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, 2022

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, 2022, 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, 2022) was approximately $4.2 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 22, 2023 was 36,495,387.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2023 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. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2022. 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 aortic stenosis;
- our ability to successfully execute our commercialization strategy for our approved or cleared products;
- our expected future growth, including growth in international sales;
- the size and growth potential of the markets for our 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;
- the expected timing for completion and benefits of our proposed acquisition of Neovasc Inc., 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 macroeconomic conditions, including inflation, rising interest rates and volatile market conditions, and global events, including the COVID-19 pandemic, 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 catheters, making us vulnerable to supply problems and price fluctuations.
- 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.
- 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. 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, expand our indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire and develop other products, we may be unable to grow our business over the long-term.
- 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.
- Our success depends in large part on our IVL technology (our "IVL Technology"). If we are unable to successfully market and sell products incorporating our IVL Technology, 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 currently 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 may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

PART I

Item 1. Business.

Company Overview

We are a medical device company focused on developing products intended to transform the way calcified cardiovascular disease is treated. 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.

Our Products and Product Pipeline

Our IVL catheters 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:

Products for Treatment of Peripheral Artery Disease ("PAD"):

- Our Shockwave M^5 IVL catheter ("M^5 catheter") and Shockwave M^{5+} IVL catheter ("M^{5+} catheter") are five-emitter catheters for use in our IVL System in medium-diameter vessels for the treatment of PAD. The M^5 catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018. The M^{5+} catheter was CE-Marked in November 2020 and cleared by the FDA in April 2021. In May 2022, we obtained regulatory approval, through our joint venture with Genesis MedTech International Private Limited ("Genesis"), from the China National Medical Products Administration ("NMPA") to sell our M^5 catheter in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "PRC").
- Our Shockwave S^4 IVL catheter ("S^4 catheter") is a four-emitter catheter for use in our IVL System in small-diameter vessels for the treatment of PAD. The S^4 catheter was CE-Marked in April 2018. The second version of our S^4 catheter was cleared by the FDA in August 2019 and accepted by our EU notified body in May 2020 for use in our IVL System. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our S^4 catheter in the PRC.
- Our Shockwave L^6 IVL catheter ("L^6 catheter") is a six-emitter catheter for use in our IVL System in large diameter vessels for the treatment of PAD. Our L^6 catheter was cleared by the FDA in August 2022 for use in our IVL System. We commenced a U.S. limited market release for our L^6 catheter in the fourth quarter of 2022.

Product for the Treatment of Coronary Artery Disease ("CAD"):

- Our Shockwave C^2 IVL catheter ("C^2 catheter") and Shockwave C^{2+} IVL catheter ("C^{2+} catheter") are two-emitter catheters for use in our IVL System for the treatment of CAD. The C^2 catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C^2 catheter using our IVL System for the treatment of CAD. We received FDA approval of our C^2 catheter in February 2021. In March 2022, we received regulatory approval in Japan for our C^2 catheter and commenced a limited market release in Japan in May 2022 followed by a full market release in January 2023. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our C^2 catheter in the PRC. The C^{2+} catheter was CE-Marked in August 2022 and approved by the FDA in December 2022. In the fourth quarter of 2022, we commenced a limited market release for our C^{2+} catheter in select international locations.

Our differentiated range of IVL catheters enables delivery of IVL therapy to diseased vasculature throughout the body for calcium modification. Our IVL catheters resemble in form a standard balloon angioplasty catheter, the device most commonly used by interventionalists. This familiarity makes our IVL System easy to learn, adopt and use on a day-to-day basis.

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our IVL Technology. These studies have consistently shown low rates of complications regardless of which vessel was being studied. In addition to supporting our regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of our IVL Technology across multiple therapies in existing and new market segments. Our past studies have also guided optimal IVL procedure technique and informed the design of our IVL System and future 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 2022, we were engaged in the following CAD clinical trials:

- DISRUPT CAD III: This global study was designed to support our PMA application and, together with the DISRUPT CAD IV study, our Shonin submission in Japan, for our C^2 catheter. In October 2018, we received staged investigational device exemption ("IDE") approval for our DISRUPT CAD III global study. We began enrollment in the DISRUPT CAD III global study in 2019 and completed enrollment in March 2020. We submitted CAD III data to the FDA to support PMA application approval. We commenced the U.S. launch of our C^2 catheter following FDA approval in February 2021. In 2022, final two-year data had been presented and the DISRUPT CAD III study is in the process of study close-out.
- DISRUPT CAD IV: This study is designed, along with DISRUPT CAD III, to support our Shonin submission in Japan for our C^2 catheter. We began enrollment in the DISRUPT CAD IV Japan study in 2019 and completed enrollment in April 2020. We submitted CAD III and CAD IV data to support our Shonin submission in March 2021 and received regulatory approval of our C^2 catheter in Japan in March 2022.
- DISRUPT CAD III Post-Approval Study (CAD PAS): This is a required post-approval study in the United States for our C^2 catheter. We began the initial collection of data in the last quarter of 2021 and concluded in January 2023.

In addition, we were engaged in the following PAD clinical trials in 2022:

- DISRUPT PAD III. This global study was a prospective, multicenter, randomized study designed to demonstrate the safety and effectiveness of IVL as a vessel preparation procedure in moderate to severely calcified superficial femoral and popliteal lesions, followed by a drug-coated balloon or stent. We began enrollment in the DISRUPT PAD III study in February 2017 and completed enrollment in May 2020. We disclosed the 30-day results of the study in November 2020, and the 1-year results in May 2022. Our PAD III study is the largest randomized study in heavily calcified femoropopliteal lesions to date and demonstrated that our IVL Technology was superior to balloon angioplasty. PAD III also has an observational registry component. The additional registry data demonstrates that IVL reduces residual stenosis and vascular complications in a variety of peripheral lesions including calcified infrapopliteal PAD, and successfully facilitates large bore access for transcatheter aortic valve implantation procedures. Enrollment in the registry portion was completed in June 2021 and results were disclosed in October 2022.
- PAD+: This was a prospective, multi-center, single-arm study to assess the safety and performance of the M^{5+} catheter in our IVL System to treat calcified peripheral arteries. PAD+ is intended to support approval in pre-market countries, and to assess continued safety and effectiveness in the United States. We began enrollment in the PAD+ study in February 2021 and completed enrollment in September 2021. Initial results were disclosed in April 2022.
- 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 the BTK II study in November 2021, and study enrollment is ongoing.
- Mini S Feasibility: This is a prospective, multi-center, single-arm feasibility study to assess the safety and performance of the Shockwave Medical Mini S Peripheral IVL System for the treatment of heavily calcified, stenotic peripheral arteries. We began enrollment in January 2022 and enrollment is ongoing.

A development program is also currently underway to explore the ability of our IVL Technology to directly treat calcified aortic valves to safely reduce the symptoms of aortic stenosis ("AS").

The Opportunity

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. In the future, we see significant opportunity in the potential treatment of AS, a condition in which the heart's aortic valve becomes increasingly calcified with age, causing it to narrow and obstruct blood flow from the heart.

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 transcatheter aortic valve replacements ("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, but we believe the aggregate addressable market for IVL is estimated to be over $8.5 billion.

Coronary IVL is utilized to treat patients with CAD undergoing a percutaneous coronary intervention ("PCI") who have severe or moderate arterial calcium that hinder a balloon angioplasty and subsequent stent implantation. According to Clarivate, over six million PCI procedures will be performed in 2023 in the markets we serve. 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 coronary artery disease, which we believe is likely due to safety risks and the inherent challenges associated with their use. Despite significant under-penetration of the market, these devices still represented a market of $200 million in 2022 within the United States alone, according to Clarivate; we believe this market is significantly larger globally. We believe the safety, ease of use and efficient impact on calcium of our IVL System resulted in the adoption and market expansion in markets where our C^2 catheter was introduced. We believe there is an over $3.6 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 over 1.9 million interventions are performed annually to treat symptomatic occlusive PAD. The presence of severe and moderate calcium ranges between 50 – 70% in the iliac, femoropoliteal and infrapopliteal arterial beds that are treated as part of PAD interventions. Current technologies are often not able to safely and effectively treat heavily calcified vessels. Accordingly, we believe our IVL system to treat symptomatic occlusive PAD has a total addressable market opportunity of $1.9 billion.

In addition to PAD treatment, lower extremity arteries are sometimes 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. In 2023 Clarivate estimates that 260,000 TAVR procedures will be performed globally and up to 20% of these procedures are at risk for barriers to transfemoral access due to calcium. Similarly, Clarivate estimates that 215,000 EVAR and TEVAR procedures are performed globally with up to 20% of procedures at risk due to calcified lower extremity arteries. IVL is able to treat these calcified arteries and enable these so-called large bore procedures to be performed via standard transfemoral access technique, thereby reducing a risk of increased complications due to alternative access methods. We estimate that in aggregate large bore access procedures represent an additional addressable market opportunity of over $200 million.

The global market for aortic valve replacement ("AVR"), 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 an article published in the Journal of Thoracic Disease in 2017, the global market for TAVR was anticipated to be over 175,000 procedures performed worldwide in 2020 and is expected to grow to over 400,000 by 2028. We believe our IVL System may be able to improve the treatment of AS among patients in whom currently available solutions are

inadequate. We are currently working to develop an IVL catheter which we believe can safely and effectively treat patients with AS. If successful, we believe this represents a potential total addressable market of over $3 billion for our IVL System to treat AS.

Current Challenges

The primary approaches to treat cardiovascular disease are angioplasty balloons ("balloons"), drug-coated balloons ("DCB"), bare metal stents, and DES. 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.

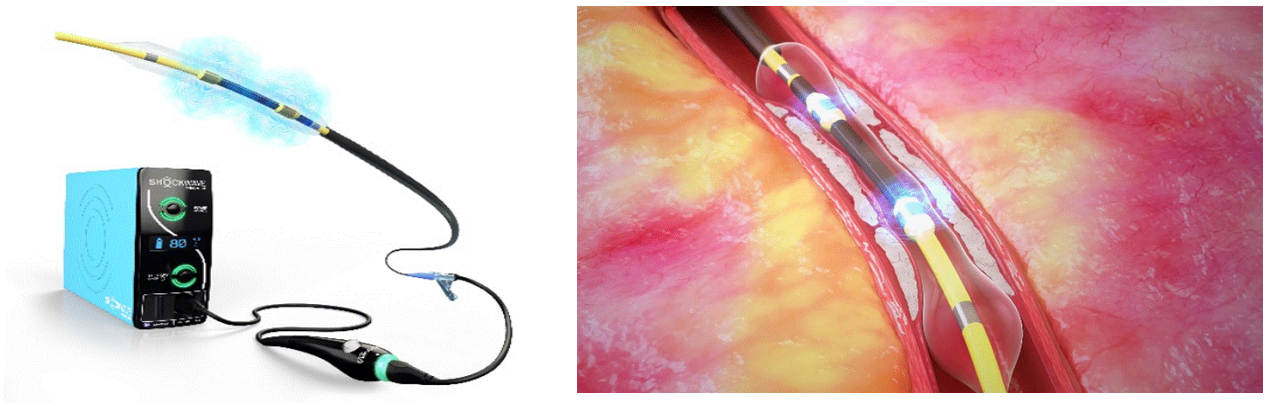
Plaque modification devices (including atherectomy and specialty balloons) have enhanced the treatment of some moderately calcified cardiovascular lesions by improving the ability of stent and balloon therapies to effectively expand in the vessel. Atherectomy devices are designed to break or remove superficial 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 TAVR, and cardiac support devices for high-risk 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 Solution

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 shockwaves 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 shockwaves crack this calcium and enable the stenotic 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



(Left) Our IVL System consisting of a generator, connector cable and IVL catheter. (Right) Our IVL System delivering lithotripsy directly to a calcified vessel.

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.

We believe there is a significant opportunity to apply our IVL Technology as a platform to treat a wide array of indications throughout the cardiovascular system. Ultimately, our plan is to have a broad portfolio of IVL catheters that can treat calcium-related diseases across a wide variety of vasculatures and structures.

Why Shockwave?

Safe – Simple – Effective.

- Treatment calcium throughout the coronary and peripheral arteries.
- Improved safety of these challenging procedures through a unique mechanism of action.
- Seamless integration into interventional practice with exceptional ease-of-use.
- Ensure complex procedures can be performed in a predictable manner.
- Expanded access to interventional techniques for patients.

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.

- Address unmet clinical needs in multiple large markets.
- Advance our IVL System as a common treatment for calcified PAD and CAD.
- Grow our specialized sales force across indications and geographies to foster deep relationships with physicians and drive revenue growth.
- Execute on our clinical program to expand indications and build a robust body of clinical evidence.
- Leverage our IVL Technology and our experienced team to develop new products that satisfy significant unmet clinical needs.
- Drive profitability by scaling our business operations to achieve cost and production efficiencies.

On January 16, 2023, we entered into an arrangement agreement to acquire Neovasc Inc., a company focused on the minimally invasive treatment of refractory angina ("Neovasc"), pursuant to which we will acquire all outstanding Neovasc shares for an upfront cash payment of $27.25 per share, corresponding to an enterprise value of approximately $100 million, inclusive of certain deal-related costs. Neovasc shareholders will also receive a potential deferred payment in the form of a non-tradable contingent value right entitling the holder to receive up to an additional $12 per share in cash if certain regulatory milestones are achieved. The transaction will be effected by way of a court-approved plan of arrangement pursuant to the Canada Business Corporations Act, and is subject to customary closing conditions, including requisite Neovasc shareholder approval. We expect to complete the transaction in the first half of 2023.

Research and Development

We invest in research and development efforts that advance our IVL Technology and related technologies with the goal to expand and improve 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 technology 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.

Manufacturing

The manufacturing of our IVL catheters is principally done at our facilities in Santa Clara, California, except that a portion of demand for certain catheters is manufactured by a third-party contract manufacturer in Costa Rica. In 2022, we entered into a land purchase agreement and certain other related agreements for the purchase of real property in Costa Rica, where we are in the process of building a new manufacturing facility.

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 IVL products from our manufacturing sites 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 IVL products directly to our hospital customers through our direct sales representatives, who deliver such products to hospital customers in the field. We have offered consignment sales arrangements to certain customers, including some customers in Germany, Austria, Switzerland, France, Ireland and the United Kingdom (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 manufacturing facilities are compliant with International Organization for Standardization ("ISO") 13485:2016. 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 are working to achieve compliance for our other IVL catheters under the MDR, which supersedes the MDD, subject to certain transition provisions contained in the MDR. 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 have received 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 IVL System to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD and CAD. We have dedicated meaningful resources to establish direct sales capability in the United States, Germany, Austria, Switzerland, France, Ireland, Japan and the UK 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 who treat patients with PAD and CAD. 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.

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.

Our IVL System is simple, intuitive, and easy to install and use. This provides value to our customers, but also makes our sales model a source of competitive advantage. Lower service burden means we can develop a cost-efficient sales model by optimizing a mix of clinical specialists and salespeople. Moreover, our coronary and peripheral IVL catheters have similar call points, meaning we can further leverage our field sales team.

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.

Medicare has established dedicated coding and payment for peripheral IVL procedures performed in the hospital inpatient, hospital outpatient and ambulatory surgical settings of care. Coronary IVL is an FDA-designated Breakthrough Device with coding and payment 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.

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, Cardiovascular Systems, Inc. ("CSI"), Medtronic plc, Philips N.V. and Abbott Laboratories. 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 proprietary IVL Technology, 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 unique 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.

We seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our

proprietary information. However, trade secrets and proprietary information can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets and proprietary information may otherwise become known or be independently discovered by competitors.

