) days following the effective date of any registration statement of the Company filed under the Securities Act (or such other period as may be requested by the Company or the underwriters to accommodate regulatory restrictions on (i) the publication or other distribution of research reports and (ii) analyst recommendations and opinions, including, but not limited to, the restrictions contained in NASD Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto).

(b) Participant agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or necessary to give further effect thereto. In addition, if requested by the Company or the representative of the underwriters of Common Stock (or other securities) of the Company, Participant shall provide, within ten (10) days of such request, such information as may be required by the Company or such representative in connection with the completion of any public offering of the Company's securities pursuant to a registration statement filed under the Securities Act. The obligations described in this Section 19 shall not apply to a registration relating solely to employee benefit plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a Securities Exchange Commission Rule 145 transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of said one hundred and eighty (180) day (or other) period. Participant agrees that any transferee of the Award shall be bound by this Section 20.

22. Severability. If any provision of this Agreement is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction, or would disqualify the Plan or this Agreement under any law deemed applicable by the Board, such provision shall be construed or deemed amended to conform to applicable laws, or if it cannot be so construed or deemed amended without, in the determination of the Board, materially altering the intent of this Agreement, such provision shall be stricken as to such jurisdiction, and the remainder of this Agreement shall remain in full force and effect.

23. Country-Specific Appendix. The Performance-Based Restricted Stock Units shall be subject to the additional terms and conditions set forth in the appendix attached hereto for Participant's country, if any. Moreover, if Participant relocates to one of the countries included in the appendix during the life of the Award, the terms and conditions for such country shall apply to Participant, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The appendix constitutes part of this Agreement.

24. Amendment; Waiver. No amendment or modification of any provision of this Agreement that has a material adverse effect on Participant shall be effective unless signed in writing by or on behalf of the Company and Participant; provided that the Company may amend or modify this Agreement without Participant's consent in accordance with the provisions of the Plan or as otherwise set forth in this Agreement. No waiver of any breach or condition of this Agreement shall be deemed to be a waiver of any other or subsequent breach or condition, whether of like or different nature. Any amendment or modification of or to any provision of this Agreement, or any waiver of any provision of this Agreement, shall be effective only in the specific instance and for the specific purpose for which such amendment, modification or waiver is made or given.

25. Assignment. Neither this Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assignable by Participant.

26. Successors and Assigns; No Third-Party Beneficiaries. This Agreement shall inure to the benefit of and be binding upon the Company and Participant and their respective heirs, successors, legal representatives, and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the Company and Participant, and their respective heirs, successors, legal representatives and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

27. Dispute Resolution. All controversies and claims arising out of or relating to this Agreement, or the breach hereof, shall be settled by the Company's or Participant's Employer's mandatory dispute resolution procedures, if any, as may be in effect from time to time.

28. Governing Law; Venue. The Award as well as the terms and conditions set forth in the Plan and/or matters arising out of or relating to this Agreement and the transactions contemplated hereby, including its validity, interpretation, construction, performance and enforcement, shall be governed by and construed in accordance with the internal laws of the State of California, without giving effect to its principles of conflict of laws. For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to the sole and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts.

29. Waiver. Participant acknowledges that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by me or any other Participant.

30. Entire Agreement. This Agreement, the Plan, the Notice and any other agreements, schedules, exhibits and other documents referred to herein or therein constitute the entire agreement and understanding between the parties in respect of the subject matter hereof and supersede all prior and contemporaneous arrangements, undertakings, agreements and understandings, both oral and written, whether in term sheets, presentations or otherwise, between the parties with respect to the subject matter hereof.

31. Imposition of Other Requirements. The Company reserves the right to impose other requirements on Participant's participation in the Plan, on the Award and on any Shares to be issued upon settlement of the Award, to the extent the Company determines it is necessary or advisable for legal or administrative reasons. Participant agrees to take whatever additional action and execute whatever additional documents the Company may deem necessary or advisable to accomplish the foregoing or to carry out or give effect to any of the obligations or restrictions imposed on either Participant or the Award pursuant to this Agreement.

[Signature Page Follows]

Participant Acknowledgment. Participant acknowledges receipt of a copy of the Plan and represents that Participant is familiar with the terms and provisions thereof, and hereby accepts the Award subject to all of the terms and provisions of the Notice, this Agreement and the Plan. Participant has reviewed the Notice, this Agreement and the Plan in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands all provisions of the Plan, the Notice and this Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Notice, this Agreement or the Plan. Participant further agrees to notify the Company upon any change in the residence address indicated below.

PARTICIPANT

Signature

Print Name

Residence Address

Email Address

SHOCKWAVE MEDICAL, INC.

By:

Name:

Title:

ANNEX A

Performance Goals and Vesting Schedule

The Performance-Based Restricted Stock Units ("**PRSUs**") shall be eligible to be earned in two tranches, based on the Company's achievement of the CAGR (as defined herein) performance goal set forth in this Annex A (the "**Performance Goal**") for the applicable Measurement Period as follows:

	Target Number of PRSUs	Relevant Dates of Measurement
First Measurement Period	50% of Total Target PRSUs	January 1, 20__ through December 31, 20__
Second Measurement Period	50% of Total Target PRSUs	January 1, 20__ through December 31, 20__

Earned PRSUs. The number of PRSUs that will be earned and become "**Earned PRSUs**" will be based on the Company's CAGR (as defined herein) over the First Measurement Period and the Second Measurement Period, as set forth in the table below. "**CAGR**" means the compound annual growth rate of revenue, which will be the percentage increase in the annual growth rate of revenue as determined by the Committee during the relevant Measurement Period. The number of Earned PRSUs for each Measurement Period shall be determined in accordance with the following formula:

Target Number of PRSUs for Applicable Measurement Period	x	Achievement Percentage	=	Number of Earned PRSUs for Applicable Measurement Period

The "**Achievement Percentage**" means a percentage between 0% and 200% that will be determined based on the level of performance attained for each Measurement Period against the Performance Goals set forth below.

	Performance Goal		
	Threshold Performance (Achievement Percentage is 50%)	**Target Performance (Achievement Percentage is 100%)**	**Maximum Performance (Achievement Percentage is 200%)**
First Measurement Period	___% CAGR	___% CAGR	___% CAGR
Second Measurement Period	___% CAGR	___% CAGR	___% CAGR

If the achieved CAGR for a Measurement Period is less than the Threshold Performance amount, then the Achievement Percentage shall be zero for that Measurement Period; if the achieved CAGR for a Measurement Period is equal to the Threshold Performance amount, then the Achievement Percentage shall be 50% for that Measurement Period; if the achieved CAGR for a Measurement Period is equal to the Target Performance amount, then the Achievement Percentage shall be 100% for that Measurement Period; and if the achieved CAGR for a Measurement Period is equal to or greater than the Maximum Performance amount, then the Achievement Percentage shall be 200% for that Measurement Period. Notwithstanding the foregoing, there will be linear interpolation (rounded to two decimal places) to derive

the Achievement Percentage for any achieved CAGR that is between the Threshold Performance level and the Target Performance level, or between the Target Performance level and the Maximum Performance level. Any fractional Shares resulting from the application of the Achievement Percentage will be rounded down to the nearest whole Share. In the event that the Threshold Performance level (as indicated in the table below) for any Measurement Period is not achieved, the number of Earned PRSUs for that Measurement Period will be zero.

Determination Date and Vesting; Change in Control. As soon as practicable after the end of each Measurement Period (but no later than February 25, 20__ for the First Measurement Period and February 25, 20__ for the Second Measurement Period), the Administrator shall determine the Company's CAGR for the applicable Measurement Period, the resulting Achievement Percentage for the applicable Measurement Period and the number of PRSUs that are earned and become PRSUs for the applicable Measurement Period (the date of the Administrator's determination (except as otherwise set forth in this Section 2), the "**Determination Date**"). The Earned PRSUs for the relevant Measurement Period shall vest on the corresponding Determination Date, subject to the Participant's continued employment through such Determination Date.

Notwithstanding the foregoing, in the event of a "merger or Change in Control" (within the meaning of Section 15(c) of the Plan):

(i) if such merger or Change in Control occurs before a Measurement Period has been completed:

(A) the number of PRSUs that become Earned PRSUs for such Measurement Period shall be based on an Achievement Percentage equal to the greater of (x) 100% or (y) a percentage determined by the Administrator reflecting the Company's actual performance through the date of the Change in Control;

(B) notwithstanding such determination of the Achievement Percentage and the number of PRSUs that become Earned PRSUs for such Measurement Period, (1) if such Measurement Period is the First Measurement Period, the Determination Date for such Measurement Period shall be deemed to occur on February 25, 20__; and (2) if such Measurement Period is the Second Measurement Period, the Determination Date for such Measurement Period shall be deemed to occur on February 25, 20__; and

(C) the Earned PSUs for such Measurement Period shall vest on the corresponding Determination Date, subject to the Participant's continued employment through such Determination Date; and

(ii) if such merger of Change in Control occurs after a Measurement Period has been completed but before the Determination Date for such Measurement Period:

(A) the Administrator shall determine the Company's CAGR for the applicable Measurement Period, the resulting Achievement Percentage for the applicable Measurement Period and the number of PRSUs that are earned and become Earned PRSUs for the applicable Measurement Period prior to the consummation of such merger or Change in Control;

(B) the Determination Date for such Measurement Period shall be deemed to occur on the date of such merger or Change in Control; and

(C) the Earned PRSUs for such Measurement Period shall vest on the date of such merger of Change in Control, subject to the Participant's continued employment through such merger of Change in Control.

Any target PRSUs from a Measurement Period that do not become Earned PRSUs on the Determination Date applicable to such Measurement Period shall be immediately forfeited.

Continued Employment. Unless otherwise provided in any employment, severance or similar contract with the Participant, to the extent that the Participant experiences a Termination of Service before any Determination Date, any PRSUs that have not yet become Earned PRSUs shall immediately be forfeited.

Adjustments; Discretion. The Performance Goals may be adjusted by the Committee to exclude the impact, if any, of a disposition of any of the Company's business units or assets (or disposed part thereof) during the Measurement Period or acquisition of any business or assets during the Measurement Period. In the event of a disposition or an acquisition of the type described in the immediately preceding sentence, adjustments to the Performance Goals shall be made as reasonably determined by the Committee. The Committee shall have sole and exclusive authority and discretion to make all determinations and resolve all ambiguities, questions and disputes relating to the calculation of the Performance Goals and the level of earning and vesting of the PRSUs. With respect to the determination of CAGR, the Committee may, in its discretion, modify or adjust such performance objectives or related level of achievement in accordance with the terms of the Plan.

Exhibit 10.16

SHOCKWAVE MEDICAL, INC.

CONSULTING AGREEMENT

This Consulting Agreement (this "***Agreement***") is made and entered into as of the date of the last signature below to be effective on and after February 5, 2024 (the "***Effective Date***"), between Shockwave Medical, Inc., a Delaware corporation with its principal place of business at 5403 Betsy Ross Dr., Santa Clara, CA 95054 (the "***Company***"), and **Daniel Puckett,** an individual, with a business or other address set forth on the signature page hereto ("***Consultant***"). Consultant and Company are referred to herein from time to time individually as a "***Party***," or collectively as the "***Parties***").

The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the Parties agree as follows:

1. Services and Compensation.

A. Services and Compensation. Consultant shall perform the services described in Exhibit A (the "***Services***") for the Company (or its designee), and the Company agrees to pay Consultant the compensation described in Exhibit A for Consultant's performance of the Services.

B. Prior Equity Grants. The Parties acknowledge that Consultant was previously an employee of Company and in such capacity was granted various equity awards under the Company's equity incentive plans in respect of the common stock of the Company. The continued vesting of such equity awards will be considered a portion of the compensation payable for the Services in addition to the cash compensation described in, and as otherwise set forth in, Exhibit A.

C. Annual Performance Bonus. Consultant shall receive the annual performance bonus Consultant would have received for calendar 2023 had Consultant been an employee of the Company on the payment date of such performance bonus (the "**Bonus**"). The Bonus will be paid in accordance the Company's normal timeframes for annual employee performance bonuses. No bonus amounts will be payable for periods during which Consultant was an employee of Company (or otherwise) on and after January 1, 2024.

2. Confidentiality.

A. Definition of Confidential Information. "***Confidential Information***" means any non-public information that relates to the actual or anticipated business and/or products, research or development of the Company, its affiliates or subsidiaries, or to the Company's, its affiliates' or subsidiaries' technical data, trade secrets, or know-how, including, but not limited to, research, product plans, or other information regarding the Company's, its affiliates' or subsidiaries' products or services and markets therefor, customer lists and customers (including, but not limited to, customers of the Company on whom Consultant called or with whom Consultant became acquainted during the term of this Agreement), software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finances, and other business information disclosed by the Company, its affiliates or subsidiaries, either directly or indirectly, in writing, orally or by drawings or inspection of premises, parts, equipment, or other property of Company, its affiliates, or subsidiaries. Notwithstanding the foregoing, Confidential Information shall not include any such information which Consultant can establish: (i) was publicly known or made generally available prior to the time of disclosure to Consultant; (ii) becomes publicly known or made generally available after disclosure to Consultant through no wrongful action or inaction of Consultant; or (iii) is in the rightful possession of Consultant, without confidentiality obligations, at the time of disclosure as shown by Consultant's then-contemporaneous written records.

B. Nonuse and Nondisclosure. During and after the term of this Agreement, Consultant will hold in the strictest confidence, and take all reasonable precautions to prevent any unauthorized use or disclosure of Confidential Information, and Consultant will not (i) use the Confidential Information for any purpose whatsoever

other than as necessary for the performance of the Services on behalf of the Company, or (ii) disclose the Confidential Information to any third party without the prior written consent of an authorized representative of Company. Consultant may disclose Confidential Information to the extent compelled by applicable law; *provided however*, prior to such disclosure, Consultant shall provide prior written notice to Company and seek a protective order or such similar confidential protection as may be available under applicable law. Consultant agrees that no ownership of Confidential Information is conveyed to the Consultant. Without limiting the foregoing, Consultant shall not use or disclose any Company property, intellectual property rights, trade secrets or other proprietary know-how of the Company to invent, author, make, develop, design, or otherwise enable others to invent, author, make, develop, or design identical or substantially similar designs as those developed under this Agreement for any third party. Consultant agrees that Consultant's obligations under this Section 2.B shall continue after the termination of this Agreement.