As of December 31, 2022, we owned 55 issued U.S. patents and 88 issued foreign patents, 20 pending U.S. non-provisional patent applications and 41 pending foreign patent applications (including five 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, 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 CSI, one of our competitors. On March 9, 2022, the Patent Trial and Appeal Board (the "PTAB") issued an order authorizing us to file a motion for additional discovery. On March 23, 2022, we filed a motion for additional discovery, relating to additional information publicized by CSI after the PTAB's decision on the patents. On February 2, 2023, the PTAB denied the motion for additional discovery and issued a final decision, ruling again that Claim 5 is valid and that all other claims are invalid. For more information regarding these proceedings, see the section titled "*Legal Proceedings*."

These issued patents, and any patents granted from such applications, are expected to expire between 2029 and 2041, 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 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 claims 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. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend cases brought under the False Claim Act. 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. The Affordable Care Act also included a provision, commonly referred to as the Sunshine Act, which requires that any manufacturer 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 Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made to physicians and teaching hospitals, 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. Such reporting requirement was expanded by the SUPPORT for Patients and Communities Act, which requires manufacturers, beginning January 1, 2021, to report payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives in addition to physicians and teaching hospitals. Similar laws have been enacted at the state level and in foreign jurisdictions, including France.

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, 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 already started to update our technical documentation and other quality management system processes in preparation 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 the end of the UK-EU transitional period on January 1, 2021. Although the CE mark will continue to be recognized in Northern Ireland whilst the Northern Ireland Protocol is in force, it will only be recognized in Great Britain until June 30, 2024, and after this date, an equivalent UK

mark (UKCA mark) will become mandatory in Great Britain. We will only be able to affix the UKCA mark on our products following completion of a conformity assessment procedure which currently is based on that under the MDD, except that it needs to be supervised by a UK-based Approved Body. We will commence preparations to ensure we can use the UKCA mark by July 2024. The UK government has already made some changes to the MDD-derived regime, including requiring that we appoint a UK-based Responsible Person to serve a point of contact (where previously the UK would be covered by our EU-based Authorized Representative) and register our devices – and is considering further changes. We expect that over time the two processes will continue to diverge.

China. The country has been actively improving and updating its regulatory regime on medical devices, addressing the whole lifecycle of medical devices, including, product registration/record-filing, distribution, labeling and advertisement, post-marketing compliance including adverse event reporting, and 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 the medical device. Medical devices in different classes are subject to different registration/record-filing: foreign Class I 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 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 registered with the NMPA and, any other types of changes must be record-filed.

In China, the distribution of Class II devices is subject to the record-filing with competent municipal branches of the NMPA, while that of Class III devices is subject to the approval granted by competent municipal branches of the NMPA. In addition, Genesis, as the distributor of our products, 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 device products by, for example, providing accurate, complete and authentic information in Chinese that is consistent with the registration with the NMPA. Moreover, the advertising of medical devices is subject to the review and approval of competent authorities and must be restricted within the scope registered with the NMPA.

As the marketing authorization holder of our medical devices, we are also subject to post-marketing responsibilities, including the monitoring of adverse events and handling of product defects. In the event 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 Ministry of Health, Labour, and Welfare (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 require us to comply with various 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"); U.S. and foreign export control, trade embargo and custom laws; U.S. and foreign tax laws; 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 PRC, 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, 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 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, 2022, we had 1,001 full-time and part-time employees worldwide, of which 560 were located at our headquarters in Santa Clara, California, 371 were remote and field-based employees throughout the country and 70 were located outside of the United States. Of these employees, 422 were in sales, marketing and commercial operations, 340 were in manufacturing, operations and quality, 147 were in research and development, clinical and regulatory, and 92 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, 2022 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, 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, 2022, our workforce was made up of approximately 49% 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 M^5," "Shockwave C^2," "Shockwave S^4," "Shockwave L^6," 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 report. 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

We have a history of net losses, and we may continue to incur losses. Therefore, we may not be able to reach the point of sustainable profitability.

Although we incurred net income for the fiscal year ended December 31, 2022, we may incur net losses in the future. For the years ended December 31, 2022 and 2021, we had net income of $216.0 million and a net loss of $9.1 million, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $36.8 million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, seek regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, we expect to continue to incur expenses due to the compliance and governance requirements associated with being a public company. We may continue to incur losses in the future, which may fluctuate significantly from period to period. Although we achieved profitability for all four quarters of 2022, we cannot be sure that we will remain profitable in the future. If our revenue declines or fails to grow at a rate faster than increases in our operating expenses, we will not be able to achieve and maintain profitability and may incur new losses in future periods. We cannot ensure that we will achieve profitability in the future or that, if we do remain profitable, we will be able to sustain profitability.

Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operations, including our revenue, net income (loss) and cash flow, may fluctuate significantly, 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;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the timing and cost of obtaining regulatory approvals or clearances for planned or future products or indications;
- the rate at which we grow our sales force and the speed at which newly hired salespeople 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 develop or competing products;
- our ability to attract new customers and improve our business with existing customers;
- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- seasonality, including the seasonal slowing of demand for our products we have experienced in the fourth quarter and summer months based on the elective nature of procedures performed using our products, and which we expect may become more pronounced in the future as our business grows;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities relating to our products, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- interruption in the manufacturing or distribution of our products;
- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability, including in light of ongoing global supply-chain disruptions;
- future accounting pronouncements or changes in our accounting policies; and
- changes in domestic and global geopolitical and macroeconomic conditions, including as a result of the COVID-19 pandemic and the responses thereto, the ongoing conflict between Russia and Ukraine and the responses thereto, rising interest rates, inflation and a tightening of the global labor market.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could have a material adverse effect on our business, financial condition and results or operations.

If we do not effectively hire, integrate, train, manage and retain additional sales personnel, and expand our sales, marketing and distribution capabilities, we may be unable to increase our customer base, achieve broader market acceptance of our products, or increase our global sales.

We are at an early stage in our growth and have limited experience operating as a commercial company. Our ability to increase our customer base, achieve broader market acceptance of our products, and increase our global sales depends to a significant extent on our ability to expand our marketing operations. We have dedicated, and will 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:

- building the requisite sales, marketing or distribution capabilities is expensive and time-consuming and requires significant attention from management;
- the competition for talented individuals experienced in selling and marketing medical device products is intense, and we cannot assure you that we can assemble or maintain an effective team; and

- training qualified sales personnel on the use of our products, applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense, and attention and it can take a significant amount of time before our sales representatives are fully trained and productive.

Our recent hires and planned hires may not become productive as quickly as we expect, or at all, and we may be unable to hire or retain sufficient numbers of qualified individuals in the markets where we do business or plan to do business. Moreover, our international expansion may be slow or unsuccessful if we are unable to retain qualified personnel with international experience, language skills and cultural competencies in the geographic markets in which we target. Any failure or delay in the development of our sales, marketing, or distribution capabilities, to hire, train and retain our sales force, or of our sales force to meet required productivity levels within a reasonable period of time, may result in us failing to realize the expected benefits of our investments or increase our revenue, which in turn would adversely impact the commercialization of our products and harm our business.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had net operating loss ("NOL") carryforwards of approximately $239.7 million for federal income tax purposes, $51.0 million for California income tax purposes and $77.9 million for other state income tax purposes. We also have research credits of $10.4 million and $10.1 million, for federal and California, respectively. Unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. Our ability to utilize our federal net operating carryforwards and certain credits may be limited under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended. The limitations 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 net operating loss carryforwards. We have previously experienced ownership changes, and although such prior ownership changes have had an immaterial impact to our utilization of affected net operating loss carryforwards, 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 net operating loss carryforwards. In addition, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited. For example, California generally suspended the use of California net operating loss carryforwards to offset taxable income in tax years beginning after 2019 and before 2022. Accordingly, our ability to use our net operating loss carryforwards to offset taxable income may be subject to such limitations or special rules that apply at the state level, which could adversely affect our results of operations.

If we cannot realize our deferred tax assets, our results of operations could be adversely affected.

We have maintained a valuation allowance on all our U.S. net deferred tax assets since our inception as it was determined that it was more likely than not that we would not recognize the benefits of these assets. We continued to record a valuation allowance through the first nine months of 2022. In the fourth quarter of 2022, we concluded that the valuation allowance related to the U.S. federal and state (excluding California) deferred tax assets was no longer required due to the assessment of our recent income/loss and forecast future taxable income. Each quarter, we consider both positive and negative evidence to determine whether all or a portion of the deferred tax assets are more likely than not to be realized. If we determine that some or all of our deferred tax assets are not realizable, it could result in a material expense in the period in which this determination is made which may have a material adverse effect on our financial condition and results of operations.

Changes in tax laws or regulations may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations. For example, the TCJA enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings and the deductibility of expenses. Although we are still awaiting guidance from the Internal Revenue Service on how some of the TCJA changes will impact us, beginning in 2022, the TCJA eliminated the option to immediately deduct research and development expenditures and required taxpayers to amortize domestic expenditures over five years and foreign expenditures over fifteen years. Absent a change in legislation, we expect it will continue to have an impact on cash from operating activities.

In addition, many countries are implementing legislation and other guidance to align their international tax rules with the Organization for Economic Co-operation and Development's ("OECD") Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. The OECD is also continuing discussions surrounding fundamental changes in allocation of profits among tax jurisdictions in which companies do business, as well as the implementation of a global minimum tax (namely the "Pillar One" and "Pillar Two" proposals). Some countries intend to implement laws based on Pillar Two proposals, which may adversely impact our provision for income taxes, net income and cash flows.

These and other changes resulting from the TCJA or future tax reform legislation (domestic U.S. or international) could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future tax expense.

We may require additional capital to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay, limit, reduce or eliminate our product development programs, commercialization efforts or other operations.

Although we incurred net income for the fiscal year ended December 31, 2022, 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 securities and our product revenue. As of December 31, 2022, we had $304.5 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $36.8 million. Based on our current planned operations, including our pending acquisition of Neovasc, we expect that our cash, cash equivalents and short-term investments will enable us to fund our cash requirements, including capital expenditures and working capital, for at least the next 12 months. We have based this estimate on assumptions that may prove to be incorrect or different, and therefore we could use our capital resources sooner than we currently expect.

We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We have made and we plan to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in research and development, regulatory affairs, and clinical studies to develop future generations of our products, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and Securities and Exchange Commission (the "SEC") compliance, investor relations and other expenses. Because of these and other factors, we may incur net losses and negative cash flows from operations in the foreseeable future. Our future capital requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing 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 rising interest rates, inflation, global supply-chain disruptions, and a tightening of the global labor market, the COVID-19 pandemic and responses thereto, and the ongoing conflict between Russia and Ukraine and the responses thereto; and
- the extent to which we acquire or invest in businesses, products, or technologies.

As a result, we may require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings and/or debt financings.

There can be no assurance that we will be successful in obtaining such additional funding at levels sufficient to fund our operations, on terms favorable to us or at all. Further, the current macroeconomic environment may make it difficult for us to raise capital on terms favorable to us or at all. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may have a material adverse effect on our business, results of operations and financial condition. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which requires, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market ("Nasdaq") to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring that we evaluate and determine the effectiveness of our internal control over financial reporting. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

Changing laws, regulations, and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social, and governance ("ESG") disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected.

Compliance with the rules and regulations applicable to public companies can be time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. For example, we expect these rules and regulations to 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 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.

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 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, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation, as well as investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, engineers, and other highly skilled personnel, and to integrate current and additional personnel in all departments. If we are not successful in attracting and retaining highly qualified personnel, including members of our senior management, it would have a material adverse effect on our business, financial condition and results of operations.

Competition for skilled personnel in our market is intense, especially in the San Francisco Bay Area where our headquarters are located, and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we have. Our competitors also may be successful in recruiting and hiring members of our management team or other key employees, and it may be difficult for us to find suitable replacements on a timely basis, on competitive terms, or at all. We have in the past, and may in the future, be subject to allegations that employees we hire have been improperly solicited, or that they have divulged proprietary or other confidential information or that their former employers own such employees' inventions or other work product, or that they have been hired in violation of non-compete provisions or non-solicitation provisions.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock awards that vest over time. The value to employees of stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice, cause or good reason. The loss of services of these personnel could prevent or delay our growth plans and the implementation and completion of our strategic objectives or divert management's attention to seeking qualified replacements. We also do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and results of operations may be adversely affected.

As of December 31, 2022, we had 1,001 full-time and part-time employees worldwide, compared to 657 full-time employees as of December 31, 2021. In response to growth in our business, including our product portfolio, customer base and research and development programs, we have significantly expanded our employee headcount and existing operations and established new operations in other countries. In order to manage this growth, we have needed, and expect to continue

to need, additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including, among others:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- 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. 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.

We may 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 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. We cannot predict the number, timing or size of 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 candidates, or if we do, we may not be able to complete such acquisitions on favorable terms;
- the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, 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, 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;
- if we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions 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, 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, 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 may require large, one-time charges and could result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which could negatively affect our future results of operations; and
- acquisitions and investments may fail to meet our expectations and negatively affect our business, financial condition and results of operations and we may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

For example, in January 2023, we announced our pending acquisition of Neovasc, a company focused on the minimally invasive treatment of refractory angina, in connection with which we are exposed to the above-listed risks, among others. The completion of the acquisition is conditional upon, among other things, the requisite approval of Neovasc's shareholders and the issuance of a final order by the Supreme Court of British Columbia. There can be no assurance that any or all such approvals will be obtained. We will not control Neovasc and its subsidiaries until completion of the acquisition, and the business and results of operations at Neovasc may be adversely affected by events that are outside of our control during the interim period.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or product improvements or the generation of significant future revenue.

In the ordinary course of our business, we may enter into or modify collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements (each, a "Collaboration") to develop new products or product improvements and to pursue new markets. Any such Collaboration may subject us to business risks that could have a material adverse effect on our business, financial condition, and results of operations, including the following:

- we may be delayed or not successful in our efforts to identify or consummate any Collaboration;
- we face significant competition in seeking appropriate strategic partners, including from other companies with substantially greater financial, marketing, sales, technology or other business resources;
- the negotiation process for any Collaboration may be time-consuming and complex and may distract senior management;
- we may be delayed, or not be successful, in integrating such Collaboration with our existing operations and/or in achieving the revenue or specific net income or other targets that we anticipated as a result of such Collaboration;
- provisions contained in the operative documents for any Collaboration may limit our rights, control, or decision-making authority in a manner that is not in our best interest;
- any delay or termination of a Collaboration related to our products could delay the development and commercialization of our products and reduce their competitiveness if they reach the market;
- counterparties in any Collaboration may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals;
- conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights, which may result in litigation or arbitration which would increase our expenses and divert the attention of our management; and
- we may be required to incur non-recurring and other charges, increase our near and long-term expenditures, or issue securities that dilute our existing stockholders and disrupt our management and business.

For example, in March 2021, we entered into a joint venture with Genesis to establish a long-term strategic partnership to develop, manufacture and commercialize certain of our interventional products in the PRC. Under the joint venture agreement, Genesis Shockwave Private Ltd. was formed under the laws of Singapore to serve as a joint venture between us and Genesis for the purpose of establishing and managing such a strategic partnership. The termination of our joint venture with Genesis would disrupt our ability to commercialize our products in China.

We have limited experience operating as a commercial company.

We were incorporated in 2009. We began commercializing our products in the United States and Europe in 2018, and we continue to expand our product offering. Our limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects. These factors also make it difficult for us to forecast our future financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to: (i) successfully complete on-going clinical trials and other clinical trials we may undertake in the future, (ii) continue to successfully commercialize and expand usage of our products in the U.S. and international markets, and (iii) obtain

regulatory approvals and successfully commercialize future planned products in the United States or in key international markets. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

We have a limited operating history in China and we face risks with respect to conducting business in connection with our joint venture in China due to certain legal, political, economic and social uncertainties relating to China. Our ability to monetize our joint venture in China may be limited.

Our participation in the joint venture with Genesis in China is subject to general, as well as industry-specific, economic, political 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. Accordingly, any adverse change in the Chinese economy, the Chinese legal system or Chinese governmental, economic or other policies could have a material adverse effect on our business and operations in China and our prospects generally.

We face additional risks in China 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. Unauthorized use of our technologies and intellectual property rights by China partners or competitors may dilute or undermine the strength of our brands. 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.

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, the Company entered into the Credit Agreement. The Credit Agreement provides for a revolving credit facility in an aggregate principal amount of $175 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 million or (y) the Company's consolidated EBITDA for the four fiscal quarter period most recently ended prior to the date of such increase.

The Credit Agreement is secured by all of the Company's assets, excluding intellectual property and certain other assets. The Credit Agreement is subject to customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, and pay any dividend or make any distributions to stockholders.

If we fail to comply with the covenants or payments in connection with the Credit Agreement, it will be an event of default, which would give the lenders the right to terminate their commitments to provide additional loans and declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, Wells Fargo Bank, National Association, as administrative agent, would have the right to proceed against the assets we provided as collateral pursuant to the loan. The foregoing may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry or take future actions.

If we experience significant disruptions in, or breaches of, our information technology systems, our business may be adversely affected.

We depend on increasingly complex information technology systems, both with our own systems and those of our cloud and third-party service providers, for the efficient functioning of our business, including the manufacture, distribution, and maintenance of our products, management of clinical trial data and employee data, as well as for accounting, data storage (including systems that store our sensitive personal, intellectual property and confidential information), compliance, purchasing and inventory management.

Our information technology systems require an ongoing commitment of significant financial and human resources designed to maintain, protect and enhance those systems. However, a number of issues could impact the integrity of our systems including:

- Technology risks, including failures during the process of upgrading or replacing software, databases or components thereof, upgrades, expansions or replacements of our internal systems, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors ("Technology Risks"); and
- Enduring data- and cyber-security threats, including computer viruses, ransomware or other malware, crypto-jacking, cloud vulnerabilities, phishing attacks, social engineering, and attacks by computer hackers or wrongdoing from our own employees or others granted access to our information technology systems ("Cyber Risks").

We continue to work to monitor and address potential Cyber Risks and Technology Risks, including in relation to the following:

- As we become more dependent on information technologies to conduct our operations, Technology Risks may become more widespread and Cyber Risks may increase in frequency and sophistication.
- Due to the nature of Cyber Risks and the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems that change frequently and often are not recognized until launched against a target, we and our service providers may be unable to anticipate these techniques or to implement timely adequate preventative measures.
- We rely on third-party systems that could also become vulnerable to Technology Risks or Cyber Risks that could result in disruption or compromise of our systems.
- A greater number of our employees working remotely as a result of the COVID-19 pandemic and changing remote work expectations has exposed us, and may continue to expose us, to increased Technology Risks and Cyber Risks.
- We are in the process of implementing a new company-wide enterprise resource planning ("ERP") system to upgrade certain existing business, operational, and financial processes. The new ERP system could be impacted by Technology Risks, the occurrence of which could adversely impact our business processes, internal controls and operating results, including if the ERP system, once implemented, does not function as intended or is not sufficient to meet our operating requirements, or if any subsequently planned upgrades or expansions to the ERP system adversely impact existing processes.

While we have made investments, we will likely continue to need to expend significant resources and to make significant capital investment in efforts designed to protect against Cyber Risks and Technology Risks or to mitigate the impact of any actual events. We realize that Technology Risks and Cyber Risks are a threat, and there can be no assurance that our efforts to mitigate Technology Risks and Cyber Risks will prevent information security breaches that may result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition.

While we have not experienced any material Technology Risk or Cyber Risk 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.

We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.

We collect and use personal information, such as name, mailing address, email addresses, mobile phone number, medical and location information, and the collection and use of this information is regulated by privacy and data protection laws, rules and regulations. We also receive personal information from third parties subject to the same legal obligations. Violations of these laws could lead to civil and criminal penalties as well as adverse publicity that could harm our ability to initiate and complete clinical trials. We also face risks inherent (i) in the collection, use, and selective disclosure of large volumes of personal and non-personal proprietary data and (ii) in the protecting of personal and sensitive information from the Cyber and Technology Risks discussed above.

Any failure by us or any of our third-party service providers to follow such laws, regardless of fault, could result in significant liability or reputational harm under various state, federal and international privacy, data protection and other laws, including, the laws listed below. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues that may affect our business and increase the uncertainty of inconsistent regulator enforcement across jurisdictions that, include but not limited to:

- The Federal Trade Commission (the “FTC”), who is responsible for enforcement against unfair and deceptive business practices and expects a company’s data security measures to be reasonable and appropriate. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may constitute unfair or deceptive acts or practices in violation of the FTC 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, and the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), which may be

enforced separately by the Health and Human Services Agency that could result in civil and criminal penalties. HIPAA imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, which are applicable to "business associates"—certain persons or entities that create, receive, maintain or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity.

- California, which continues to be a critical state with respect to evolving consumer privacy laws after enacting the California Consumer Privacy Act (the "CCPA"), later amended by ballot measure through the California Privacy Rights Act (the "CPRA"). The CPRA took effect in January 2023 with enforcement beginning on July 1, 2023, subject to regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency ("CPPA"). Failure to comply with the CCPA and the CPRA may result in significant civil penalties, injunctive relief, or statutory or actual damages as determined by the CPPA and California Attorney General through its investigative authority. Notably, comparable consumer privacy laws are set to take effect in 2023 in other states including the Virginia Consumer Data Protection Act (which took effect January 1, 2023), the Colorado Privacy Act and the Connecticut Data Privacy Act (both effective July 1, 2023), and the Utah Consumer Privacy Act (effective December 31, 2023). Compliance with these new privacy regulations may result in additional costs and expense of resources to maintain compliance.
- The European Union (the "EU") and United Kingdom ("UK") General Data Protection Regulation ("GDPR"), which applies extraterritorially, and imposes several strict requirements for controllers and processors of personal information, including higher standards for obtaining consent from individuals to process their personal information, increased requirements pertaining to the processing of special categories of personal information (such as health information) and pseudonymized (i.e., key-coded) data, and transfer of personal information from the EEA/UK/Switzerland to countries not deemed to have adequate data protections laws. In October 2022, President Biden issued an executive order to implement EU-U.S. data privacy safeguards. The European Commission is expected to review the executive order and could propose an adequacy decision concerning the level of personal information protection in the United States under which personal information could flow freely from the EEA to the United States. 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 noncompliance of up to €20 million or 4 percent of the annual global revenues of the noncompliant company, whichever is greater.
- In Japan, The Act on the Protection of Personal Information (the "APPI"), in effect since 2003 and amended several times, with the most recent amendments coming into effect in April 2022, provides a comprehensive data privacy and protection regime comparable to the GDPR to every Personal Information Controller ("PIC") in Japan that is either a person or an entity that handles personal information in the course of their or its business. PICs have legal obligations to secure personal information and report losses to the Japanese government. Noncompliance is regulated by the Personal Information Protection Commission, which has the power to issue orders for "improvement" in response to violations of privacy law by PICs that include civil and criminal penalties.

Compliance with these laws and regulations may require significant additional cost expenditures or changes in products or our business that increase competition or reduce revenue. As stated above, noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities, or withdrawal of non-compliant products from a market.

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.

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 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, 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, the COVID-19 pandemic and the responses thereto, the ongoing conflict between Russia and Ukraine and the responses thereto, global supply-chain disruptions or the tightening of the global labor market, or otherwise, our business, financial condition, and operating results could be adversely affected. A severe or prolonged economic downturn, could result in a variety of risks to our business, including driving hospitals to tighten budgets and curtail spending, which would negatively impact our sales and business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition, and results of operations.

Natural disasters, pandemics and man-made business disruptions such as war and terrorism could seriously harm 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 manufacturing facilities are located in Santa Clara, California, near major earthquake faults and fire zones. If a major earthquake, wildfire or other natural disaster were to damage our facilities or the facilities of our suppliers and service providers, or impact the ability of our employees or the employees of our suppliers and service providers to continue business operations, we may experience potential impacts ranging from production and shipping delays to lost revenues and increased costs. The occurrence of any of these natural or man-made disasters or other business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

In addition, our global operations expose us to risks associated with public health crises, such as pandemics and epidemics, which could harm our business and cause our operating results to suffer. The COVID-19 pandemic and related containment measures adversely affected our financial results and business operations during the year ended December 31, 2022 as we continued to experience disruptions in the operations of certain of our third-party suppliers. While the COVID-19 pandemic and related containment measures may continue to adversely impact our financial results and business operations in the future, the extent to which the pandemic will continue to adversely affect us will depend on numerous evolving factors and future developments that we are not able to predict, including the duration, spread and severity of any outbreak, the availability and effectiveness of vaccines against COVID-19, continued mutations of the virus and the impact of such mutations on transmission rates and vaccine efficacy, the nature, extent and effectiveness of

containment measures, the extent and duration of the effect on the economy, and how quickly and to what extent normal economic and operating conditions can resume.

Further, acts of war, terrorism, labor activism or unrest and other geopolitical unrest, including the ongoing conflict between Russia and Ukraine and the responses thereto, could cause disruptions in our business, the businesses of our partners or the economy as a whole. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Regulations related to conflict minerals may cause us to incur additional expenses and could limit the supply and increase the costs of certain materials used in the manufacturing of our products.

We are subject to requirements under the Dodd-Frank Act that require us to conduct due diligence on and disclose whether or not our products contain conflict minerals as defined under these provisions. The implementation of these requirements could adversely affect the sourcing, availability, and pricing of the materials used in the manufacture of components used in our products. In addition, we incur additional costs to comply with the disclosure requirements, including costs related to conducting diligence procedures to determine the sources of minerals that may be used or necessary to the production of our products and, if applicable, potential changes to products, processes, or sources of supply as a consequence of such due diligence activities. It is also possible that we may face reputational harm if we determine that certain of our products contain minerals not determined to be conflict free or if we are unable to alter our products, processes, or sources of supply to avoid such materials.

Investors' expectations of our performance relating to ESG factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, 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.

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, customers, employees and other stakeholders or our initiatives are not executed as planned, our reputation and business, operating results and financial condition could be adversely impacted. In addition, the SEC has also proposed a draft rule that requires climate disclosures in financial filings. To the extent the SEC proposal becomes effective for our company, we will be required to establish additional internal controls, engage additional consultants, and incur additional costs related to evaluating, managing and reporting on our environmental impact and climate-related risks and opportunities. If we fail to implement sufficient oversight or accurately capture and disclose on environmental matters, our reputation, business, operating results and financial condition may be materially adversely affected.

RISKS RELATED TO OUR PRODUCTS

We currently manufacture and sell products that are used in a limited number of procedures and for only certain specified indications, which could negatively affect our operations and financial condition.

Currently, our commercialized products consist primarily of our IVL system ("IVL System") using M^5 catheter, M^{5+} catheter and S^4 catheter for the treatment of PAD, and C^2 catheter for the treatment of CAD, each of which is available in the United States, Europe, and other international markets. We also market and sell our C^{2+} catheter for the treatment of CAD only in select markets in Europe and our L^6 catheter for the treatment of PAD only in the United States. We are therefore dependent on widespread market adoption of these products and we will continue to be dependent on the success of these products for the foreseeable future. There can be no assurance that our products will gain a substantial degree of market acceptance among specialty physicians, patients, or healthcare providers. Our failure to successfully increase sales

of these products or any other event impeding our ability to sell these products would result in a material adverse effect on our business, financial condition, and results of operations.

Our long-term growth depends on our ability to enhance our products, expand our indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire, and develop other products, we may be unable to grow our business over the long-term.

As a significant part of our growth strategy, we intend to develop and commercialize additional products through our research and development program or by licensing or acquiring additional products and technologies from third parties. The success of this strategy depends upon our ability to identify, select, and acquire the rights to products and technologies on terms that are acceptable to us. The success of any new product offering or product enhancements 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 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. We may not be able to acquire or license the rights to additional approved or cleared products on terms that we find acceptable, or at all.

If we are unable to develop suitable potential products through internal research programs or by obtaining rights from third parties, it could have a material adverse effect on our business, financial condition and results of operations.

If our products are not approved for planned or new indications, our commercial opportunity will be limited.

Our commercial strategy includes pursuing additional vascular indications for our products. Conducting clinical studies to obtain data for new or additional indications may require substantial additional funding. We cannot assure you that we will be able to successfully obtain clearance or approval for any of these additional product indications. Even if we obtain clearance or approval to market our products for additional indications in the United States or internationally, we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for new or additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations.

Product clearances and approvals can often be denied or significantly delayed and material modifications to our products may require new clearances or pre-market approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the *de novo* classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data. Our ability to enroll patients in clinical trials has been and may continue to be impacted by the ongoing COVID-19 pandemic.

The PMA process typically is more costly, lengthy, and stringent than either the 510(k) process or the *de novo* classification process. Unlike a 510(k) review, which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements, de novo classification, or additional 510(k) pre-market clearances to market modifications to our existing products, such as changes to the intended use or technological characteristics of our products. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether a device modification requires new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. For Class III devices, changes that affect safety and effectiveness will require the submission and approval of a PMA supplement. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing of the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications for new products or modifications to, or additional indications for, our products on a timely basis or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

The FDA may also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

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

Our products are approved for use in a limited number of countries and for only the indications and uses specified in the applicable approval. This prohibits our ability to market or advertise our products for any other indication, which could limit our growth. Additionally, our products are contra-indicated for use in the carotid or cerebrovascular arteries. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for a use that has not been cleared or approved by the FDA.

Use of a device outside of its cleared or approved indication is known as "off-label" use. We cannot prevent a physician from using our products for off-label uses, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, we are not allowed to actively promote or advertise our products for off-label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which are expensive and time-consuming. For more information regarding our regulatory risks, including those related to off-label use, see the section titled "*—Risks Related to Government Regulation and Our Industry*" below.

We currently require limited training in the use of our products incorporating our IVL technology ("IVL Technology") because we market primarily to physicians who are experienced in the interventional techniques required to use our devices. If demand for our products continues to grow, less experienced physicians will likely use our products, potentially leading to more injury and an increased risk of product liability claims. The use, misuse or off-label use of our products may in the future result in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We may experience numerous unforeseen events in relation to a clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products, modifications of existing products or new indications for existing products, including:

- risks relating to clinical trial approvals, including:
  - delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities, including in relation to the design, protocol or implementation of our clinical trials; and
  - delay or refusal of regulators or institutional review boards ("IRBs") to authorize us to commence a clinical trial at a prospective trial site.

- risks relating to clinical trial enrollment and trial management, including:
  - delays or failure to reach agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
  - slower enrollment in our clinical trials than anticipated, high screen failure rates in our clinical trials, or delays in patient enrollment and variability in the number and types of patients available for clinical trials;
  - lower than anticipated retention rates of patients and volunteers in clinical trials or difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
  - delays relating to adding new clinical trial sites or issues managing multiple clinical sites;
  - our CROs or clinical trial sites may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or deviate from the protocol or drop out of a trial;
  - we, the applicable IRBs, the Data Safety Monitoring Board for such trial, or the FDA or other applicable regulatory authorities may require that we or our investigators suspend or terminate our clinical trials for various reasons, including, among others (i) failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current GCP, regulations, or our clinical protocols, (ii) inspection of the clinical trial operations or trial site by the FDA or other applicable regulatory authority resulting in the imposition of a clinical hold, (iii) unforeseen safety issues or adverse side effects, (iv) failure to demonstrate safety and effectiveness, (v) changes in governmental regulations or administrative actions, (vi) lack of adequate funding to continue the clinical trial, (vii) exposure of participating patients to unacceptable health risks, (viii) noncompliance with regulatory requirements, or (ix) other safety concerns; and
  - we may exceed our budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.
- risks related to clinical trial results, including:
  - our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials and/or preclinical testing which may be expensive and time-consuming, or we may elect to abandon projects that we expected to be promising;
  - reports from preclinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
  - trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
  - the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans; and
  - the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials differently than we do.
- risks related to investigation devices used in the clinical trial, including:
  - the quality of the investigation devices may fall below acceptable standards;
  - we may be unable to manufacture sufficient quantities of our products to commence or complete clinical trials; and
  - the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory.