C. Other Client Confidential Information. Consultant agrees that Consultant will not improperly use, disclose, or induce the Company to use any proprietary information or trade secrets of any former or concurrent employer of Consultant or other person or entity with which Consultant has an obligation to keep in confidence. Consultant also agrees that Consultant will not bring onto the Company's premises or transfer onto the Company's technology systems any unpublished document, proprietary information, or trade secrets belonging to any third party unless disclosure to, and use by, the Company has been consented to in writing by such third party.

D. Third Party Confidential Information. Consultant recognizes that the Company has received and, in the future, will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that at all times during the term of this Agreement and thereafter, Consultant owes the Company and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to use it or to disclose it to any person, firm, corporation, or other third party except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

3. Ownership

A. Assignment of Inventions. Consultant agrees that all right, title, and interest in and to any copyrightable material, notes, records, drawings, designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, authored, invented, developed, or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement and arising out of, or in connection with, performing the Services under this Agreement and any copyrights, patents, trade secrets, mask work rights, or other intellectual property rights relating to the foregoing (collectively, "***Inventions***"), are the sole property of the Company. Consultant also agrees to promptly make full written disclosure to the Company of any Inventions and to deliver and assign (or cause to be assigned) and hereby irrevocably assigns fully to the Company all right, title, and interest in and to the Inventions.

B. Pre-Existing Materials. Subject to Section 3.A, Consultant agrees that if, in the course of performing the Services, Consultant incorporates into any Invention or utilizes in the performance of the Services any pre-existing invention, discovery, original works of authorship, development, improvements, trade secret, concept, or other proprietary information or intellectual property right owned by Consultant or in which Consultant has an interest ("***Prior Inventions***"), (i) Consultant will provide the Company with prior written notice and (ii) the Company is hereby granted a nonexclusive, royalty-free, perpetual, irrevocable, transferable, worldwide license (with the right to grant and authorize sublicenses) to make, have made, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. Consultant will not incorporate any invention, improvement, development, concept, discovery, work of authorship, or other proprietary information owned by any third party into any Invention without Company's prior written permission.

C. Moral Rights. Any assignment to the Company of Inventions includes all rights of attribution, paternity, integrity, modification, disclosure, and withdrawal, and any other rights throughout the world that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively, "***Moral Rights***"). To the extent that Moral Rights cannot be assigned under applicable law, Consultant hereby waives and agrees not

to enforce any and all Moral Rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law.

D. Maintenance of Records. Consultant agrees to keep and maintain adequate, current, accurate, and authentic written records of all Inventions made by Consultant (solely or jointly with others) during the term of this Agreement, and for a period of three (3) years thereafter. The records will be in the form of notes, sketches, drawings, electronic files, reports, or any other format that is customary in the industry and/or otherwise specified by the Company. Such records are and remain the sole property of the Company at all times and upon Company's request, Consultant shall deliver (or cause to be delivered) the same.

E. Further Assurances. Consultant agrees to assist Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments, and all other instruments that the Company may deem necessary in order to apply for, register, obtain, maintain, defend, and enforce such rights, and in order to deliver, assign, and convey to the Company, its successors, assigns, and nominees the sole and exclusive right, title, and interest in and to all Inventions and testifying in a suit or other proceeding relating to such Inventions. Consultant further agrees that Consultant's obligations under this Section 3.E shall continue after the termination of this Agreement.

F. Attorney-in-Fact. Consultant agrees that, if the Company is unable because of Consultant's unavailability, dissolution, mental, or physical incapacity, or for any other reason, to secure Consultant's signature with respect to any Inventions, including, without limitation, for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in Section 3.A, then Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any papers and oaths and to do all other lawfully permitted acts with respect to such Inventions to further the prosecution and issuance of patents, copyright, and mask work registrations with the same legal force and effect as if executed by Consultant. This power of attorney shall be deemed coupled with an interest, and shall be irrevocable.

4. Conflicting Obligations; Subcontracting.

A. No Conflicting Obligations. Consultant represents and warrants that Consultant has no agreements, relationships, or commitments to any other person or entity that conflict with the provisions of this Agreement, Consultant's obligations to the Company under this Agreement, and/or Consultant's ability to perform the Services. Consultant will not enter into any such conflicting agreement during the term of this Agreement.

B. Subcontracting. Consultant shall have no right to subcontract the performance of any Services.

5. Return of Company Materials. Upon the termination or expiration of this Agreement, or upon Company's earlier request, Consultant will immediately deliver to the Company, and will not keep in Consultant's possession, recreate, or deliver to anyone else, any and all Company property, including, but not limited to, Confidential Information, tangible embodiments of the Inventions, all devices and equipment belonging to the Company, all electronically-stored information and passwords to access such property, those records maintained pursuant to Section 3.D and any reproductions of any of the foregoing items that Consultant may have in Consultant's possession or control.

6. Reports. Consultant agrees that Consultant will keep the Company advised as to Consultant's progress in performing the Services under this Agreement. Consultant further agrees that Consultant will, as requested by the Company, prepare written reports with respect to such progress. The Company and Consultant agree that the reasonable time expended in preparing such written reports will be considered time devoted to the performance of the Services.

7. Term and Termination

A. Term. The term of this Agreement will begin on the Effective Date of this Agreement and will continue until the earlier of: (i) February 4, 2025; or (ii) termination as provided in Section 7.B.

B. Termination.

(1) Either Party may terminate this Agreement upon giving the other Party not fewer than thirty (30) days' prior written notice of such termination pursuant to Section 13.G of this Agreement.

C. Survival. Upon any termination, all rights and duties of the Company and Consultant toward each other shall cease except:

(1) The Company will pay, within thirty (30) days after the effective date of termination, all amounts owing to Consultant for Services completed and accepted by the Company prior to the termination date and related reimbursable expenses, if any, submitted in accordance with the Company's policies and in accordance with the provisions of Article 1 of this Agreement; and

(2) Article 2 (Confidentiality), Article 3 (Ownership), Article 5 (Return of Company Materials), Article 7 (Term and Termination), Article 8 (Independent Contractor; Benefits), Article 9 (Indemnification), Article 10 (Noninterference), Article 11 (Limitation of Liability), Article 12 (Arbitration and Equitable Relief), and Article 13 (Miscellaneous) will survive termination or expiration of this Agreement in accordance with their terms.

8. Independent Contractor; Benefits.

A. Independent Contractor. It is the express intention of the Company and Consultant that Consultant perform the Services as an independent contractor to the Company. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the Company. Without limiting the generality of the foregoing, Consultant is not authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and shall incur all expenses associated with performance, except as expressly provided in Exhibit A. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement. Consultant agrees to and acknowledges the obligation to pay all self-employment and other taxes on such income.

B. ***Benefits.*** The Company and Consultant agree that Consultant will receive no Company-sponsored benefits from the Company where benefits include, but are not limited to, paid vacation, sick leave, medical insurance and 401k participation. If Consultant is reclassified by a state or federal agency or court as the Company's employee, Consultant will become a reclassified employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the Company's benefit plans or programs of the Company in effect at the time of such reclassification, Consultant would otherwise be eligible for such benefits.

9. Indemnification. Consultant agrees to indemnify and hold harmless the Company and its affiliates and their directors, officers and employees from and against all taxes, losses, damages, liabilities, costs, and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with (i) any negligent, reckless, or intentionally wrongful act of Consultant or Consultant's assistants, employees, contractors, or agents, (ii) a determination by a court or agency that the Consultant is not an independent contractor, (iii) any breach by the Consultant or Consultant's assistants, employees, contractors, or agents of any of the covenants contained in this Agreement and corresponding Confidential Information and Invention Assignment Agreement, (iv) any failure of Consultant to perform the Services in accordance with all applicable laws, rules, and regulations, or (v) any violation or claimed violation of a third party's rights resulting in whole or in part from the Company's use of the Inventions or other deliverables of Consultant under this Agreement.

10. Non-solicitation. To the fullest extent permitted under applicable law, from the date of this Agreement until twelve (12) months after the termination of this Agreement for any reason (the "***Restricted Period***"), Consultant will not, without the Company's prior written consent, directly or indirectly, solicit any of the Company's employees to leave their employment, or attempt to solicit employees of the Company, either for Consultant or for any other person or entity. Consultant agrees that nothing in this Article 10 shall affect Consultant's continuing obligations

under this Agreement during and after this twelve (12)-month period, including, without limitation, Consultant's obligations under Article 2.

11. Limitation of Liability

IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOST PROFITS OR LOSS OF BUSINESS, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHER THEORY OF LIABILITY, REGARDLESS OF WHETHER COMPANY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. IN NO EVENT SHALL COMPANY'S LIABILITY ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CONSULTANT UNDER THIS AGREEMENT FOR THE SERVICES, DELIVERABLES OR INVENTION GIVING RISE TO SUCH LIABILITY.

12. Arbitration and Equitable Relief

A. Arbitration. IN CONSIDERATION OF CONSULTANT'S CONSULTING RELATIONSHIP WITH COMPANY, CONSULTANT' PROMISE TO ARBITRATE ALL DISPUTES RELATED TO CONSULTANT'S CONSULTING RELATIONSHIP WITH THE COMPANY AND CONSULTANT'S RECEIPT OF THE COMPENSATION AND OTHER BENEFITS PAID TO CONSULTANT BY COMPANY, AT PRESENT AND IN THE FUTURE, CONSULTANT AGREES THAT ANY AND ALL CONTROVERSIES, CLAIMS, OR DISPUTES WITH ANYONE (INCLUDING COMPANY AND ANY EMPLOYEE, OFFICER, DIRECTORS, SHAREHOLDER, OR BENEFIT PLAN OF THE COMPANY IN THEIR CAPACITY AS SUCH OR OTHERWISE), WHETHER BROUGHT ON AN INDIVIDUAL, GROUP, OR CLASS BASIS, ARISING OUT OF, RELATING TO, OR RESULTING FROM CONSULTANT'S CONSULTING RELATIONSHIP WITH THE COMPANY OR THE TERMINATION OF CONSULTANT'S CONSULTING RELATIONSHIP WITH THE COMPANY, INCLUDING ANY BREACH OF THIS AGREEMENT, SHALL BE SUBJECT TO BINDING ARBITRATION UNDER THE ARBITRATION RULES SET FORTH IN CALIFORNIA CODE OF CIVIL PROCEDURES SECTION 1280 THROUGH 1294.2, INCLUDING SECTION 1281.8 (THE "***ACT***") AND PURSUANT TO CALIFORNIA LAW. THE FEDERAL ARBITRATION ACT SHALL CONTINUE TO APPLY WITH FULL FORCE AND EFFECT NOTWITHSTANDING THE APPLICATION OF PROCEDURAL RULES SET FORTH IN THE ACT. **DISPUTES WHICH CONSULTANT AGREES TO ARBITRATE, AND THEREBY AGREES TO WAIVE ANY RIGHT TO A TRIAL BY JURY, INCLUDE ANY STATUTORY CLAIMS UNDER LOCAL, STATE, OR FEDERAL LAW, INCLUDING, BUT NOT LIMITED TO, CLAIMS UNDER TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, THE AMERICANS WITH DISABILITIES ACT OF 1990, THE AGE DISCRIMINATION IN EMPLOYMENT ACT OF 1967, THE OLDER WORKERS BENEFIT PROTECTION ACT, THE SARBANES-OXLEY ACT, THE WORKER ADJUSTMENT AND RETRAINING NOTIFICATION ACT, THE California Fair Employment and Housing Act, the FAMILY AND MEDICAL LEAVE ACT, THE CALIFORNIA FAMILY RIGHTS ACT, THE California Labor Code, claims of harassment, discrimination AND wrongful termination and any statutory OR COMMON LAW claims.** Consultant further understands that this Agreement to arbitrate also applies to any disputes that the Company may have with Consultant.

B. Procedure. Consultant agrees that any arbitration will be administered by Judicial Arbitration & Mediation Services, Inc. ("***JAMS***") pursuant to its EMPLOYMENT Arbitration Rules & Procedures (the "***JAMS Rules***"). Consultant agrees that the arbitrator shall have the power to decide any motions brought by any party to the arbitration, including motions for summary judgment and/or adjudication and motions to dismiss and demurrers, prior to any arbitration hearing. Consultant agrees that the arbitrator shall issue a written decision on the merits. CONSULTANT ALSO AGREES THAT THE ARBITRATOR SHALL HAVE THE POWER TO AWARD ANY REMEDIES AVAILABLE UNDER APPLICABLE LAW, AND THAT THE ARBITRATOR SHALL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. CONSULTANT AGREES that the decree or award rendered by the arbitrator may be entered as a final and binding judgment in any court having jurisdiction thereof. Consultant agrees that the arbitrator shall administer and conduct any arbitration in ACCORDANCE with CALIFORNIA LAW, including the California Code of Civil Procedure,

and that the arbitrator shall apply substantive and procedural California law to any dispute or claim, without reference to rules of conflict of law. To the extent that the JAMS Rules conflict with California law, California law shall take precedence. Consultant further agrees that any arbitration under this agreement shall be conducted in SANTA CLARA County, CALIFORNIA.

C. Remedy. Except as provided by the ACT AND THIS AGREEMENT, arbitration shall be the sole, exclusive, and final remedy for any dispute between Consultant and the Company. Accordingly, except as provided for by the ACT AND this agreement, neither Consultant nor the Company will be permitted to pursue court action regarding claims that are subject to arbitration.

D. Availability of Injunctive Relief. In accordance with Rule 1281.8 of the California Code of Civil Procedure, the Parties agree that any party may also petition the court for injunctive relief where either party alleges or claims a violation of any agreement regarding INTELLECTUAL PROPERTY, confidential information OR NONINTERFERENCE. In the event either party seeks injunctive relief, the prevailing party shall be entitled to recover reasonable costs and attorneys' fees.