In addition, we may encounter delays if the FDA concludes that our financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or

and stock awards in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

We do not know whether any of our future preclinical studies or clinical trials will commence as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence sales and generate associated revenue with respect to the applicable product. Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial, suspension, or revocation of expanded regulatory clearance or approval of our products. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products.

From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products.

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, including GCP guidelines, the Common Rule, and FDA human subject protection regulations. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials on our products properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant, or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products.

The continuing development of our products depends upon our 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 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.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. For example, we may be required to change our production processes and assembly methods in order to accommodate any significant future expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

We produce a significant majority of our IVL catheters at our facility in Santa Clara, California, therefore any contamination of the controlled environment, equipment malfunction or failure to strictly follow procedures could significantly reduce our yield. A drop in yield could increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield could require substantial time and resources.

If our manufacturing activities are adversely impacted or if we are otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

We depend upon third-party suppliers and contract manufacturers, including single source component suppliers and a third-party contract manufacturer that produces a portion of our demand for certain catheters, making us vulnerable to supply problems and price fluctuations.

We depend on our third-party contract manufacturer located in Costa Rica to manufacture a portion of the demand for certain catheters. If our contract manufacturers fail to deliver the required commercial quantities of finished products on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue.

We also rely on third-party suppliers to provide us with components used in the manufacturing of our products. Certain components of our products are provided by single source suppliers. In some cases, we purchase supplies through purchase orders and do not have long-term supply agreements with, or guaranteed commitments from, our component suppliers, including single source suppliers.

We depend on our suppliers and contract manufacturers to provide us with materials or products in a timely manner that meet our quality, quantity, and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, including as a result of the ongoing COVID-19 pandemic and ongoing global supply chain disruptions, any of which could delay or impede their ability to meet our demand. For example, the COVID-19 pandemic has disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times for our purchases of some components and, in certain cases, requiring us to incur higher logistics expenses. We have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand and have not experienced material disruptions in our supply chain to date. However, there is no assurance that we will not experience more significant disruptions in our supply

chain in the future, particularly if the operations of our contract manufacturing partners or any of our critical single source component providers are more severely impacted by the pandemic and associated containment measures. Any supply interruption from our suppliers and contract manufacturers or failure to obtain additional suppliers or contract manufacturers for products or any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. These suppliers and contract manufacturers may cease producing the products or components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation.

In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe alternate suppliers and contract manufacturers exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers or contract manufacturers for any of these materials, components or services, if required, could be time-consuming, expensive and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers or contract manufacturers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay or which may not be obtained at all. If our third-party suppliers or contract manufacturers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or contract manufacturers capable of production at a substantially equivalent cost, volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

We and our third-party manufacturers and suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and various non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain Good Manufacturing Practices (“cGMP”), including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our product and component manufacturers and suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we, our products, our component suppliers or our contract manufacturers comply or will continue to comply with all regulatory requirements. The failure by us or one of our suppliers or contract manufacturers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, until a new supplier or contract manufacturer has been identified and evaluated. Our or any product or component supplier’s or contract manufacturer's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers or contract manufacturers to satisfy our business requirements, we can locate new suppliers or contract manufacturers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

In the EU, we must maintain certain International Organization for Standardization certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution (“BSI”), to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations.

Our success depends in large part on our IVL Technology. If we are unable to successfully market and sell products incorporating our IVL Technology, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.

Our future financial success will depend substantially on our ability to effectively and profitably market and sell our products incorporating our IVL Technology. The commercial success of our products and any of our planned or future products will depend on a number of factors, including:

- the actual and perceived effectiveness and reliability of our products, especially relative to alternative products;
- the prevalence and severity of any adverse patient events involving our products;
- the results of clinical trials relating to the use of our products;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to obtain regulatory approval to market our planned or future products for use in treating PAD, CAD and aortic stenosis ("AS") in the United States;
- 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 IVL Technology and our products that incorporate our IVL Technology;
- our ability to treat medial calcium and sustain a meaningful clinical benefit better than our competitors and alternative treatments or therapies;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products;
- the extent to which we are successful in educating physicians about PAD, CAD and AS in general, and the benefits of our products in treating such conditions;
- the strength of our marketing and distribution infrastructure;
- the effectiveness of our and our distributors' marketing and sales efforts outside the United States and our own efforts to build and manage our internal sales team;
- the level of education and awareness among physicians and hospitals concerning our products;
- our reputation among physicians and hospitals;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current cGMP and the Quality System Regulation ("QSR"); and
- whether the FDA or comparable non-U.S. regulatory authorities require us to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition, and results of operations. Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our products and any new product or product indications that we introduce, which will, in turn, depend in part on our success in growing our customer base and driving increased use of our products. New products or product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition, and results of operations.

The commercial success of our products will depend upon attaining significant brand awareness and market acceptance of our products among physicians, healthcare payors and the medical community.

Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to providers, cost effective. To accomplish this, we need to continue to educate the medical community about the safety, efficacy, necessity, and efficiency of our products. This will require educating them not only about the benefits of our technology, but also about the impact of calcified plaque on treatment choices and outcomes. We believe that focusing on calcified plaque is a paradigm shift in the treatment of atherosclerotic cardiovascular diseases because other interventions have not specifically focused on this source of atherosclerosis. Additionally, we will need to convince the medical community that the additional cost and time of integrating the IVL procedure, designed to prepare the vessel for the subsequent stenting or angioplasty procedure, is worth the increased efficacy of the overall procedure and improvement in patient outcomes.

The failure of our clinical, marketing, and executive teams to drive this shift in thinking among physicians, patients, practitioners, third-party payors, and regulators could adversely affect our ability to grow our business. We cannot predict how quickly, if at all, physicians will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop, may never gain broad market acceptance among physicians and the medical community for some or all of our targeted indications. The degree of market acceptance of any of our products will depend on a number of factors, including:

- whether physicians and others in the medical community consider our products to be safe and cost-effective treatment methods;
- the potential and perceived advantages of our products over alternative treatment methods;
- the prevalence and severity of any side effects associated with using our products;
- product labeling or product insert requirements by the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities;
- the cost of treatment in relation to alternative treatments methods;
- the convenience and ease of use of our products relative to alternative treatment methods;
- pricing pressure, including from group purchasing organizations (“GPOs”), seeking to obtain discounts on our products based on the collective buying power of the GPO members;
- a substantial shift in the number of PAD procedures that are performed in office-based labs (“OBLs”) compared to those performed in a hospital as OBLs tend to have higher price sensitivity than hospitals;
- the availability of coverage and adequate reimbursement for procedures using our products from third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- our ability to provide incremental clinical and economic data that show the safety, clinical efficacy and cost effectiveness of, and patient benefits from, our products; and
- the effectiveness of our sales and marketing efforts for our products.

If we do not educate physicians about PAD and the existence of our products, our products may not gain market acceptance since many physicians do not routinely screen for PAD while screening for CAD. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies, which are more cost effective or received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

In addition, we believe that developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our products.

We manufacture and sell products that are used in a limited number of procedures and there is a limited total addressable market for our products. The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with calcified cardiovascular disease and 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 PAD and CAD patient populations include patients who are asymptomatic or in the early stages of disease; these patients might never progress to more advanced disease stages and, accordingly, might never be likely candidates for treatment with our products. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition, and results of operations.

The market in which we participate is highly competitive, and if we do not compete effectively, our business, operating results and financial condition could be adversely impacted.

There are numerous approved products for treating vascular diseases in the indications in which we have received clearance or approval and those that we are pursuing or may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients, and third-party payors who may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete or plan to compete with manufacturers and distributors of cardiovascular medical devices. The cardiovascular field is highly competitive and certain of our products may compete with products manufactured or reportedly under development by other companies, including Boston Scientific Corporation, Cardiovascular Systems, Inc. ("CSI"), Medtronic plc, Philips N.V. and Abbott Laboratories. Many of these competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We may also compete with smaller medical device companies that have single products or a limited range of products. Some of our competitors have:

- more established reputations and significantly greater name recognition within the medical community;
- greater ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets;
- broader or deeper relations with healthcare professionals, customers, regulatory agencies and third-party payors;
- larger and more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing, clinical resources and patent litigation.

We believe that our proprietary IVL Technology, our focus on calcified cardiovascular disease, and our organizational culture and strategy, will be important factors in our future success. In response to attempts by companies to claim their products are competitive, we emphasize that our products are unique and treat patients with calcified cardiovascular disease safely and effectively, with improved outcomes and procedural cost savings.

In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business. Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide products and services to industry participants, as well as competition for materials and supplies for our products, will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, results of operations or financial condition.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our products, which would have a material adverse effect on our business, financial condition, and results of operations.

In the future our products may become obsolete, which would negatively affect operations and financial condition.

The medical device industry is characterized by extensive research and rapid and significant technological change. There can be no assurance that other companies will not succeed in developing or marketing devices and products that are more effective than our IVL System or that would render our IVL System obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend, in part, on our ability to anticipate technological advancements and competitive innovations and introduce new products to adapt to these advancements and innovations.

There can be no assurance that (i) our new product development efforts will result in any commercially successful products, (ii) we will be able to respond more quickly than our competitors, many of whom have greater financial, marketing, product development, and other resources, to new or emerging technologies or a changing clinical landscape, or (iii) we will be more successful in attracting potential customers and strategic partners than our competitors. Given these factors, we cannot assure you that we will be able to sustain or increase our level of success. Our failure to introduce new and innovative products in a timely manner, and our inability to maintain or grow the market acceptance of our existing products, could have a material and adverse effect on our business, results of operations, financial condition, and cash flows.

Adequate reimbursement may not be available for the procedures that utilize our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Third-party payors in the United States generally do not provide direct reimbursement for our products. Rather, we expect certain components of our IVL System to continue to be purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using our products. While third-party payors generally cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, to permit hospitals and physicians to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. Third-party payors are increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Furthermore, although we believe there is potential to improve on the current reimbursement profile for our devices in the future, the overall amount of reimbursement available for PAD and CAD procedures could remain at current levels or decrease in the future. Additionally, we cannot be sure that the PAD and CAD procedure reimbursement amounts will not reduce or otherwise negatively affect the demand for our marketed products. Failure by hospitals and other users of our products to obtain coverage and adequate reimbursement for the procedures using our products would cause our business to suffer.

Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such marketed products.

We have established safety and effectiveness data in specific patient populations in the treatment of PAD and CAD. Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for such products and other planned or future products, which would affect market acceptance of these products.

Because our IVL Technology is relatively new in the treatment of CAD and PAD, we have performed clinical trials only with limited patient populations. The long-term, one-year results of coronary IVL has been studied within stable coronary disease. Short-term and long-term results in this patient population are not predictive for other coronary indications including acute coronary syndromes. Short-term results of peripheral IVL in the treatment of PAD have been studied across a variety of peripheral vessel beds and severity of PAD. The long-term effects of peripheral IVL in a large number of patients have not been released yet and the results of short-term clinical outcomes do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

The results of preclinical studies and clinical trials of our products conducted to date may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier, feasibility clinical trials have nonetheless failed to replicate results in later, pivotal clinical trials and subsequently failed to obtain marketing approval. Products in later, pivotal stages of clinical trials may fail to show the desired safety and effectiveness despite having progressed through nonclinical studies and earlier, feasibility clinical trials.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.

The medical device industry has historically been subject to extensive litigation over product liability claims. We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing, or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales. Defending a product liability suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals. In addition, the occurrence of an adverse event relating to our products, a product recall or a product liability claim against us may cause our stock price to decline, which could result in securities class action litigation claims against us.

Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

We intend to continue to expand sales of our products internationally, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our products internationally even if approved. A variety of risks associated with marketing our products internationally could materially adversely affect our business.

While the majority of our revenue to date has been in the United States, our current products are cleared in the EU and certain other international markets for the treatment of PAD and CAD, and international sales comprised 17% of our revenue for the year ended December 31, 2022. Our future growth may depend, in part, on our ability to develop and commercialize our planned and future products in foreign markets. Sales of our products outside of the United States are and will be subject to foreign regulatory requirements governing clinical trials and marketing approval. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our planned or future products. We will incur substantial expenses in connection with our international expansion. Additional risks related to operating in foreign countries include:

- reliance on distributors;
- differing regulatory requirements for approval of medical devices in foreign countries;
- differing reimbursement, pricing and insurance regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses, reduced revenue and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties in penetrating markets in which our competitors' products or alternative procedures that do not use our products are more established;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the U.K. Bribery Act 2010, or comparable foreign regulations;
- the impact of the UK's departure from the EU;
- the existence of additional third-party patent rights of potential relevance to our business;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities domestically or abroad, including as a result of the ongoing global supply chain disruptions;
- inflation and rising interest rates;
- events resulting in negative impacts to, or uncertainty regarding, global trade, such as the COVID-19 pandemic, and the reversal or renegotiation of international trade agreements and partnerships; and
- business interruptions resulting from geopolitical actions, including war and terrorism, such as the ongoing conflict between Russia and Ukraine and the responses thereto, or natural disasters, including earthquakes, typhoons, floods and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, there can be no guarantee that we will receive approval to sell our products in every international market we target, nor can there be any guarantee that any sales would result even if such approval is received. Even if the FDA grants marketing approval for a product, comparable regulatory authorities of foreign countries must also approve the manufacturing or marketing of the product in those countries. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties, and costs for us and require additional trials and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could negatively affect our business, financial results, and results of operations.

We face additional credit and compliance risks related to our international sales using foreign distributors.

We partner with distributors for our products in select geographies outside of the United States. Specifically, as of December 31, 2022, we have contracted with distributors who are actively selling our products in over 55 countries in North and South America, Europe, the UK, the Middle East, Asia, Africa, and Australia/New Zealand. For the year ended December 31, 2022, approximately 17% of our sales were outside of the United States. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our results of operations. In addition, 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 export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of 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 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 prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new 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 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 U.K. Bribery Act and violations of these laws could result in substantial penalties and prosecution.

For our sales and operations outside the United States, we are subject to various heavily enforced anti-bribery and anti-corruption laws, such as the FCPA, U.K. Bribery Act 2010, and similar laws around the world. These laws generally prohibit offering, promising, authorizing or making improper payments, directly or indirectly, for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we or our third-party business partners and intermediaries fail to comply with the FCPA or other anti-corruption and anti-bribery laws.