E. Administrative Relief. Consultant understands that this Agreement does not prohibit Consultant from pursuing an administrative claim with a local, state, or federal administrative body OR GOVERNMENT AGENCY such as the Department of Fair Employment and Housing, the Equal Employment Opportunity Commission, the National Labor Relations Board, or the workers' compensation board. This Agreement does, however, preclude Consultant from pursuing court action regarding any such claim, except as permitted by law.

F. Voluntary Nature of Agreement. Consultant acknowledges and agrees that CONSULTANT is executing this Agreement voluntarily and without any duress or undue influence by the Company or anyone else. Consultant further acknowledges and agrees that CONSULTANT has carefully read this Agreement and that Consultant has asked any questions needed for Consultant to understand the terms, consequences and binding effect of this Agreement and fully understand it, including that ***Consultant is waiving CONSULTANT'S right to a jury trial***. Finally, Consultant agrees that CONSULTANT has been provided an opportunity to seek the advice of an attorney of Consultant's choice before signing this Agreement.

13. Miscellaneous

A. Governing Law; Consent to Personal Jurisdiction. This Agreement shall be governed by the laws of the State of California, without regard to the conflicts-of-law provisions of any jurisdiction. To the extent that any lawsuit is permitted under this Agreement, the Parties hereby expressly consent to the personal and exclusive jurisdiction and venue of the state and federal courts located in California.

B. ***Assignability.*** This Agreement will be binding upon Consultant's heirs, executors, assigns, administrators, and other legal representatives, and will be for the benefit of the Company, its successors, and its assigns. There are no intended third-party beneficiaries to this Agreement, except as expressly stated. Except as may otherwise be provided in this Agreement, Consultant may not sell, assign, or delegate any rights or obligations under this Agreement. Notwithstanding anything to the contrary herein, Company may assign this Agreement and its rights and obligations under this Agreement, without consent, to any successor to all or substantially all of Company's relevant assets, whether by merger, consolidation, reorganization, reincorporation, sale of assets or stock, or otherwise.

C. ***Entire Agreement.*** This Agreement, together with its Exhibits, constitutes the entire agreement and understanding between the Parties with respect to the subject matter herein and supersedes all prior written and oral agreements, discussions, or representations between the Parties with respect to such subject matter. Consultant represents and warrants that Consultant is not relying on any statement or representation not contained in this Agreement. To the extent any terms set forth in any exhibit or schedule conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise expressly agreed by the Parties in such exhibit or schedule.

D. Headings. Headings are used in this Agreement for reference only and shall not be considered when interpreting this Agreement.

E. Severability. If a court or other body of competent jurisdiction finds, or the Parties mutually believe, any provision of this Agreement, or portion thereof, to be invalid or unenforceable, such provision will be enforced to the maximum extent permissible so as to effect the intent of the Parties, and the remainder of this Agreement will continue in full force and effect.

F. Modification, Waiver. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in a writing signed by the Parties. Waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

G. Notices. Any notice or other communication required or permitted by this Agreement to be given to a Party shall be in writing and shall be deemed given (i) if delivered personally or by commercial messenger or courier service, (ii) when sent by confirmed facsimile, or (iii) if mailed by U.S. registered or certified mail (return receipt requested), to the Party at the Party's address written below or at such other address as the Party may have previously specified by like notice. If by mail, delivery shall be deemed effective three business days after mailing in accordance with this Section 13.G.

(1) If to the Company, to:
Shockwave Medical, Inc.
5403 Betsy Ross Dr.
Santa Clara, CA 95054
Attention: General Counsel
Email: legal@shockwavemedical.com

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company.

H. Attorneys' Fees. In any court action at law or equity that is brought by one of the Parties to this Agreement to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable attorneys' fees, in addition to any other relief to which that Party may be entitled.

I. Signatures. This Agreement may be signed in two counterparts, each of which shall be deemed an original, with the same force and effectiveness as though executed in a single document.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Consulting Agreement to be effective on and after the Effective Date.

DANIEL PUCKETT **SHOCKWAVE MEDICAL, INC.**

By: /s/ Dan Puckett By: /s/ Douglas Godshall

Name: Daniel Puckett Name: Douglas Godshall

Date: 01/29/24 | 08:01 CST Title: Chief Executive Officer
Date: 01/29/24 | 07:40 CST

Address for Notice:

[private address]

Email: [private email address]

EXHIBIT A

SERVICES AND COMPENSATION

1. **Contact.** Consultant's principal Company contact: Doug Godshall (Email: dgodshall@shockwavemedical.com).

2. **Services**.

A. Description of Services. The Services will include, but will not be limited to, the following: (a) providing advice and support to the Company's new Company Chief Financial Officer; (b) providing general advice regarding the Company's financial structure and planning, historical financial issues, and audit planning and structure; (c) supporting business development diligence and planning as requested by the Company's business development team; and (d) such other activities related or ancillary to the foregoing as requested by the Company from time to time.

B. Services As Needed. Consultant will provide these Services on an as-needed basis, to be mutually agreed upon by Consultant and Company.

3. **Compensation.**

A. Compensation. For Consultant's performance of the Services, Consultant shall be paid a flat monthly fee (with each month being measured from the fifth day of a month through the fourth day of the following month) (1) in the amount of 20,000.00 per month during the period of February 5, 2024 through and including October 4, 2024; and (2) in the amount of 10,000.00 per month during the period from October 5, 2024 through and including February 4, 2025.

B. Invoicing; Payment. Consultant shall present an invoice to Company each month for Services performed and expenses (see Section 3.C). Payment shall be due in full within thirty (30) days from receipt of the invoice. All payments shall be made by direct deposit into Consultant's banking account; provided that Consultant provides the necessary information and permissions for direct deposit. Any invoices not previously submitted under the terms of this Agreement can be "caught up" during the term according to the terms stated herein.

C. Expenses. The Company will reimburse Consultant, in accordance with Company policy, for all reasonable expenses incurred by Consultant in performing the Services pursuant to this Agreement, if Consultant receives written consent from an authorized agent of the Company prior to incurring such expenses and submits receipts for such expenses to the Company in accordance with Company policy. Company must approve in advance in writing any travel and associated out-of-pocket expenses to be incurred by Consultant in connection with the performance of the Services.

D. Pre-Approval. Services and expenses shall be subject to the approval of the contact person listed above or other designated agent of the Company.

Exhibit 10.17

January 16, 2024

Renee Gaeta
[private address]

VIA EMAIL
[private email address]

Dear Renee,

This offer supersedes all previous offers of employment.

On behalf of Shockwave Medical, Inc. (the "Company"), I am pleased to offer you an exempt position of Chief Financial Officer, beginning on February 5, 2024, subject to your appointment by the Company's board of directors. You will receive an annual salary of $500,000.00 which will be paid bi-weekly in accordance with our normal payroll schedule. This position is exempt under California law, which means your annual compensation is intended to compensate you for all hours worked.

In addition to your base salary, you will also be entitled to participate in the Company's Annual Bonus Plan (the "Bonus Plan"). Your target bonus under this plan is 60% of your base salary for the applicable bonus period and subject to the terms and conditions of the Bonus Plan. The Company reserves the right to modify or terminate (with or without replacement) any bonus scheme in place at the time.