We leverage various third parties to conduct our business and sell our products abroad, including to government-owned universities and hospitals. We, our distributors, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations or licenses or sales to government owned or controlled healthcare facilities, universities, institutes, clinics, etc.) and we may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, representatives, contractors, business partners, intermediaries, or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO GOVERNMENT REGULATION AND OUR INDUSTRY

If we fail to comply with U.S. federal and state and international fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business operations and financial condition could be adversely affected.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have obtained or may in the future obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals, third-party payors, and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures,

but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute (the "Anti-Kickback Statute") and the federal civil False Claims Act (the "False Claims Act"). Our relationships and our distributors' relationships with physicians, other health care professionals and hospitals are subject to scrutiny under various state and federal anti-kickback laws. There are similar laws in other countries.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include the Anti-Kickback Statute, the False Claims Act, federal Civil Monetary Penalties Statute, the federal Health Insurance Portability and Accountability Act ("HIPAA"), and the Physician Payments Sunshine Act, along with analogous state and foreign law equivalents, each as more fully described in in the sections titled "*Business—Government Regulation—United States*" and "*Business—Government Regulation—International.*"

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies recently have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, False Claims Act and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including certain sales and marketing practices of our marketed IVL System, and financial arrangements with physicians, other healthcare providers, and other customers, could be subject to challenge under one or more such laws. For example, in the United States and certain foreign countries, we may loan for free to customers both the reusable IVL generator and connector cable so long as the customer is purchasing our single-use catheters. Customers also have the option to purchase the IVL generator and connector cable either at the initiation of the relationship or following the consignment period. Additionally, we may consign catheters to our customers, free of charge, until a catheter is used at which time the customer is billed for the catheter. The Anti-Kickback Statute includes, among others, space and equipment rental safe harbors. These safe harbors require, among other things, that the aggregate payment between the parties is set in advance and consistent with fair market value. As the IVL generator and connector cable are provided for free, and no payment is made for storage of our catheters at customers' facilities, these arrangements may not satisfy these or other safe harbors or statutory exceptions. Therefore, if these arrangements were investigated, they would be subject to a facts and circumstances analysis to determine whether they include prohibited remuneration under the Anti-Kickback Statute. If an arrangement were deemed to violate the Anti-Kickback Statute, 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 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.

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 agencies specific to medical devices are wide-ranging and include, among other things, oversight of:

- product design, development, manufacturing (including suppliers) and testing;
- laboratory, preclinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- 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 C^2 catheter for the treatment of CAD is designated as a Class III product and will follow the PMA process. As a company, 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 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, injunctions, fines, civil penalties, and criminal prosecution. The FDA 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 or state agencies, 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;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- 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 also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, 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 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.

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 in the United States and in certain non-U.S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, effectiveness and other post-market information, including both federal and state requirements in the United States and requirements of comparable non-U.S. regulatory authorities.

Our manufacturing facility is required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) or PMA application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals 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 IVL catheters in-house at our facility in Santa Clara, California, which, together with our research and development, controlled environment room and office space, currently totals approximately 166,000 square feet. Our Santa Clara facility has been inspected by the FDA and audited by the BSI. We have also entered into a contract manufacturing agreement with a third-party contract manufacturer to produce a portion of the demand for certain catheters. We can provide no assurance that the FDA or other inspecting bodies will continue to find us or our suppliers to be in compliance with the QSR. If our or our contract manufacturer's facilities are found to be in noncompliance or if we fail to take satisfactory corrective action in response to adverse QSR inspectional findings, the FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the recall of distributed products, which could impair our ability to manufacture our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Taking corrective action may be expensive, time-consuming and a distraction for management, and if we experience a shutdown or delay at our manufacturing facilities, we may be unable to manufacture our products, which would harm our business.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA and other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend or prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or pursuing the operations and activities in question, including the continued manufacturing and sale of any impacted product.

Various claims, design features or performance characteristics of our medical devices that we may regard as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in our products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended (the "ACA"), was enacted. The ACA is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, (the latter of which since made non-enforceable), the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. The ACA has impacted existing government healthcare programs and has resulted in the development of new programs.

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to modify them or to alter their interpretation and implementation. It is possible that the ACA will be subject to further judicial challenges or Congressional modifications in the future. It is unclear how any efforts to challenge or modify the ACA or its implementing regulations, or portions thereof, or other healthcare reform measures, will impact our business.

In addition, other healthcare reform legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of, on average, 2% per fiscal year. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031.

Legislation affecting the implementation of certain taxes under the ACA has also been signed into law, including the TCJA, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 20, 2019, the Further Consolidated Appropriations Act of 2020 repealed the medical device excise tax. Prior to the repeal, the tax was on a 4-year moratorium. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We cannot assure you that the ACA, as currently enacted or as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels, as well as internationally, directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In the United States in recent years, new legislation has been proposed and adopted at the federal and state levels that is effecting major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted and we may not be able to comply with the changed laws, they could increase the cost of manufacturing, marketing, or selling our product, could make approvals of pipeline products more difficult or prevent us from selling our products at all. We expect there will continue to be a number of legislative and regulatory changes to the U.S. health care system that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof and may impose additional costs or lengthen regulatory review times of planned or future products.

If, as a result of legislative or regulatory healthcare reform, we cannot sell our products profitably, whether due to our own inability to comply with, or the inability of other economic operators in our supply chain to qualify under, any legislative reform, our business would be harmed. In addition, any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

For example, in April 2017, the EU adopted a new Medical Devices Regulation (Regulation 2017/745) (“MDR”), which became effective May 26, 2021 and replaced the EU’s Medical Devices Directive (93/42/EEC) (“MDD”). Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The MDR is significantly more comprehensive and detailed than the MDD. Among other things, the MDR requires manufacturers to report on the composition of their products and verify the presence of any of 1,200 substances referenced in the MDR. Medical devices that have a valid CE Mark under MDD can continue to be sold until May 2024 or until the CE Mark expires, whichever comes first, provided there are no significant changes to the design or intended use of the device. Complying with the new requirements of MDR may cause regulatory authorization timelines for future medical device products to become extended and significantly increase the costs of obtaining and maintaining CE Marks for our products. Adjusting to MDR may be costly and disruptive to our business.

Broader legislative changes may also impact our operations. The UK held a referendum on June 23, 2016, in which voters approved withdrawal from the EU (commonly referred to as Brexit). On January 31, 2020, the UK withdrew from the EU and the transition period ended on December 31, 2020. The UK and EU reached agreement regarding their future relationship on December 24, 2020. As a result of Brexit, there may be greater restrictions on imports and exports into and out of the UK and EU countries and regulatory complexities that could adversely impact our business.

Environmental and health safety laws may result in liabilities, expenses, and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers’ operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs.

Environmental laws and regulations could become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition, and results of operation.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain patent or other intellectual property protection for our products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be adversely affected.

As with other medical device companies, our success depends in large part on our ability to maintain and solidify a proprietary position for our products, which will depend upon our success in obtaining and enforcing effective intellectual property (including patent claims) that cover the use, functionality and manufacture of such products. With respect to patents specifically, the process for filing, maintaining and enforcing rights in or obtaining licenses for patents is complex and subject to many risks and uncertainties, including the following:

- ***Protection of Confidential Information***. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.
- ***Patentability***. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. We cannot be certain that we were the first to make or file the inventions claimed in any of our patents or pending patent applications. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.
- ***Patent Prosecution Process***. The patent prosecution process is expensive, time-consuming, and complex, 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 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.
- ***Reduction in Scope of Patent***. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or reduced after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage.
- ***Patent Maintenance Requirements***. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the U.S. Patent and Trademark Office (the "USPTO") and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. Failure to comply with such requirements may result in the abandonment of a patent application or the lapse of a patent in one or more jurisdictions.

- ***Patent Lifespan***. Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. While various extensions may be available, the life of a patent, and the protection it affords, is limited. 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.
- ***Third-Party Claims***. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. For more information on the risks relating to third party claims, see "*—Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad."*
- ***Third-Party Rights***. Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.
- ***Patent Licenses***. Many medical device companies and academic institutions are competing with us and filing patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for planned or future products, for a variety of reasons, including actions of competitors and interests of the potential licensor. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products.
- ***Changes in Patent Laws***. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. For more information on the risks relating to changes in patent laws, see "*—Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products*."

Consequently, we do not know whether our IVL products and technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, and results of operations. If we or any current or future licensors or licensees fail to

establish, maintain, protect, or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. Any such outcome could impair our ability to prevent competition from third parties, which may have an adverse impact on our business and results of operations.

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, petitions for IPR of U.S. Pat. No. 9,642,673 (the "'673 patent"), U.S. Pat. No. 8,956,371 (the "'371 patent") and U.S. Pat. No. 8,728,091 (the "'091 patent"), which are three of our issued U.S. patents that relate to our IVL Technology, were filed in December 2018 at the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB") by CSI, one of our competitors. The PTAB instituted IPR proceedings for all three patents and held oral hearings in April 2020. On January 18, 2022, the U.S. Court of Appeals for the Federal Circuit issued two opinions affirming the previous decisions of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, finding that the claims for the '673 patent and the '091 were invalid. Accordingly, the IPR proceedings initiated by CSI for the '091 patent and the '673 patent are concluded and resulted in the loss in scope of these two patents, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

On July 8, 2020, the PTAB ruled that one claim ("Claim 5") in the '371 patent is valid and ruled that all other claims in the '371 patent are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB's decision in the '371 patent proceeding. In addition, the PTAB reset the time for commencement of an appeal in the '371 patent proceeding pending the entry of a final decision after the requested briefing. The requested briefing is complete and the PTAB's decision is pending. On March 9, 2022, the PTAB issued an order authorizing us to file a motion for additional discovery. On March 23, 2022, we filed a motion for additional discovery, relating to additional information publicized by CSI after the PTAB's decision on the patents. On February 2, 2023, the PTAB denied the motion for additional discovery and issued a final decision, ruling again that Claim 5 is valid and that all other claims are invalid. We will be pursuing further review and appeal of this ruling. Accordingly, Claim 5 and all other claims in the '371 patent remain valid and enforceable until all appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the '371 patent proceedings could result in the loss or narrowing in scope of the '371 patent, which could further limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art,

of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products.

Any loss or limitation of patent protection could have a material adverse effect on our business, financial condition, and results of operations.

Changes in 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 will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. The number of IPR challenges filed is increasing, and in many cases, the USPTO is canceling or significantly narrowing issued patent claims. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs 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 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 that may ultimately issue with claims that we 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 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 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 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 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 may become involved 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 may 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 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 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 OWNERSHIP OF OUR COMMON STOCK

The market price of our common stock has been and may continue to be highly volatile.

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control. From January 1, 2022 through December 31, 2022, the closing price of our common stock has ranged from $115.91 per share to $310.53 per share. Stock markets in general and the market for medical device companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm 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 rising interest rates, inflation, as well as the COVID-19 pandemic and the ongoing conflict in Ukraine and the responses thereto; and
- other events or factors, many of which are beyond our control.

In addition, in recent years the trading prices for common stock of other medical device companies have been highly volatile. In the past, following periods of volatility in the trading price of a company's securities, securities class action litigation has often been brought against that company. If the market price of our common stock is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could have an adverse effect on our business, operating results, and financial condition.

An active trading market for our common stock may not be sustained.

Our common stock is currently listed and trades on the Nasdaq under the symbol "SWAV." We cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our common stock when desired, or the prices that you may obtain for your shares.

We do not intend to pay dividends on our common stock, so any returns will be limited to increases, if any, in our stock's value. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2022, our executive officers, directors and 5% stockholders beneficially owned approximately 33% of the outstanding shares of capital stock. As of December 31, 2022, we had 36,235,546 shares of common stock outstanding. Accordingly, these stockholders have a material influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, mergers, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with the interests of our other stockholders. For example, these stockholders could attempt to delay or prevent a change in control of the Company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise.

As of December 31, 2022, our executive officers and directors held options to purchase an aggregate of 882,481 shares of our common stock at a weighted-average exercise price of $5.50 per share and 264,153 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 restated certificate of incorporation provides 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 restated certificate of incorporation provides 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 restated certificate of incorporation provides 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 restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices are located in Santa Clara, California where we lease approximately 166,000 square feet of office, lab and manufacturing space under leases expiring in December 2031. In addition, we produce a significant number of our IVL catheters 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 we are in the process of constructing two buildings to build-out our manufacturing capabilities. We believe that our facilities are adequate to fit our current and future anticipated needs.

Item 3. Legal Proceedings.

Petitions for inter partes review ("IPR") of U.S. Pat. No. 9,642,673 (the "'673 patent"), U.S. Pat. No. 8,956,371 (the "'371 patent") and U.S. Pat. No. 8,728,091 (the "'091 patent"), which are three of our issued U.S. patents that relate to our current IVL technology, were filed in December 2018 at the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc. ("CSI"), one of our competitors. The PTAB instituted IPR proceedings for all three patents and held oral hearings in April 2020. On January 18, 2022, the U.S. Court of Appeals for the Federal Circuit issued two opinions affirming the previous decisions of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, finding that the claims for the '673 patent and the '091 were invalid. Accordingly, the IPR proceedings initiated by CSI for the '091 patent and the '673 patent are concluded and resulted in the loss in scope of these two patents, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

On July 8, 2020, the PTAB ruled that one claim ("Claim 5") in the '371 patent is valid and ruled that all other claims in the '371 patent are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB's decision in the '371 patent proceeding. In addition, the PTAB reset the time for commencement of an appeal in the '371 patent proceeding pending the entry of a final decision after the requested briefing. The requested briefing is complete and the PTAB's decision is pending. On March 9, 2022, the PTAB issued an order authorizing us to file a motion for additional discovery. On March 23, 2022, we filed a motion for additional discovery, relating to additional information publicized by CSI after the PTAB's decision on the patents. On February 2, 2023, the PTAB denied the motion for additional discovery and issued a final decision, ruling again that Claim 5 is valid and that all other claims are invalid. We will be pursuing further review and appeal of this ruling. Accordingly, Claim 5 and all other claims 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 22, 2023, there were 18 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.

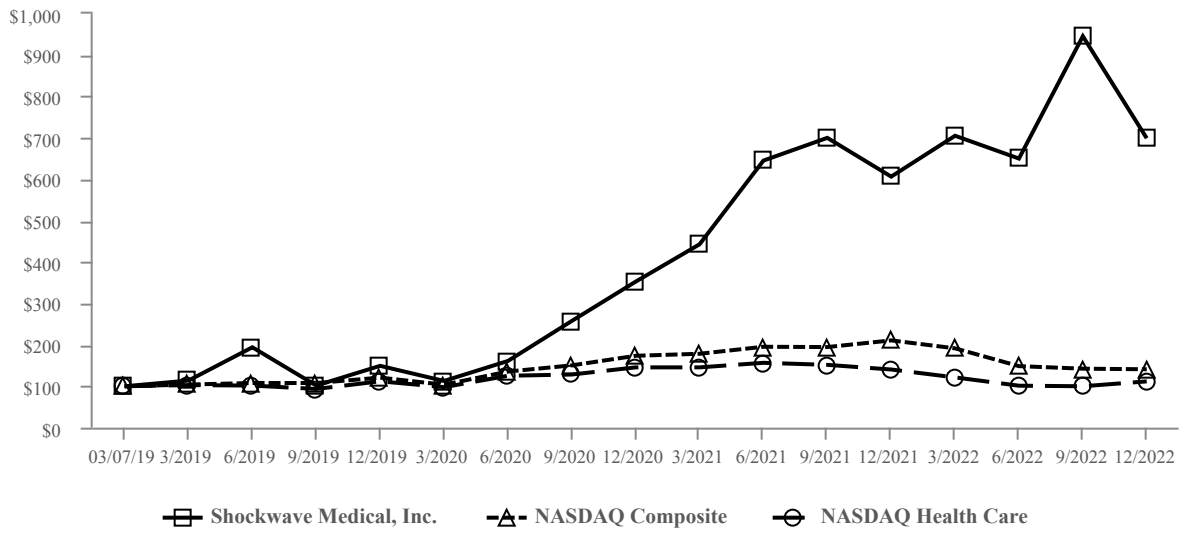
Stock Performance Graph

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 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, 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 products intended to transform the way calcified cardiovascular disease is treated. 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. Our IVL catheters 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:

Products for Treatment of Peripheral Artery Disease ("PAD"):

- Our Shockwave M^5 IVL catheter ("M^5 catheter") and M^{5+} IVL catheter ("M^{5+} catheter") are five-emitter catheters for use in our IVL System in medium diameter vessels for the treatment of PAD. The M^5 catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018. The M^{5+} catheter was CE-Marked in November 2020 and cleared by the FDA in April 2021. In May 2022, we obtained regulatory approval, through our joint venture with Genesis MedTech

International Private Limited ("Genesis"), from the China National Medical Products Administration ("NMPA") to sell our M^5 catheter in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "PRC").

- Our Shockwave S^4 IVL catheter ("S^4 catheter") is a four-emitter catheter for use in our IVL System in small diameter vessels for the treatment of PAD. The S^4 catheter was CE-Marked in April 2018. The second version of our S^4 catheter was cleared by the FDA in August 2019 and accepted by our EU notified body in May 2020 for use in our IVL System. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our S^4 catheter in the PRC.
- Our Shockwave L^6 IVL catheter ("L^6 catheter") is a six-emitter catheter for use in our IVL System in large diameter vessels for the treatment of PAD. Our L^6 catheter was cleared by the FDA in August 2022 for use in our IVL System. We commenced a U.S. limited market release for our L^6 catheter in the fourth quarter of 2022.

Product for the Treatment of Coronary Artery Disease ("CAD"):

- Our Shockwave C^2 IVL catheter ("C^2 catheter") and C^{2+} IVL catheter ("C^{2+} catheter") are two-emitter catheters for use in our IVL System for the treatment of CAD. The C^2 catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C^2 catheter using our IVL System for the treatment of CAD. We received FDA approval of our C^2 catheter in February 2021. In March 2022, we received regulatory approval in Japan for our C^2 catheter and commenced a limited market release in Japan in May 2022 followed by a full market release in January 2023. In May 2022, we obtained regulatory approval, through our joint venture with Genesis, from the NMPA to sell our C^2 catheter in the PRC. The C^{2+} catheter was CE-Marked in August 2022 and approved by FDA in December 2022. In the fourth quarter of 2022, we commenced a limited market release for our C^{2+} catheter in select international locations.

Our differentiated range of IVL catheters enables delivery of IVL therapy to diseased vasculature throughout the body for calcium modification. Our IVL catheters resemble in form a standard balloon angioplasty catheter, the device most commonly used by interventionalists. This familiarity makes our IVL System easy to learn, adopt and use on a day-to-day basis.

Since inception, we have focused on generating clinical data to demonstrate the safety and effectiveness of our IVL Technology. These studies have consistently shown low rates of complications regardless of which vessel was being studied. In addition to supporting our regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of our IVL Technology across multiple therapies in existing and new market segments. Our past studies have also guided optimal IVL procedure technique and informed the design of our IVL System and future 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. For a discussion of our current clinical trials, see the section titled "*Business – Company Overview – Our Products and Product Pipeline*" in Part 1, Item 1 of this Annual Report on Form 10-K.

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. In the future, we see significant opportunity in the potential treatment of aortic stenosis, a condition where the heart's aortic valve becomes increasingly calcified with age, causing it to narrow and obstruct blood flow from the heart.

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 shockwaves 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 shockwaves crack this calcium and enable the stenotic 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.

We market our products to hospitals whose interventional cardiologists, vascular surgeons and interventional radiologists treat patients with PAD and CAD. We have dedicated meaningful resources to establish a direct sales capability in the United States, Germany, Austria, Switzerland, France, Ireland, Japan and the United Kingdom, which we have complemented with distributors actively selling our products 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.

For the years ended December 31, 2022, 2021 and 2020, we generated revenue of $489.7 million, $237.1 million and $67.8 million, respectively. For the years ended December 31, 2022, 2021 and 2020, 17%, 21% and 45%, 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, 2022, 2021 and 2020, we had net income of $216.0 million and incurred net losses of $9.1 million and $65.7 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 year ended December 31, 2022, we may continue to 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 the sales of our common stock in our public offerings, private sales of our equity securities, payments received from customers purchasing our products and, to a lesser extent, proceeds from our debt financings. For the year ended December 31, 2022, we had generated positive cash flows from operations of $117.7 million. As of December 31, 2022, we had $304.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of $36.8 million.

Impact of current global economic conditions

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including as a result of inflation and rising interest rates, geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, supply chain disruptions and the remaining effects of the COVID-19 pandemic. 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 IVL catheters, 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 representatives, as well as through distributors in selected international markets. For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. Additionally, a portion of our revenue is generated through a consignment model under which inventory is maintained at hospitals. For consignment inventory, control is transferred at the time the catheters are consumed in a procedure.

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 depreciation 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 depreciate the equipment over a three-year period. We expect cost 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 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 expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and Securities and Exchange Commission ("SEC") compliance and investor relations.

Loss from equity method investment

Loss from equity method investment, represents our proportionate share of the underlying income or loss incurred in connection with our joint venture with Genesis. Also included in 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 Amended SVB Credit Agreement and Credit Agreement (as defined below) and the loss on debt extinguishment related to the repayment of our Amended SVB 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 and the release of a substantial portion of our valuation allowance on our deferred tax assets.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021:

	Year Ended December 31,		Change	Change
	2022	2021	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 489,733	$ 237,146	$ 252,587	107%
Cost of revenue:				
Cost of product revenue	64,996	41,438	23,558	57%
Gross profit	424,737	195,708	229,029	117%
Operating expenses:				
Research and development	81,679	50,544	31,135	62%
Sales and marketing	161,995	111,288	50,707	46%
General and administrative	56,929	34,747	22,182	64%
Total operating expenses	300,603	196,579	104,024	53%
Income (loss) from operations	124,134	(871)	125,005	*
Loss from equity method investment	(2,475)	(6,286)	3,811	(61%)
Interest expense	(1,886)	(1,096)	(790)	72%
Other income (expense), net	1,055	(582)	1,637	(281)%
Net income (loss) before taxes	120,828	(8,835)	129,663	*
Income tax (benefit) provision	(95,168)	301	(95,469)	*
Net income (loss)	$ 215,996	$ (9,136)	$ 225,132	*

* Not meaningful.

Product revenue. Product revenue increased by $252.6 million, or 107%, from $237.1 million in 2021 to $489.7 million in 2022, 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
	2022	2021	$	%
	(in thousands, except percentages)			
Coronary	$ 353,859	$ 161,463	$ 192,396	119%
Peripheral	132,284	74,064	58,220	79%
Other	3,590	1,619	1,971	122%
Product revenue	$ 489,733	$ 237,146	$ 252,587	107%

Coronary product revenue increased by $192.4 million, or 119%, from $161.5 million in 2021 to $353.9 million in 2022. In February 2021, we received 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 in the United States and increased adoption of our products internationally.

Peripheral product revenue increased by $58.2 million, or 79%, from $74.1 million in 2021 to $132.3 million in 2022. The change was due to an increase in the purchase volume of our M^5 catheter, M^{5+} catheter and S^4 catheter within the United States and internationally driven by increased adoption of our products.

Other product revenue increased by $2.0 million, or 122%, from $1.6 million in 2021 to $3.6 million in 2022. The change was due to an increase in the purchase volume of our IVL generators and other accessories within the United States and internationally.

We sold to a greater number of customers in the United States and to a greater number of distributors internationally in 2022 compared to 2021. Product revenue, classified by the major geographic areas in which our products are shipped, was $407.4 million or 83% within the United States and $82.3 million or 17% for all other countries in 2022 compared to $186.3 million or 79% within the United States and $50.8 million or 21% for all other countries in 2021.

Cost of product revenue, gross profit, and gross margin percentage. Cost of product revenue increased by $23.6 million, or 57%, from $41.4 million in 2021 to $65.0 million in 2022. The increase was driven by higher product sales volume compared to the prior year. Gross margin percentage improved to 87% in 2022, compared to 83% in 2021. This change in gross margin percentage was primarily due to a higher average selling price and lower fixed costs per unit from increased sales volume of our IVL catheters and efficiencies from improvements to operations and production.

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

	Year Ended December 31,		Change	Change
	2022	2021	$	%
	(in thousands, except percentages)			
Compensation and personnel-related costs	$ 47,634	$ 29,051	$ 18,583	64%
Facilities and other allocated costs	11,115	5,547	5,568	100%
Materials and supplies	8,611	3,382	5,229	155%
Other research and development costs	1,787	956	831	87%
Outside consultants	3,672	3,022	650	22%
Clinical-related costs	8,860	8,586	274	3%
Total research and development expenses	$ 81,679	$ 50,544	$ 31,135	62%

Research and development expenses increased by $31.1 million, or 62%, from $50.5 million in 2021 to $81.7 million in 2022. The increase was primarily due to a $18.6 million increase in compensation and personnel-related costs due to an increase in head count. There was also a $5.6 million increase due to increased information technology, rent and building expenditures, a $5.2 million increase in materials and supplies, a $0.8 million increase in other research and development costs, a $0.6 million increase for outside consultants, and a $0.3 million increase in clinical-related costs.

Sales and marketing expenses. Sales and marketing expenses increased by $50.7 million, or 46%, from $111.3 million in 2021 to $162.0 million in 2022. The increase was primarily due to a $32.3 million increase in compensation and personnel-related costs, resulting from increased headcount and commissions driven by increased sales of our products in 2022. There was also a $9.7 million increase due to travel-related costs, a $4.2 million increase in marketing and promotional expenses to support the continued commercialization of our products, a $4.1 million increase in facilities and other allocated costs, due to increased information technology, rent and building expenditures, a $0.6 million increase in general corporate costs, a $0.4 million increase due to consulting fee and professional services, and a $0.1 million increase due to recruiting and training fees. These increases were offset by a $0.7 million decrease in materials and supplies.

General and administrative expenses. General and administrative expenses increased by $22.2 million, or 64%, from $34.7 million in 2021 to $56.9 million in 2022. The change was primarily due to a $10.9 million increase in compensation and personnel-related costs due to an increase in head count, a $6.8 million increase in consulting and professional services, a $2.1 million increase in general corporate costs, a $1.6 million increase in facilities and other allocated costs, a $0.7 million increase due to travel-related costs, and a $0.1 million increase in recruiting and training.

Loss from equity method investment. Loss from equity method investment decreased by $3.8 million, or 61%, from $6.3 million in 2021 to $2.5 million in 2022. The decrease in loss from equity method investment was due to in-process research and development costs expensed in 2022, partially offset by increased sales by the JV to end customers following the NMPA approval of products in the PRC, 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 $0.8 million or 72% from $1.1 million in 2021 to $1.9 million in 2022. The increase was related to our Credit Agreement which matures in October 2027 and the loss on debt extinguishment related to the repayment of our Amended SVB Credit Agreement.

Other income (expense), net. Other income (expense), net increased by $1.6 million, or 281%, from $0.6 million in other expense, net in 2021 to $1.1 million in other income, net in 2022. 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 benefit of $95.2 million for the year ended December 31, 2022 was primarily due to the release of a substantial portion of our valuation allowance on our deferred tax assets. See Note 9, Income Taxes in our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information. We had no income tax benefit for the corresponding period in 2021.

Comparison of the Years Ended December 31, 2021 and 2020

For a discussion regarding our financial condition and our results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020, 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, 2021, filed with the SEC on February 25, 2022.

Liquidity and Capital Resources

Sources of liquidity

To date, our principal sources of liquidity have been the net proceeds we received through the sales of our common stock in our public offerings, private sales of our equity securities, payments received from customers purchasing our products and, to a lesser extent, proceeds from our debt financings. On March 11, 2019, upon completion of our initial public offering ("IPO"), we received net proceeds of $99.9 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the IPO, we completed a private placement for net proceeds of $10.0 million. On November 15, 2019, we completed a follow-on offering for net proceeds of $96.7 million, after deducting underwriting discounts and commissions and offering expenses. On June 19, 2020, we completed an offering for net proceeds of $83.4 million, after deducting underwriting discounts and commissions and offering expenses.

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 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, which provides for a revolving credit facility in an aggregate principal amount of $175 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 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 million. We also 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 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 IVL Technology, 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, 2022, we may incur net losses and have negative cash flows from operations in the future.

As of December 31, 2022, we have $304.5 million in cash, cash equivalents and short-term investments and an accumulated deficit of $36.8 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 and capital expenditure requirements. 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;
- macroeconomic conditions, including a potential recession, inflation and rising interest rates;
- 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, 2022, our debt, principal and interest commitments consist of our debt obligations under the Credit Agreement.

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 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 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 million. We also 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 Credit Agreement is secured by all of our assets, excluding intellectual property and certain other assets. The Credit Agreement is subject to customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, and pay any dividend or make any distributions to stockholders.

As of December 31, 2022, we had $24.2 million of outstanding principal, net of unamortized debt issuance costs which matures in October 2027.

Manufacturing Purchase Obligations

We have engaged a contract manufacturer to produce and supply us with certain products. We have fixed commitments of approximately $20.7 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, as well as for laboratory and manufacturing space. Our total operating lease commitments as of December 31, 2022 are approximately $52.6 million, of which $5.2 million is expected to be paid within the next twelve months.

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,		
	2022	2021	2020
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ 117,732	$ 15,036	$ (71,184)
Investing activities	(62,150)	26,416	(107,473)
Financing activities	12,999	(2,451)	90,035
Effect of exchange rate changes on cash and cash equivalents	(1,153)	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 67,428	$ 39,001	$ (88,622)

Operating activities

In 2022, cash provided by operating activities was $117.7 million, attributable to a net income of $216.0 million, partially 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 partially offset by a $11.9 million increase in accrued and other current liabilities.

In 2021, cash provided by operating activities was $15.0 million, attributable to a net loss of $9.1 million, non-cash charges of $40.7 million, partially offset by a net change in our net operating assets and liabilities of $16.5 million. Non-cash charges primarily consisted of $27.3 million in stock-based compensation, $6.3 million in loss from equity method investment, $3.6 million in depreciation and amortization, $2.0 million in non-cash lease expenses, $1.1 million in accretion of discount on available-for-sale securities, and $0.5 million in amortization of debt issuance costs. The change in our net operating assets and liabilities was primarily due to a $25.7 million increase in accounts receivable due to an increase in sales, a $12.1 million increase in inventory driven by an increase in raw material, work in progress, and finished goods inventory to support sales growth, a $2.1 million increase in prepaid expenses and other current assets, and a $0.2 million decrease in lease liability due to lease payments. These changes were partially offset by a $21.6 million increase in accrued and other current liabilities resulting from expansion in our operating activities and accrued employee

compensation driven by increased headcount, a $1.9 million increase in accounts payable due to the timing of vendor billings and payments, and a decrease in other assets of $0.1 million.

Investing activities

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, partially offset by proceeds from maturities of available-for-sale investments of $100.8 million.

In 2021, cash provided by investing activities was $26.4 million, attributable to proceeds from maturities of available-for-sale investments of $156.1 million, partially offset by purchase of available-for-sale investments of $117.2 million and purchases of property and equipment of $12.4 million.

Financing activities

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, partially offset by $18.2 million in principal term loan payments under the Amended SVB Credit Agreement.

In 2021, cash used in financing activities was $2.5 million, attributable to $8.3 million for the payment of taxes withheld on net settled vesting of restricted stock units, partially offset by proceeds of $3.0 million from stock option exercises and proceeds of $2.8 million from the issuance of shares under our employee stock purchase plan.

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 to our audited 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.

Revenue

Product Revenue

We record product revenue primarily from the sale of our IVL catheters. We sell our products to hospitals, primarily through direct sales representatives, as well as through distributors in selected international markets. Additionally, a portion of our revenue is generated through a consignment model under which inventory is maintained at hospitals.

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

For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. For consignment inventory, control is transferred at the time the IVL catheters are consumed in a procedure. We have 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.

We may provide for the use of an IVL generator and connector cable under an agreement to customers at no charge to facilitate 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 our functional intellectual property with a customer, we consider 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 we satisfy our 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.