Should you accept this offer and become an employee of the Company, it will be recommended to the administrator of the Company's 2019 Equity Incentive Plan (the "Plan") that you are granted an award of restricted stock units (RSUs) with a grant date value of $4,500,000.00. The number of shares will be determined at the time of the grant using the average closing price of the 10 trading days prior to grant. The New Hire RSUs shall vest into shares of the Company's common stock. The RSUs will be granted under and subject to the terms and conditions of the Plan and the applicable Global RSU Award Agreement (the "RSU Agreement"). Twenty-five percent (25%) of the RSUs shall vest on the one (1) year anniversary of the vesting commencement date, with the remaining seventy-five percent (75%) vesting quarterly over the following thirty-six (36) months, subject to your continued employment with the Company through each such date. The vesting commencement date shall be February 5, 2024.

A copy of the Plan and RSU Agreement will be provided to you as soon as practicable after the grant date. In order to receive your grant, you will be required to accept and return the RSU Agreement provided to you by the Company in connection with this grant. Additionally, you will also be required to sign any other agreements or documents provided by the Company that may be required under applicable laws to receive RSUs and any shares under the Plan.

We are also pleased to offer you a one-time relocation bonus in the amount of $250,000.00, less applicable taxes and withholdings, to help cover your moving expenses associated with your move. This bonus will be paid within thirty (30) days of confirmation of your relocation to within fifty (50) miles of our Santa Clara location. If you voluntarily terminate employment with the Company for any reason, other than a Good Reason termination (as defined in the form of Separation Pay Agreement), within one year of employment, you will be responsible for reimbursing the Company for the gross amount of the entire relocation bonus.

In addition, full-time employees are eligible for various benefits in accordance with the Company's policies and benefit plans. Among other things, these benefits currently include medical, dental, vision, paid time

off, paid company holidays, life insurance and a 401(k) retirement plan. In addition, you will be covered by the Company's form of Separation Pay Agreement and the Company's form of Indemnification Agreement between the Company and its directors and executive officers. Additional information and details regarding employee benefits will be provided.

As an employee, you will be subject to all applicable employment standards and other policies of the Company. By signing this offer letter, you agree to review and uphold the Company's rules of conduct, which are included in the Company's Employee Handbook and the Company's Code of Business Conduct and Ethics. Further, you commit to abide by all rules, standards, and policies of the Company, as adopted or amended from time to time.

You will be provided the Company's At-Will Employment and Confidential Information and Invention Assignment Agreement (the "CIIA Agreement") and the Employment Arbitration Agreement (the "Arbitration Agreement"). This offer is contingent on you signing these standard agreements. In accordance with current federal law, you will be asked to provide documentation proving your eligibility to work in the United States. Please plan to review the US Department of Justice Form I-9 and bring proper identification with you on your first day. *Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.*

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. If you are unsure as to whether you can work for the Company notwithstanding any agreements with prior employers, you must provide the Company with written permission from your former employer to work for the Company. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that may interfere or conflict with your job performance or with your obligations to the Company, or which may influence your business judgment. During the Employment Term, you may engage in (i) charitable, civic, community, and trade activities, serve as a member of the board of directors of Candle Therapeutics, Inc., manage your passive personal investments, and (ii) subject to, in each case, express prior written approval by the Board, engage in other advisory activities, and serve on other boards of non-competing entities (such permitted activities or engagements, the "**Outside Activities**"); *provided* that, in each case, the Outside Activities do not materially interfere with your duties hereunder, violate the terms of this Employment Offer Letter or any other agreement to which Executive and the Company or its affiliates is a party, or present a business or fiduciary conflict of interest.

Your signature to this offer of employment shall be your written consent that our Human Resources organization may utilize employment verification processes that may include: credit reports, references, criminal history, educational transcripts and civil lawsuits, and that this offer is contingent on a satisfactory report as well as satisfactory completion of and responses to an officer questionnaire, as determined by the Company.

The Company and you agree that your employment with the Company can be terminated "at-will" by either party at any time, with or without notice, and for any reason, with or without cause. This provision for at-will employment may not be modified by anyone on behalf of the Company except pursuant to a writing signed by the Chief Executive Officer. We request that, in the event of resignation, you give the Company at least two (2) weeks' notice. However, the Company reserves the right to accept a resignation immediately or to accelerate the final date of employment. Upon leaving your employment with the Company, at any time and for any reason, you must return any Company property in your possession or control, including all confidential information, work, media or records, correspondence, memoranda, drawings, pictures, reports, and any physical evidence of any reports, analysis, designs,

systems or programs, whether in written or electronic form, without keeping any copies thereof. Anything to the contrary notwithstanding, you shall be entitled to retain (i) personal papers and other materials of a personal nature, including a copy of your personal calendar, address and contacts information that is stored on an electronic database such as Outlook or similar program; provided, that such papers or materials do not include Confidential Information, (ii) information showing your compensation or relating to reimbursement of expenses, (iii) copies of plans, programs and agreements relating to your employment, or termination thereof, with the Company which you received in your capacity as a participant, and (iv) limited Company books and records as required for any substantial *bona fide* estate or tax considerations pertaining to your employment, compensation, management incentive plan participation or transactions associated therewith.

This offer letter and the agreements referenced herein are the complete statement of the terms and conditions of your employment with the Company and supersede all prior agreements, understandings or representations between you and the Company.

Renee, we are confident the Company is well positioned in the medical technology marketplace and has tremendous potential. We feel that you can make a significant contribution and we look forward to welcoming you to Shock Nation! To indicate your acceptance of this offer, please sign and return this offer letter, no later than 5:00 p.m. Pacific Time on Wednesday, January 17, 2024.

Sincerely,
/s/ Doug Godshall
Doug Godshall
CEO

I have read, understand, and accept the offer of employment stated above:

/s/ RENEE GAETA

Name
RENEE GAETA

Date
01/16/24 | 19:49 CST

SHOCKWAVE MEDICAL, INC.

Subsidiary Name	Jurisdiction of Incorporation
Neovasc Inc.	Canada
Neovasc Tiara Inc.	Canada
SWAV CR Sociedad de Responsabilidad Limitada	Costa Rica
Shockwave Medical France SàRL	France
Shockwave Medical GmbH	Germany
Neovasc GmbH	Germany
Shockwave Medical India Private Limited	India
Shockwave Medical Ireland Limited	Ireland
Shockwave Medical Italy S.R.L.	Italy
Shockwave Medical Japan KK	Japan
Shockwave Medical Portugal, Unipessoal Lda.	Portugal
Genesis Shockwave Private Limited	Singapore
SWAV Medical Spain, S.L.	Spain
Shockwave Medical UK Limited	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-230113) pertaining to the ShockWave Medical, Inc. 2019 Equity Incentive Plan, the ShockWave Medical, Inc. Employee Stock Purchase Plan, and the ShockWave Medical, Inc. 2009 Equity Incentive Plan,
(2) Registration Statements (Form S-8 No. 333-270045, 333-263040, 333-253623, and 333-237448) pertaining to the ShockWave Medical, Inc. 2019 Equity Incentive Plan and the ShockWave Medical, Inc. Employee Stock Purchase Plan, and
(3) Registration Statement on Form S-3 (No. 333-239202) of Shockwave Medical, Inc.;

of our reports dated February 26, 2024, with respect to the consolidated financial statements of Shockwave Medical, Inc. and the effectiveness of internal control over financial reporting of Shockwave Medical, Inc. included in this Annual Report (Form 10-K) of Shockwave Medical, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Mateo, California
February 26, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Douglas Godshall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Shockwave Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2024

By: /s/ Douglas Godshall

Douglas Godshall

President, Chief Executive Officer & Director

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Renee Gaeta, certify that:

1. I have reviewed this Annual Report on Form 10-K of Shockwave Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2024

By: /s/ Renee Gaeta
Renee Gaeta
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Shockwave Medical, Inc. (the "Company") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2024

By: /s/ Douglas Godshall

Douglas Godshall

President, Chief Executive Officer & Director

(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Shockwave Medical, Inc. (the "Company") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2024

By: /s/ Renee Gaeta

Renee Gaeta

Chief Financial Officer

(Principal Financial Officer)

Exhibit 97.1

Shockwave Medical, Inc.