On March 19, 2021, we 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 our interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau (the "PRC"). Under the JV Agreement, Genesis Shockwave Private Ltd. (the "JV") was formed under the laws of Singapore to serve as a joint venture of Genesis and us for the purpose of establishing and managing the strategic partnership.

In connection with the formation of the JV on March 19, 2021, we received a 45% equity stake in the JV in exchange for the contribution of intellectual property. We determined that the JV met the definition of a customer under Topic 606, *Revenue from Contracts with Customers*, and that the promised goods and services of the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV were considered to be a single performance obligation. The transaction price of $12.3 million was estimated by reference to the cash value of the shares which were issued at the formation of the JV.

As of December 31, 2022, the associated manufacturing technology transfer to the JV has not yet been completed. We recorded a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation. No license revenues were recognized for the years ended December 31, 2022 and 2021.

Equity Method Investment

Entities for which we have significant influence over the activities of the entity, but do not control, are accounted for under the equity method of accounting in accordance with Topic 323, *Investments - Equity Method and Joint Ventures*.

Our carrying value in the equity method investment is reported as equity method investment on our consolidated balance sheets. We record our proportionate share of the underlying income or loss which is recognized in earnings or loss from the equity method investment. We eliminate a portion of intra-entity profit to the extent the goods sold by us 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 us 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.

We assess our equity method investment for impairment when events or circumstances suggest that the carrying amount of the investment may be impaired. We consider 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.

Accrued Research and Development Costs

We accrue liabilities for estimated costs of research and development activities conducted by our third-party service providers, which include the conduct of preclinical and clinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities on the consolidated balance sheet and within research and development expense on the consolidated statements of operations and comprehensive loss.

We accrue for these costs based on factors, such as estimates of the work completed and budget provided and in accordance with agreements established with our third-party service providers. We make significant judgments and

estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

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 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.

We also account for uncertain tax positions in accordance with Topic 740, *Income Taxes – Simplifying the 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 review by federal or state examiners. We 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. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

Recent Accounting Pronouncements

No recently issued accounting standards are expected to have a material impact 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, 2022 consist of $304.5 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. 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, 2022, we had $24.2 million in debt outstanding, consisting of the revolving credit facility under our Credit Agreement. The revolving credit facility accrues 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 ranging from 1% to 2%, depending on the Company's Consolidated Total Net Leverage Ratio (which rate is currently 1%). 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 5.3% as of December 31, 2022.

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, 2022 and 2021, approximately 8% and 12% 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, 2022, we incurred $1.1 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 10% change in exchange rates could result in a change in fair value of $4.2 million and $2.1 million in foreign currency cash and accounts receivable as of December 31, 2022 and 2021, respectively. As our operations in countries outside of the United States grow, 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

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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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 27, 2023 expressed an unqualified 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition

Description of the Matter	The Company recorded product revenue of $489.7 million for the year ended December 31, 2022. As disclosed in Note 2, the Company records revenue when a customer obtains control of promised goods or services. For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and to certain customers that purchase stocking orders in the United States, control is transferred based on the contractual shipping terms. Auditing the Company's revenue recognition was challenging given the volume of transactions and the timing of revenue recognition varies by customer.
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, testing a sample of revenue transactions recognized during the year by inspecting source documentation, and 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.

/s/ Ernst & Young LLP

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

San Mateo, California
February 27, 2023

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

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 156,586	$ 89,209
Short-term investments	147,907	111,772
Accounts receivable, net	71,366	37,435
Inventory	75,112	42,978
Prepaid expenses and other current assets	8,292	4,508
Total current assets	459,263	285,902
Operating lease right-of-use assets	32,365	27,496
Property and equipment, net	48,152	24,361
Equity method investment	3,512	5,987
Deferred tax assets	97,568	—
Other assets	5,229	1,936
TOTAL ASSETS	$ 646,089	$ 345,682
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,721	$ 3,520
Debt, current portion	—	5,500
Accrued liabilities	55,375	40,870
Lease liability, current portion	1,278	1,738
Total current liabilities	63,374	51,628
Lease liability, noncurrent portion	34,928	28,321
Debt, noncurrent portion	24,198	11,630
Related party contract liability, noncurrent portion	12,273	12,273
TOTAL LIABILITIES	134,773	103,852
Commitments and contingencies (Note 6)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized; No shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, $0.001 par value per share; 281,274,838 shares authorized; 36,235,546 and 35,444,472 issued and outstanding as of December 31, 2022 and 2021	36	35
Additional paid-in capital	548,960	494,806
Accumulated other comprehensive loss	(867)	(202)
Accumulated deficit	(36,813)	(252,809)
TOTAL STOCKHOLDERS' EQUITY	511,316	241,830
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 646,089	$ 345,682

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,		
	2022	**2021**	**2020**
Revenue:			
Product revenue	$ 489,733	$ 237,146	$ 67,789
Cost of revenue:			
Cost of product revenue	64,996	41,438	20,991
Gross profit	424,737	195,708	46,798
Operating expenses:			
Research and development	81,679	50,544	36,926
Sales and marketing	161,995	111,288	51,672
General and administrative	56,929	34,747	23,863
Total operating expenses	300,603	196,579	112,461
Income (loss) from operations	124,134	(871)	(65,663)
Loss from equity method investment	(2,475)	(6,286)	—
Interest expense	(1,886)	(1,096)	(1,212)
Other income (expense), net	1,055	(582)	1,256
Net income (loss) before taxes	120,828	(8,835)	(65,619)
Income tax (benefit) provision	(95,168)	301	80
Net income (loss)	$ 215,996	$ (9,136)	$ (65,699)
Unrealized loss on available-for-sale securities, net of tax	(659)	(211)	(5)
Adjustment for net gain realized and included in other income, net	(6)	—	(21)
Total comprehensive income (loss)	$ 215,331	$ (9,347)	$ (65,725)
Net income (loss) per share			
Basic	$ 6.02	$ (0.26)	$ (1.99)
Diluted	$ 5.70	$ (0.26)	$ (1.99)
Shares used in computing net income (loss) per share			
Basic	35,900,738	35,098,130	33,088,095
Diluted	37,881,590	35,098,130	33,088,095

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)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2019	31,446,787	$ 31	$ 370,561	$ 35	$ (177,974)	$ 192,653
Exercise of stock options	1,185,764	2	4,315	—	—	4,317
Issuance of common stock under employee stock purchase plan	52,612	—	1,795	—	—	1,795
Issuance of common stock in connection with vesting of restricted stock units	69,900	—	—	—	—	—
Issuance of common stock in connection with public offering, net of issuance costs of $6.1 million	1,955,000	2	83,366	—	—	83,368
Restricted stock units withheld in net settlement for tax	(25,726)	—	(1,420)	—	—	(1,420)
Stock-based compensation	—	—	10,666	—	—	10,666
Net gain reclassified from accumulated other comprehensive income	—	—	—	(21)	—	(21)
Unrealized loss on available-for-sale securities	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(65,699)	(65,699)
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 income	—	—	—	(6)	—	(6)
Net income	—	—	—	—	215,996	215,996
Balance — December 31, 2022	36,235,546	$ 36	$ 548,960	$ (867)	$ (36,813)	$ 511,316

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,		
	2022	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 215,996	$ (9,136)	$ (65,699)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	4,856	3,579	1,863
Loss from equity method investment	2,475	6,286	—
Stock-based compensation	44,890	27,257	10,350
Non-cash lease expense	3,042	1,957	1,483
Amortization of premium and discount on available-for-sale securities	(68)	1,093	300
Loss on write down of fixed assets	81	7	187
Loss on extinguishment of debt	562	—	—
Deferred income taxes	(97,276)	—	—
Amortization of debt issuance costs	533	511	646
Foreign currency remeasurement	572	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(33,313)	(25,746)	(4,312)
Inventory	(29,711)	(12,073)	(17,056)
Prepaid expenses and other current assets	(3,786)	(2,110)	(501)
Other assets	(3,243)	91	(306)
Accounts payable	1,945	1,870	(1,392)
Accrued and other current liabilities	11,941	21,637	4,017
Lease liabilities	(1,764)	(187)	(764)
Net cash provided by (used in) operating activities	117,732	15,036	(71,184)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of available-for-sale securities	(137,797)	(117,245)	(167,953)
Proceeds from maturities of available-for-sale securities	100,773	156,100	72,000
Purchase of property and equipment	(25,126)	(12,439)	(11,520)
Net cash (used in) provided by investing activities	(62,150)	26,416	(107,473)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock in public offering, net of issuance costs paid	—	—	83,368
Payments of taxes withheld on net settled vesting of restricted stock units	(23)	(8,337)	(1,420)
Proceeds from debt financing, net of issuance costs	24,169	—	3,265
Payment of deferred offering costs	—	—	(179)
Proceeds from stock option exercises	2,562	3,049	4,317
Proceeds from issuance of common stock under employee stock purchase plan	4,487	2,837	1,795
Principal payment of term loan	(18,196)	—	(1,111)
Net cash provided by (used in) financing activities	12,999	(2,451)	90,035
Effect of exchange rate changes on cash and cash equivalents	(1,153)	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	67,428	39,001	(88,622)
Cash, cash equivalents and restricted cash at beginning of period	90,874	51,873	140,495
Cash, cash equivalents and restricted cash equivalents at end of period	$ 158,302	$ 90,874	$ 51,873
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 791	$ 586	$ 549
Income tax paid	$ 2,162	$ 143	$ 22
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Right-of-use asset obtained in exchange for lease liability	$ 7,911	$ 21,885	$ 226
Property and equipment purchases included in accounts payable and accrued liabilities	$ 5,709	$ 1,923	$ 2,448
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 of 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.

In 2016, the Company began commercial and manufacturing operations, and began selling catheters based on the IVL technology. The Company's headquarters are in Santa Clara, California. The Company is located and operates primarily in the United States and has eleven wholly-owned foreign subsidiaries as of December 31, 2022.

As of December 31, 2022, the Company had cash, cash equivalents and short-term investments of $304.5 million, which are available to fund future working capital requirements. The Company believes that its cash, cash equivalents, and short-term investments as of December 31, 2022, will be sufficient for the Company to continue as a going concern for at least 12 months from the date the consolidated financial statements are filed with the Securities and Exchange Commission.

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 in 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, the allowance for doubtful accounts, the fair value of stock options, 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 balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows:

	December 31,	
	2022	2021
	(in thousands)	
Cash and cash equivalents	$ 156,586	$ 89,209
Restricted cash	1,716	1,665
Total cash, cash equivalents, and restricted cash	$ 158,302	$ 90,874

Restricted cash as of December 31, 2022 and 2021 relates to letters of credit established for real property leases relating to buildings housing the Company's office leases, 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.

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.

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, 2022 and 2021. 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 twelve months ended December 31, 2022, 2021, and 2020.

Equity Method Investments

Entities which the Company has significant influence over activities of the entity, but does not control, are accounted for under the equity method of accounting in accordance with Topic 323, *Investments - Equity Method and Joint Ventures*. 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.

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, 2022, 2021 and 2020 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, 2022 and 2021.

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. Management believes that its term notes bear interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value.

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

The Company adopted Accounting Standards Update ("ASU") 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, effective January 1, 2020 using the modified retrospective method. The adoption of this standard did not have a cumulative effect on opening accumulated deficit as of January 1, 2020 and did not have a material impact on the Company's financial statements.

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,		
	2022	2021	2020
	(in thousands)		
Beginning balance	$ 350	$ 380	$ 194
Amounts charged (reversed) to costs and expenses	364	(12)	205
Write-offs	(4)	(18)	(19)
Ending balance	$ 710	$ 350	$ 380

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 and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over the lesser of their useful life or the remaining life of the lease. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet 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 Topic 606, *Revenue from Contracts with Customers*, 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. The Company sells its products to hospitals, primarily through direct sales representatives, as well as through distributors in selected international markets. Additionally, a portion of the Company's revenue is generated through a consignment model under which inventory is maintained at hospitals.

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

For products sold through direct sales representatives, control is transferred upon delivery to customers. For products sold to distributors internationally and products sold to customers that utilize stocking orders, control is transferred upon shipment or delivery to the customer's named location, based on the contractual shipping terms. For consignment inventory, control is transferred at the time the IVL catheters are consumed in a procedure. 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 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, 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 sheet. 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 $3.7 million, $2.5 million, and $1.1 million for the years ended December 31, 2022, 2021, and 2020, 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 $1.1 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively. There was net foreign currency transaction gains of $0.3 million for the year ended 2020.

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 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.

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 Topic 740, *Income Taxes – Simplifying the Accounting for Income Taxes*, 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 certain equipment on loan to customers held internationally, which was not material for the periods presented.

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.

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, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 111,631	$ —	$ —	$ 111,631
Money market funds	12,076	—	—	12,076
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

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 80,155	$ —	$ —	$ 80,155
Money market funds	47,541	—	—	47,541
Commercial paper	—	20,472	—	20,472
Corporate bonds	—	11,145	—	11,145
Total assets	$ 127,696	$ 31,617	$ —	$ 159,313

4. Cash Equivalents and Short-Term Investments

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

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 112,719	$ 3	$ (1,091)	$ 111,631
Money market funds	12,076	—	—	12,076
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

	December 31, 2021			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 80,353	$ —	$ (198)	$ 80,155
Money market funds	47,541	—	—	47,541
Commercial paper	20,472	—	—	20,472
Corporate bonds	11,149	—	(4)	11,145
Total	$ 159,515	$ —	$ (202)	$ 159,313
Reported as:				
Cash equivalents				$ 47,541
Short-term investments				111,772
Total				$ 159,313

There were $123.8 million and $86.5 million of investments in unrealized loss positions of $1.2 million and $0.2 million as of December 31, 2022 and 2021, respectively. During the years ended December 31, 2022, 2021, and 2020 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, 2022 and 2021. 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, 2022 and 2020 the Company recognized $6,000 and $21,000 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, 2022
	Fair Value
	(in thousands)
Money market funds	$ 12,076
One year or less	110,947
Greater than one year and less than two years	36,960
Total	$ 159,983

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	December 31,	
	2022	2021
	(in thousands)	
Raw material	$ 18,456	$ 7,685
Work in progress	7,666	13,315
Finished goods	48,735	20,326
Consigned inventory	255	1,652
Total inventory	$ 75,112	$ 42,978

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2022	2021
	(in thousands)	
Equipment	$ 11,434	$ 6,234
Equipment on loan to customers	1,350	1,714
Office furniture	1,171	549
Software	904	742
Leasehold improvements	33,703	17,742
Construction in progress	9,765	3,544
Property and equipment, gross	58,327	30,525
Less: accumulated depreciation and amortization	(10,175)	(6,164)
Total property and equipment, net	$ 48,152	$ 24,361

Depreciation and amortization expense amounted to $4.9 million, $3.6 million and $1.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. The construction in progress balance primarily relates to the construction costs for the manufacturing facility in Costa Rica.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Employee compensation	$ 32,885	$ 25,749
Asset purchases	4,600	4,101
Professional services	4,044	2,636
Research and development costs	4,007	4,605
Excise, sales, income and other taxes	4,036	1,232
Other	5,803	2,547
Total accrued liabilities	$ 55,375	$ 40,870

6. Commitments and Contingencies

Operating Leases

The Company's operating leases consist of leased facilities for the Company's headquarter offices, as well as 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, 2022, 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 a First Amendment to Office Lease (Net) (the "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 Lease Amendment. The 3003 Bunker Hill Lease and the 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, 2022, the Company is not reasonably certain it will exercise these extension options.

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, were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Operating lease cost	$ 4,667	$ 2,891	$ 2,208
Variable lease cost	1,186	496	505
Total lease cost	$ 5,853	$ 3,387	$ 2,713

During the years ended December 31, 2022, 2021 and 2020, the Company recorded operating lease expense of $4.7 million, $2.9 million, and $2.2 million and paid $3.4 million, $2.2 million, and $1.3 million of operating lease

payments respectively related to the lease liabilities, which the Company includes 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 9 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.

The following are minimum future rental payments owed under lease agreements which have commenced as of December 31, 2022:

	(in thousands)
2023	$ 5,238
2024	5,367
2025	5,526
2026	5,690
2027	5,832
Thereafter	24,958
Total minimum lease payments	$ 52,611
Less: imputed interest	(10,737)
Less: lease incentive	(5,668)
Total lease liability	$ 36,206
Less: current portion	(1,278)
Lease liability, noncurrent portion	$ 34,928

7. 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 million with the right to request increases to the revolving commitments (subject to certain conditions) of up to the greater of (x) $100 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 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. 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 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%). 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 5.3% as of December 31, 2022.

The Company recorded interest expense of $1.9 million, $1.1 million and $1.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Long-term debt and net premium balances are as follows:

	December 31,	
	2022	2021
	(in thousands)	
Principal amount of debt	$ 25,000	$ 16,500
Net premium (discount) associated with accretion of final payment, and other debt issuance costs	(802)	630
Debt	24,198	17,130
Less: debt, current portion	—	(5,500)
Debt, noncurrent portion	$ 24,198	$ 11,630

Future minimum payments of principal and estimated payments of interest on the Company’s outstanding debt as of December 31, 2022 are as follows:

Year ending December 31:	(in thousands)
2023	$ 1,338
2024	1,353
2025	1,349
2026	1,349
2027	26,101
Thereafter	—
Total future payments	$ 31,490
Less: amounts representing interest	(6,490)
Total principal amount of debt payments	$ 25,000

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Cost of product revenue	$ 2,193	$ 1,153	$ 496
Research and development	10,354	6,240	2,464
Sales and marketing	18,387	11,043	3,478
General and administrative	13,956	8,821	3,912
Total stock-based compensation	$ 44,890	$ 27,257	$ 10,350

Stock-based compensation of $2.2 million, $0.7 million, and $0.3 million was capitalized into inventory for the years ended December 31, 2022, 2021, and 2020, 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, 2022, the Company had reserved 4,809,769 shares of common stock for issuance under the 2019 Plan.

Stock Options

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

	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Term	Aggregate Intrinsic Value
				(in years)	(in thousands)
Balance, December 31, 2021	3,745,216	1,524,985	$ 6.01	5.76	$ 262,793
Awards authorized	1,063,334	—			
Options exercised	—	(401,757)	6.38		
Options cancelled	1,219	(1,219)	11.21		
Balance, December 31, 2022	4,809,769	1,122,009	$ 5.87	4.60	$ 224,115
Vested and exercisable, December 31, 2022		1,105,414	$ 5.69	4.58	$ 220,997
Vested and expected to vest, December 31, 2022		1,122,009	$ 5.87	4.60	$ 224,115

There were no options granted during the years ended December 31, 2022, 2021, and 2020. The total grant date fair value of options vested was $1.0 million, $1.6 million and $2.3 million for the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, total unrecognized stock-based compensation related to unvested stock options was $0.1 million, which the Company expects to recognize over a remaining weighted-average period of 0.2 years.

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, 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, 2021	1,156,683	$ 93.27	—	$ —
RSUs granted	399,541	190.26	38,797	165.74
RSUs forfeited	(70,459)	135.74	—	—
RSUs vested	(359,774)	85.91	—	—
Balance, December 31, 2022	1,125,991	127.39	38,797	165.74

The total grant date fair value of RSUs vested was $30.9 million, $11.3 million, and $2.7 million, for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, there was $121.9 million of unrecognized stock-based compensation expense related to RSUs to be recognized over a weighted-average period of 2.2 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 $2.3 million, $1.3 million and $0.8 million of stock-based compensation expense related to the ESPP for the years ended December 31, 2022, 2021 and 2020, respectively. At December 31, 2022, a total of 1,197,296 shares were available for issuance under the ESPP.

	Years Ended December 31,		
	2022	**2021**	**2020**
Expected term (in years)	0.5	0.5	0.5
Expected volatility	61.8%-73.8%	48.9%-64.8%	44.3%-74.0%
Risk-free interest rate	0.1%-3.7%	0.1%	0.1%-0.3%
Expected dividend yield	0%	0%	0%

9. Income Taxes

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

	December 31,		
	2022	**2021**	**2020**
		(in thousands)	
Domestic	$ 119,901	$ (9,388)	$ (65,957)
Foreign	927	553	338
Total income (loss) before income taxes	$ 120,828	$ (8,835)	$ (65,619)

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

	December 31,		
	2022	**2021**	**2020**
		(in thousands)	
Current provision for income taxes:			
Federal	$ 403	$ —	$ —
State	1,446	84	3
Foreign	259	217	77
Total current tax provision:	2,108	301	80
Deferred tax provision:			
Federal	(85,618)	—	—
State	(11,658)	—	—
Foreign	—	—	—
Total deferred tax (benefit) provision	(97,276)	—	—
Total (benefit) provision for income taxes	$ (95,168)	$ 301	$ 80

The income tax benefit for the year ended December 31, 2022 resulted primarily from the partial release of the Company's valuation allowance, described below.

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

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Net operating loss carryovers	$ 60,467	$ 85,764
Fixed and intangible assets	—	512
Accruals and reserves	10,876	7,603
Stock-based compensation	8,504	5,523
Research and development credits	15,250	4,698
Contributions	—	42
Lease liability	9,316	7,398
Capitalized research and development	17,791	—
Total deferred tax assets	122,204	111,540
Less valuation allowance	(13,371)	(104,773)
Gross deferred tax assets	108,833	6,767
Deferred tax liabilities:		
Fixed and intangible assets	(1,105)	—
Right-of-use-assets	(8,327)	(6,767)
Other	(1,833)	—
Gross deferred tax liabilities	(11,265)	(6,767)
Total net deferred tax assets	$ 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 has 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.

During the fourth quarter of 2022, after considering these factors, the Company determined that the positive evidence overcame any negative evidence, primarily due to the Company's transition from a cumulative loss in recent years to cumulative income in 2022 and concluded that it was more likely than not that the U.S. federal deferred tax assets and other-than-California state deferred tax assets were realizable. As a result, 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 decreased by $91.4 million for the year ended December 31, 2022, and increased by $22.7 million and $27.0 million for the years ended December 31, 2021 and 2020, respectively. 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. As a result of the release, the Company realized a total of $99.0 million of income tax benefits comprised of $87.8 million for U.S. federal and $11.2 million for other states, respectively. The remaining $7.6 million is primarily due to deferred tax asset generated in California during 2022. The Company continues to maintain a full valuation allowance of $13.1 million and $0.2 million on California and United Kingdom's deferred tax assets, respectively, which the Company believes are not more likely than not to be realized in future periods.

As of December 31, 2022, the Company had net operating loss (“NOL”) carryforwards of approximately $239.7 million for federal income tax purposes, and $51.0 million for California income tax purposes and $77.9 million for other state income tax purposes. The federal NOL carryforwards (generated prior to 2018) of $18.0 million begin expiring in 2033 and are subject to Section 382 limitation. The federal NOL carryforwards (generated after 2018) of $221.7 million

will never expire. The California NOL begin expiring in 2033 and other state NOL carryforwards begin expiring in various years, starting in 2028.

As of December 31, 2022, the Company had research and development credit carryforwards of $10.4 million for federal income tax purposes and $10.1 million for California state income tax purposes available to reduce future taxable income, if any. The federal research and development credit carryforwards expire beginning 2033 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,		
	2022	2021	2020
	(in thousands)		
Income tax provision (benefit) at federal statutory rate	$ 25,378	$ (1,856)	$ (13,780)
State and local income	(10,516)	36	(9)
Foreign tax rate differential	47	101	6
Change in valuation allowance	(87,568)	19,027	27,990
Stock-based compensation	(18,273)	(17,968)	(13,425)
Section 250 FDII deduction	(984)	—	—
Research and development credits	(3,937)	(808)	(611)
Section 382 limitation	—	575	—
Equity method investment	520	1,320	—
Other	165	(126)	(91)
Total current income tax (benefit) provision	$ (95,168)	$ 301	$ 80

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,		
	2022	2021	2020
	(in thousands)		
Beginning balance	$ 5,221	$ 3,746	$ 2,586
Reductions based on tax positions related to prior years	(1,861)	(79)	(3)
Additions based on tax positions related to current years	1,904	1,554	1,163
Balance at end of year	$ 5,264	$ 5,221	$ 3,746

As of December 31, 2022, 2021 and 2020, the total amount of unrecognized tax benefits was approximately $5.3 million, $5.2 million and $3.7 million, respectively. The unrecognized tax benefit of $2.9 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, 2022, 2021 and 2020. 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 due to its NOLs. 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 foreign, state or local jurisdictions, nor has it been notified of any other potential future income tax audit.

10. Revenue

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

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Coronary	$ 353,859	$ 161,463	$ 24,586
Peripheral	132,284	74,064	41,994
Other	3,590	1,619	1,209
Product revenue	$ 489,733	$ 237,146	$ 67,789

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 IVL catheter, and L^6 IVL catheter. 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,		
	2022	2021	2020
	(in thousands)		
United States	$ 407,425	$ 186,324	$ 37,121
Europe	51,010	38,571	23,456
All other countries	31,298	12,251	7,212
Product revenue	$ 489,733	$ 237,146	$ 67,789

11. 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"). Under the JV Agreement, Genesis Shockwave Private Ltd. (the "JV") was formed under the laws of Singapore to serve as a joint venture of Genesis and the Company for the purpose of establishing and managing the strategic partnership.

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, of which 50% was due upon signing and the remaining 50% will be due within one year of signing, 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. In May 2022, the JV obtained regulatory approval from the China National Medical Products Administration to sell the Company-manufactured Shockwave IVL System with the Shockwave C^2 catheter, M^5 catheter and S^4 catheter in the PRC.

The Company has accounted for its investment in the JV under the equity method of accounting. As of December 31, 2022, the carrying value of the Company's investment in the JV was $3.5 million and the Company owned a 45% interest in the entity. During the year ended December 31, 2022, the Company commenced recognizing product revenue on sales to the JV and eliminated a portion of intra-entity profit to the extent the goods have not yet either been consumed by the JV for use in clinical trials, or sold by the JV to an end customer at the end of the reporting period. The profit earned by the Company from the JV for items not yet sold through to an end customer is eliminated through equity method earnings or loss which is recognized in income (loss) of equity method investment.

The Company's product revenue for products sold to the JV during the year ended December 31, 2022 and related accounts receivable from the JV as of December 31, 2022 were immaterial. Intra-entity profit, which was recorded as a reduction to equity method investment as of and for the year ended December 31, 2022, was also immaterial.

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

Upon execution of the License Agreement, on March 19, 2021, the Company received a 45% equity stake in the JV. The Company determined that the JV met the definition of a customer under Topic 606, and that the promised goods and services of the contribution of the license of intellectual property and associated manufacturing technology transfer to the JV were considered to be a single performance obligation. The transaction price of $12.3 million was estimated by reference to the cash value of the shares that were issued at the formation of the JV.

As of December 31, 2022, 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.

12. Net Income (Loss) Per Share

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,		
	2022	2021	2020
Numerator:			
Net income (loss)	$ 215,996	$ (9,136)	$ (65,699)
Denominator:			
Basic:			
Weighted average number of common shares outstanding - basic	35,900,738	35,098,130	33,088,095
Diluted:			
Weighted average number of common shares outstanding - basic	35,900,738	35,098,130	33,088,095
Dilutive effect of outstanding common stock options	1,294,052	—	—
Dilutive effect of restricted stock units	684,696	—	—
Dilutive effect of common stock pursuant to employee stock purchase plan	2,104	—	—
Weighted average number of common shares outstanding - diluted	37,881,590	35,098,130	33,088,095
Net income (loss) per share:			
Basic	$ 6.02	$ (0.26)	$ (1.99)
Diluted	$ 5.70	$ (0.26)	$ (1.99)

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Year Ended December 31,	
	2021	2020
Common stock options issued and outstanding	1,524,985	2,087,202
Restricted stock units	1,156,683	859,577
Employee stock purchase plan	10,028	15,251
Total	2,691,696	2,962,030

13. Subsequent Event

On January 16, 2023, the Company entered into a definitive agreement to acquire Neovasc Inc., “Neovasc,” a company focused on the minimally invasive treatment of refractory angina. Upon the closing of the transaction, the Company will acquire all outstanding Neovasc shares for an upfront cash payment of $27.25 per share, corresponding to an enterprise value of approximately $100 million, inclusive of certain deal-related costs. Neovasc shareholders will also receive a potential deferred payment in the form of a non-tradable contingent value right entitling the holder to receive up to an additional $12 per share in cash if certain regulatory milestones are achieved. The upfront cash consideration represents a premium of 27% and 68% to the closing price and 30-day volume-weighted average price, respectively, of Neovasc’s common shares on the Nasdaq Capital Market on January 13, 2023. The transaction will be effected by way of a court-approved plan of arrangement pursuant to the Canada Business Corporations Act, and is subject to customary closing conditions, including requisite Neovasc shareholder approval. The Company expects to complete the transaction in the first half of 2023.

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 our Chief Financial Officer, have evaluated 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 the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that 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 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.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2022 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.

Management's 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 effective as of December 31, 2022. The effectiveness of our internal control over financial reporting as of December 31, 2022 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.

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, 2022, 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, Shockwave Medical, Inc (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Shockwave Medical, Inc. (the Company) as of December 31, 2022 and 2021, 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, 2022, and our report dated February 27, 2023 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 27, 2023

Item 9B. Other Information.

None.

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 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022 (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				
10.1	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
10.2	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
10.3†	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
10.4†	2019 Equity Incentive Plan and form of Stock Option Agreement	S-1/A	333-229590	10.4	February 25, 2019
10.5*	Form of Global Restricted Stock Unit Agreement				
10.6	Form of Global Performance-Based Restricted Stock Unit Award Agreement	10-K	001-38829	10.6	February 25, 2022
10.7†	Employee Stock Purchase Plan	S-1/A	333-229590	10.5	February 25, 2019
10.8†	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
10.9†	Offer Letter with Douglas Godshall	S-1	333-229590	10.7	February 8, 2019
10.10†	Amended and Restated Separation Pay Agreement with Douglas Godshall	10-Q	001-38829	10.1	May 9, 2022
10.11†	Offer Letter with Dan Puckett	S-1	333-229590	10.8	February 8, 2019
10.12†	Offer Letter with Isaac Zacharias	S-1	333-229590	10.9	February 8, 2019

10.13†	Amended and Restated Form of Separation Pay Agreement for Executive Officers (other than CEO)	10-Q	001-38829	10.2	May 9, 2022
10.14	Amended and Restated Non-Employee Director Compensation Policy	10-Q	001-38829	10.3	May 9, 2022
10.15	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
10.16	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
10.17	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.				
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, 2022 has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

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 27, 2023

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 Dan Puckett, 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 27, 2023
/s/ Daniel K. Puckett Daniel K. Puckett	Chief Financial Officer (principal financial officer)	February 27, 2023
/s/ Trinh Phung Trinh Phung	Vice President of Finance (principal accounting officer)	February 27, 2023
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman & Director	February 27, 2023
/s/ Laura Francis Laura Francis	Director	February 27, 2023
/s/ Frederic Moll Frederic Moll, M.D.	Director	February 27, 2023
/s/ Antoine Papiernik Antoine Papiernik	Director	February 27, 2023
/s/ Maria Sainz Maria Sainz	Director	February 27, 2023
/s/ Sara Toyloy Sara Toyloy	Director	February 27, 2023
/s/ F.T Jay Watkins F.T. “Jay” Watkins	Director	February 27, 2023