Amended and Restated Policy for Recoupment of Incentive Compensation

(As Adopted on December 10, 2020 (the "Prior Policy") and amended on October 12, 2023 (this "Policy"))

The Board has determined that it is in the best interests of the Company and its stockholders to adopt this Policy enabling the Company to recover from specified current and former Company executives certain incentive-based compensation in the event of an accounting restatement resulting from material noncompliance with any financial reporting requirements under the federal securities laws. Capitalized terms are defined in Section 14.

This Policy is designed to comply with Rule 10D-1 of the Exchange Act and shall become effective on the Effective Date and shall apply to Incentive-Based Compensation Received by Covered Persons on or after the Listing Rule Effective Date. On the Effective Date, this Policy will supersede the Prior Policy; provided, however, the Prior Policy applies with respect to any Incentive-Based Compensation Received by a Covered Person on or after January 1, 2021 and prior to the Listing Rule Effective Date.

1. Administration

This Policy shall be administered by the Administrator. The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Administrator may retain, at the Company's expense, outside legal counsel and such compensation, tax or other consultants as it may determine are advisable for purposes of administering this Policy.

2. Covered Persons and Applicable Compensation

This Policy applies to any Incentive-Based Compensation Received by a person (a) after beginning service as a Covered Person; (b) who served as a Covered Person at any time during the performance period for that Incentive-Based Compensation; and (c) was a Covered Person during the Clawback Period.

However, recovery is not required with respect to:

i. Incentive-Based Compensation Received prior to an individual becoming a Covered Person, even if the individual served as a Covered Person during the Clawback Period.

ii. Incentive-Based Compensation Received prior to the Listing Rule Effective Date.

iii. Incentive-Based Compensation Received prior to the Clawback Period.

iv. Incentive-Based Compensation Received while the Company did not have a class of listed securities on a national securities exchange or a national securities association, including the Exchange.

The Administrator will not consider the Covered Person's responsibility or fault or lack thereof in enforcing this Policy with respect to recoupment under the Final Rules.

3. Triggering Event

Subject to and in accordance with the provisions of this Policy, if there is a Triggering Event, the Administrator shall require a Covered Person to reimburse or forfeit to the Company the Recoupment

Amount applicable to such Covered Person. A Company's obligation to recover the Recoupment Amount is not dependent on if or when the restated financial statements are filed.

4. Calculation of Recoupment Amount
The Recoupment Amount will be calculated in accordance with the Final Rules, as provided in the Calculation Guidelines attached hereto as Exhibit A.

5. Method of Recoupment

Subject to compliance with the Final Rules and applicable law, the Administrator will determine, in its sole discretion, the method for recouping the Recoupment Amount hereunder which may include, without limitation:

i. Requiring reimbursement or forfeiture of the pre-tax amount of cash Incentive-Based Compensation previously paid;

ii. Offsetting the Recoupment Amount from any compensation otherwise owed by the Company to the Covered Person, including without limitation, any prior cash incentive payments, executive retirement benefits, wages, equity grants or other amounts payable by the Company to the Covered Person in the future;

iii. Cancellation of outstanding equity awards, including any Incentive-Based Compensation that is unexercised, unvested or otherwise unearned or any Incentive-Based Compensation that is vested but deferred;

iv. Seeking recovery of any gain realized on the vesting, exercise, settlement, cash sale, transfer, or other disposition of any equity-based awards; and/or

v. Taking any other remedial and recovery action permitted by law, as determined by the Administrator.

6. Arbitration

To the fullest extent permitted by law, any disputes under this Policy shall be submitted to mandatory binding arbitration (the "***Arbitrable Claims***"), governed by the Federal Arbitration Act (the "***FAA***"). Further, to the fullest extent permitted by law, no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in the Covered Person's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding.

SUBJECT TO THE ABOVE PROVISO, ANY RIGHTS THAT A COVERED PERSON MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS ARE WAIVED. ANY RIGHTS THAT A COVERED PERSON MAY HAVE TO PURSUE OR PARTICIPATE IN A CLASS OR COLLECTIVE ACTION PERTAINING TO ANY CLAIMS BETWEEN COVERED PERSON AND THE COMPANY ARE WAIVED.

The Covered Person is not restricted from filing administrative claims that may be brought before any government agency where, as a matter of law, the Covered Person's ability to file such claims may not be restricted. However, to the fullest extent permitted by law, arbitration shall be the exclusive remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Santa Clara County, California through JAMS before a single neutral arbitrator, in accordance with the JAMS Comprehensive Arbitration Rules and Procedures then in effect, provided however, that the FAA, including its procedural provisions for compelling arbitration, shall govern and apply to this Arbitration provision. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. If, for any reason, any term of this Arbitration provision is held to be invalid or unenforceable, all other valid terms and conditions herein shall be severable in nature and remain fully enforceable.

7. Section 3(i) Recovery Process; Impracticability

In connection with a recovery pursuant to Section 3(i) of this Policy, actions by the Administrator to recover the Recoupment Amount will be reasonably prompt.
The Administrator must cause the Company to recover the Recoupment Amount unless the Administrator shall have previously determined that recovery is impracticable and one of the following conditions is met:

i. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive-Based Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such erroneously awarded compensation, document such reasonable attempt(s) to recover, and provide such documentation to the Exchange;

ii. Recovery would violate home country law where that law was adopted prior to November 28, 2022; before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive-Based Compensation based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

iii. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

8. Non-Exclusivity

The Administrator intends that this Policy will be applied to the fullest extent of the law. Without limitation to any broader or alternate clawback authorized in any written document with a Covered Person, (i) the Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy, and (ii) this Policy will nonetheless apply to Incentive-Based Compensation as required by the Final Rules, whether or not specifically referenced in those arrangements. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other clawback policy of the Company as then in effect, or any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies or regulations available or applicable to the Company (including SOX 304). If recovery is required under both SOX 304 and this Policy, any amounts recovered pursuant to SOX 304 may, in the Administrator's sole discretion, be credited toward the amount recovered under this Policy, or vice versa.

9. No Indemnification

The Company shall not indemnify any Covered Persons against (i) the loss of erroneously awarded Incentive-Based Compensation or any adverse tax consequences associated with any incorrectly awarded Incentive-Based Compensation or any recoupment hereunder, or (ii) any claims relating to the Company's enforcement of its rights under this Policy. For the avoidance of doubt, this prohibition on indemnification will also prohibit the Company from reimbursing or paying any premium or payment of any third-party insurance policy to fund potential recovery obligations obtained by the Covered Person directly. No Covered Person will seek or retain any such prohibited indemnification or reimbursement.

Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recovery of any erroneously awarded Incentive-Based Compensation and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

10. Covered Person Acknowledgement and Agreement

All Covered Persons subject to this Policy must acknowledge their understanding of, and agreement to comply with, the Policy by executing the certification attached hereto as Exhibit B. **Notwithstanding the foregoing, this Policy will apply to Covered Persons whether or not they execute such certification.**

11. Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators or other legal representatives and shall inure to the benefit of any successor to the Company.

12. Interpretation of Policy

To the extent there is any ambiguity between this Policy and the Final Rules, this Policy shall be interpreted so that it complies with the Final Rules. If any provision of this Policy, or the application of such provision to any Covered Person or circumstance, shall be held invalid, the remainder of this Policy, or the application of such provision to Covered Persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

In the event any provision of this Policy is inconsistent with any requirement of any Final Rules, the Administrator, in its sole discretion, shall amend and administer this Policy and bring it into compliance with such rules.

Any determination under this Policy by the Administrator shall be conclusive and binding on the applicable Covered Person. Determinations of the Administrator need not be uniform with respect to Covered Persons or from one payment or grant to another.

13. Amendments; Termination

The Administrator may make any amendments to this Policy as required under applicable law, rules and regulations, or as otherwise determined by the Administrator in its sole discretion.

The Administrator may terminate this Policy at any time.

14. Definitions

"***Administrator***" means the Compensation Committee of the Board, or in the absence of a committee of independent directors responsible for executive compensation decisions, a majority of the independent directors serving on the Board.

"***Board***" means the Board of Directors of the Company.

"***Clawback Measurement Date***" is the earlier to occur of:

i. The date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described in this Policy; or

ii. The date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described in this Policy.

"***Clawback Period***" means the three (3) completed fiscal years immediately prior to the Clawback Measurement Date and any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year (that results from a change in the Company's fiscal year) within

or immediately following such three (3)-year period; provided that any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of 9 to 12 months will be deemed a completed fiscal year.

"***Company***" means Shockwave Medical, Inc., a Delaware corporation, or any successor corporation.

"***Covered Person***" means any Executive Officer (as defined in the Final Rules), including, but not limited to, those persons who are or have been determined to be "officers" of the Company within the meaning of Section 16 of Rule 16a-1(f) of the rules promulgated under the Exchange Act, and "executive officers" of the Company within the meaning of Item 401(b) of Regulation S-K, Rule 3b-7 promulgated under the Exchange Act, and Rule 405 promulgated under the Securities Act of 1933, as amended; provided that the Administrator may identify additional employees who shall be treated as Covered Persons for the purposes of this Policy with prospective effect, in accordance with the Final Rules.

"***Effective Date***" means October 12, 2023, the date this Policy was adopted by the Board.

"***Exchange***" means The Nasdaq Stock Market LLC or any other national securities exchange or national securities association in the United States on which the Company has listed its securities for trading.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Final Rules***" means the final rules promulgated by the SEC under Section 954 of the Dodd-Frank Act, Rule 10D-1 and Exchange listing standards, as may be amended from time to time.

"***Financial Reporting Measure***" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and TSR are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC.

"***Incentive-Based Compensation***" means compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure. Examples of "Incentive-Based Compensation" include, but are not limited to: non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and SARs that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure goal. "Incentive-Based Compensation" excludes, for example, time-based awards such as stock options or restricted stock units that are granted or vest *solely* upon completion of a service period; awards based on non-financial strategic or operating metrics such as the consummation of a merger or achievement of non-financial business goals; service-based retention bonuses; discretionary compensation; and salary.

"***Listing Rule Effective Date***" means the effective date of the listing standards of the Exchange.

"***Policy***" means this Compensation Recovery Policy.
Incentive-Based Compensation is deemed "***Received***" in the Company's fiscal period during which the relevant Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, irrespective of whether the payment or grant occurs on a later date or if there are additional vesting or payment requirements, such as time-based vesting or certification or approval by the Compensation Committee or Board, that have not yet been satisfied.

"***Recoupment Amount***" means the amount of Incentive-Based Compensation Received by the Covered Person based on the financial statements prior to the restatement that exceeds the amount such Covered Person would have received had the Incentive-Based Compensation been determined based on the financial restatement, computed without regard to any taxes paid (*i.e.*, gross of taxes withheld).

"***SARs***" means stock appreciation rights.

"***SEC***" means the U.S. Securities and Exchange Commission.

"***SOX 304***" means Section 304 of the Sarbanes-Oxley Act of 2002.
"***Triggering Event***" means any event in which the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***TSR***" means total stockholder return.

EXHIBIT A

Calculation Guidelines

For purposes of calculating the Recoupment Amount:

i. For cash awards not paid from bonus pools, the erroneously awarded compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was received and the amount that should have been received applying the restated Financial Reporting Measure.

ii. For cash awards paid from bonus pools, the erroneously awarded compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

iii. For equity awards, if the shares, options, restricted stock units, or SARs are still held at the time of recovery, the erroneously awarded compensation is the number of such securities received in excess of the number that should have been received applying the restated Financial Reporting Measure (or the value of that excess number). If the options or SARs have been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the excess options or SARs (or the value thereof). If the underlying shares have been sold, the Company may recoup proceeds received from the sale of shares.

iv. For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

   a. The amount must be based on a reasonable estimate of the effect of the accounting restatement on the stock price or TSR upon which the Incentive-Based Compensation was Received; and

   b. The Company must maintain documentation of the determination of that reasonable estimate and the Company must provide such documentation to the Exchange in all cases.

EXHIBIT B

Certification

I certify that:

1. I have read and understand the Company's Compensation Recovery Policy (the "***Policy***"). I understand that the General Counsel is available to answer any questions I have regarding the Policy.

2. I understand that the Policy applies to all of my existing and future compensation-related agreements with the Company, whether or not explicitly stated therein.

3. I agree that notwithstanding the Company's certificate of incorporation, bylaws, and any agreement I have with the Company, including any indemnity agreement I have with the Company, I will not be entitled to, and will not seek indemnification from the Company for, any amounts recovered or recoverable by the Company in accordance with the Policy.

4. I understand and agree that in the event of a conflict between the Policy and the foregoing agreements and understandings on the one hand, and any prior, existing or future agreement, arrangement or understanding, whether oral or written, with respect to the subject matter of the Policy and this Certification, on the other hand, the terms of the Policy and this Certification shall control, and the terms of this Certification shall supersede any provision of such an agreement, arrangement or understanding to the extent of such conflict with respect to the subject matter of the Policy and this Certification; provided that, in accordance with Section 8 of the Policy, nothing herein limits any other remedies or rights of recoupment that may be available to the Company.

5. I agree to abide by the terms of the Policy, including, without limitation, by returning any erroneously awarded Incentive-Based Compensation to the Company to the extent required by, and in a manner permitted by, the Policy.

Signature:

Name:

Title:

Date: