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, 2021

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

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, 2021, 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, 2021) was approximately $3.7 billion. For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company, or unless they hold 10% or more of our outstanding common stock. These assumptions should not be deemed to constitute an admission that all executive officers, directors and 5% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company. Further information concerning the security holdings of our officers, directors and principal stockholders is included or incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

The number of shares of Registrant's common stock outstanding as of February 18, 2022 was 35,653,563.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2022 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, 2021. 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. 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.

Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including due to the pandemic’s impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees;
- 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 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 plans and the expected timing to research, develop and commercialize our products and any other approved or cleared product;
- our ability to scale our organizational culture of cooperative product development and commercial execution;
- 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; and
- 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.

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.

- The impact of the COVID-19 pandemic and the measures implemented to contain the spread of the virus have adversely impacted, and are expected to continue to adversely impact, our business and results of operations.
- We depend upon third-party suppliers, including single source component suppliers, making us vulnerable to supply problems and price fluctuations.
- We will require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, 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.
- If we fail to identify, acquire, and develop other products, we may be unable to grow our business.
- 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 the potential growth of our revenue or increase our losses.
- 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.
- The size of the market for our current and future products has not been established with precision and may be smaller than we estimate.
- We may be unable to compete successfully with larger companies in our highly competitive industry.
- In the future our products may become obsolete, which would negatively affect operations and financial condition.
- 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 in the future, 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 medical device operations are subject to pervasive and evolving worldwide regulatory requirements.
- Our products may be subject to recalls after receiving U.S. Food and Drug Administration ("FDA") or foreign approval or clearance, 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 not be able to protect our intellectual property and proprietary rights throughout the world.
- 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 and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for medical device treatment of atherosclerotic cardiovascular disease ("atherosclerosis") through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, 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 significantly improve patient outcomes.

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 M5 IVL catheter (the "M5 catheter") and M5+ IVL catheter ("M5+ catheter") are five-emitter catheters for use in our IVL System in "medium" vessels for the treatment of above-the-knee PAD. The M5 catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018. The M5+ catheter, for which we are currently initiating a limited market release in the United States and select international locations, was CE-Marked in November 2020 and cleared by the FDA in April 2021.
- Our Shockwave S4 IVL catheter ("S4 catheter") is a four-emitter catheter for use in our IVL System in small vessels for the treatment of below-the-knee ("BTK") PAD. The second version of our S4 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.

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

- Our Shockwave C2 IVL catheter ("C2 catheter") is a two-emitter catheter for use in our IVL System for the treatment of CAD. The C2 catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C2 catheters using our IVL System for the treatment of CAD. In August 2020, we submitted an application to the FDA for U.S. pre-market approval ("PMA") of our C2 catheters, which was approved by the FDA in February 2021.

Our differentiated range of M5 catheters, M5+ catheters, S4 catheters, and C2 catheters enables delivery of IVL therapy of 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 initial studies have consistently shown low rates of complications regardless of which vessel was being studied. In addition to gaining regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of 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 also have ongoing clinical programs across several products and indications, which, if successful, will allow us to expand commercialization of our products into new geographies and indications.

During 2021, we were engaged in the following 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 C2 catheters. 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 C2 catheter following FDA approval in February 2021.

- DISRUPT CAD IV: This study is designed, along with DISRUPT CAD III, to support our Shonin submission in Japan for our C2 catheters. 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, with regulatory approval of our C2 catheters in Japan anticipated in the first half of 2022.
- DISRUPT CAD III Post-Approval Study (CAD PAS): This is a required post-approval study in the United States for our C2 catheters. We began the initial collection of data in the last quarter of 2021.

In the treatment of CAD, our combined CAD I – IV studies have demonstrated consistent safety and effectiveness outcomes for our IVL System in severely calcified coronary lesions prior to stenting in 683 patients.

- 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. 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 we anticipate that the trial results of the registry portion will be disclosed in 2022.

In addition, we initiated the following PAD studies in 2021:

- PAD+: This is a prospective, multi-center, single-arm study to assess the safety and performance of the M5+ catheters 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.
- 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.

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 and potentially delay or negate valve replacement treatment for 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 we are targeting with our IVL System are occlusive 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.

The market opportunity for 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 calcified arteries 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 the aggregate addressable market for IVL is estimated to be over $6.9 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 globally in 2022. 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, but current plaque modification devices carry meaningful safety risks and are inherently challenging to use, which is why these devices are used very sparingly for PCI procedures in patients with calcified coronary artery disease. Despite significant under-penetration of the market, these devices still represented a market of $230 million in 2021 within the United States alone, according to Clarivate; we believe this market is significantly larger globally. Due to the increasing prevalence of calcified cardiovascular disease, the market growth for plaque modification devices exceeds that of PCI procedure growth. We believe the safety, ease of use and efficient impact on calcium of our IVL System will result in rapid adoption and market expansion in markets where our C^2 catheter is introduced. We believe there is an over $3.6 billion total addressable market opportunity for our IVL System to treat CAD.

The PAD population in the United States has been estimated to be at least eight million people, according to the National Institutes of Health. Globally over 1.8 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 2022 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 vascular 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.

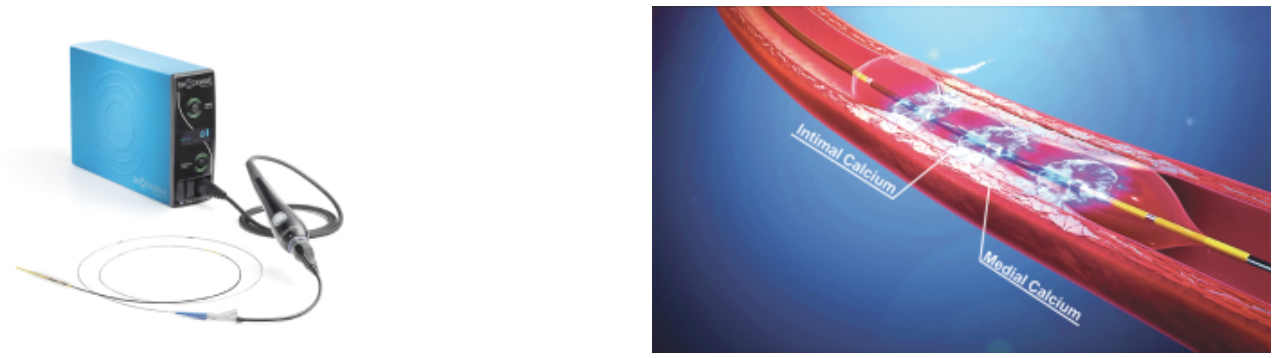
Plaque modification devices (including atherectomy and specialty balloons) have enhanced the treatment of some moderately calcified cardiovascular lesions by improving the ability of stent and balloon therapies to effectively expand in the vessel. Atherectomy devices are designed to break or remove superficial 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 in the 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 vessel wall, the existing plaque modification devices are unable to impact medial calcium 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., 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 to the cardiovascular field with the aim of creating what we believe can become the safest, most effective means of addressing the growing challenge of cardiovascular calcification. Lithotripsy has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years. 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 calcium in the medial layer of the artery, not just in the 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 tears. Preparing the vessel with IVL facilitates optimal outcomes with other therapies, including stents and drug-eluting technologies. Using IVL also avoids complications associated with atherectomy devices such as dissection, perforation, and embolism. When followed by an anti-proliferative therapy such as a DCB or DES, the micro-fractures may enable better drug penetration into the arterial wall and improve drug uptake, thereby improving the effectiveness of the combination treatment.

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. Our IVL System employs our IVL Technology to crack calcium through short, microsecond bursts of sonic pressure waves, which are generated within the IVL catheter, travel through the vessel and crack calcium without harming the soft tissue. Our IVL catheters utilize multiple lithotripsy emitters that are integrated into a standard, semi-compliant balloon-catheter platform. 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 family of IVL catheters that can treat calcium-related diseases across a wide variety of vasculatures and structures.

Why Shockwave?

Safe – Simple – Effective.

- Treatment of both superficial and deep calcium.
- Improved safety through unique mechanism of action.
- Improved efficacy for angioplasty, stents, and drug-eluting technologies.
- Seamless integration into interventional practice with exceptional ease-of-use.
- 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 to develop new products that satisfy significant unmet clinical needs.
- Drive profitability by scaling our business operations to achieve cost and production efficiencies.

Research and Development

We invest in research and development efforts that advance our IVL Technology and related technology 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, however in 2021 we entered into a contract manufacturing agreement with a third-party contract manufacturer, pursuant to which the contract manufacturer began manufacturing a portion of our demand for our M5 catheters and we are currently in the process of qualifying the contract manufacturer to manufacture our M5+ catheters.

We stock inventory of raw materials, components and finished goods at our facilities in California and 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 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.

In the United States, we generally ship our IVL products from Santa Clara to our hospital customers in the United States but also may 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 also offered consignment sales arrangements to certain customers. Internationally, we ship our IVL products from Santa Clara to either our third-party logistics provider located in the Netherlands who then ships directly to hospital customers and distributors pursuant to purchase orders or from Santa Clara directly to hospital customers and distributors pursuant to purchase orders. We also ship to some customers in Germany, Austria, Switzerland, France, and the United Kingdom (the "UK") 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. As of December 31, 2021, we had approximately 217 operations and manufacturing employees.

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 Medical Device Directive (93/42/EEC) (the "MDD") and we are working to achieve compliance with the new Medical Devices Regulation (Regulation 2017/745) (the "MDR"), which supersedes, subject to certain transition provisions contained in the MDR, the MDD. 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.

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, and the UK which we have complemented with distributors actively selling in over 50 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. In addition, in 2021, we began developing our direct sales capability in Japan in advance of our C^2 catheter launch, for which we anticipate Japanese regulatory approvals in the first half of 2022. We have been adding new US sales territories and are actively expanding our international field presence through new distributors, and additional sales and clinical personnel and expanded direct sales territories. Of note, we have received the CE Mark in Europe and 510(k) clearance in the United States for our IVL System using our peripheral catheters (our M^5 and M^{5+} catheters and S^4 catheters) and CE Mark in Europe for our IVL System using our C^2 catheters. In August 2020, we submitted a PMA application with the FDA relating to our C^2 catheters in the U.S., which was approved by the FDA in February 2021.

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. Our global sales and marketing team totaled 250 professionals as of December 31, 2021.

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 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, easy to install and easy to 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.

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.

Our ability to achieve market acceptance or significant sales volume will depend in large part on the availability of coverage and the level of reimbursement for procedures performed using our products under healthcare payment systems in the markets where we sell and distribute our products. We cannot assure you that government or private payors will continue to cover and reimburse the procedures performed using our products in whole or in part in the future or that payment rates will continue to be adequate.

In addition, we expect that we will continue to see pressure globally by third-party payors to manage the cost of healthcare. Cost management may come in a variety of forms, including rules and practices of third-party payors, judicial decisions, laws and regulations, group purchasing and managed care organizations, and medical device reimbursement policies. Cost management could potentially limit the amount which healthcare providers may be willing to pay for our products and impact demand for our products, product pricing, reimbursement, and usage, and which, in turn, may adversely affect our product sales and results of operations.

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 cardiovascular field is highly competitive and certain of our products may compete with products manufactured by other companies, including Boston Scientific Corporation, Cardiovascular Systems, Inc. (“CSI”), Medtronic plc and Philips N.V. 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 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, our focus on calcified cardiovascular disease and our organizational culture and strategy, will be important factors in our future success. We compete primarily on the basis that our products are designed to treat patients with calcified cardiovascular disease safely, easily, and effectively, with improved outcomes and procedural cost savings. 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 we compete favorably with our competitors 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, 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, 2021, we owned 52 issued U.S. patents and 73 issued foreign patents, 18 pending U.S. non-provisional patent applications and 28 pending foreign patent applications (including five Patent Cooperation Treaty applications). This portfolio includes 22 issued U.S. patents, 37 issued foreign patents, five pending U.S. non-provisional patent applications and six pending foreign patent applications relating to our current IVL Technology.

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 U.S. Pat. Nos. 9,642,673 and 8,728,091, which were two of our issued U.S. patents relating to our current IVL Technology, are unpatentable following an inter partes review ("IPR") proceedings filed by CSI, one of our competitors. U.S. Pat. No. 8,956,371, which is another of our issued U.S. patents relating to our current IVL Technology, remains the subject of an IPR proceeding also filed by CSI. 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.

There are three types of 510(k) clearance: traditional, special, and abbreviated. Special 510(k)s are typically for devices that have certain technological, design or labelling changes that require a new 510(k) but where the method(s) to evaluate the changes are well established and the results of change evaluation can be sufficiently reviewed in a summary or risk analysis format. Abbreviated 510(k)s are for devices that conform to special controls for the device type or to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review, and the FDA intends to process special 510(k)s within 30 days of receipt.

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 un-cleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removal reporting regulations, which require that manufactures 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.

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.

The 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.

In addition, the FDA 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.

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 limited or no 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 fundsor 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 established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information.

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 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 European Union (the "EU") has adopted numerous directives 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. However, we have updated 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 as of 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 July 1, 2023, 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 2023. 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.

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. Some of these laws, for example the FCPA and the UKBA, have extraterritorial effect. In countries where we sell to our customers directly, we are also subject to more specific laws and codes that regulate interactions between manufacturers of medical devices and healthcare professionals. These rules also vary from country to country.

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.

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 also anticipate that we may in the future experience 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, 2021, we had 657 full-time employees worldwide, of which 383 were located at our headquarters in Santa Clara, California, 234 were remote and field-based employees throughout the country and 40 were located outside of the United States. Of these employees, 250 were in sales and marketing, 217 were in manufacturing and quality, 100 were in research and development, clinical and regulatory, and 90 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 by establishing a new standard of care for medical device treatment of atherosclerosis, 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, 2021 was approximately 14%. 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. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes having employees work from home, while implementing additional safety measures for employees continuing critical on-site work.
- *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 the creation of 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 (“EDI”) initiatives across our entire workforce, including launching our EDI Council in 2020 to strengthen our EDI strategies and to further engage our employees in our EDI efforts and the establishment of a formal EDI policy in 2021 intended to create sustainable cultural change, led by our executive leadership and driven through diverse cross-functional teams. Our workforce was made up of approximately 50% female employees as of December 31, 2021, with 47% 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 potential. We provide formal and informal training opportunities designed to enhance learning and development. Consistent with our quarterly review process, we foster and encourage continuous manager and employee dialogue around performance and development.

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

Corporate Information

We were incorporated in 2009 as a Delaware corporation under the name Shockwave Medical, Inc. Our principal executive offices are located at 5403 Betsy Ross Drive, Santa Clara, California 95054, and our telephone number is (510) 279-4262. Our website address is www.shockwavemedical.com. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have included our website address as an inactive textual reference only.

We use "Shockwave," "Shockwave M5," Shockwave M5+," "Shockwave C2," "Shockwave S4" 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

The impact of the COVID-19 pandemic and the measures implemented to contain the spread of the virus have adversely impacted and are expected to continue to adversely impact our business and results of operations.

The global COVID-19 pandemic presents significant risks to us, not all of which we are able to fully evaluate or even to foresee at the current time. The COVID-19 pandemic and related containment measures adversely affected our financial results and business operations during the year ended December 31, 2021 and are expected to continue to adversely impact our financial results and business operations. The extent to which the pandemic will continue to materially adversely affect our business and results of operations will depend on numerous evolving factors and future developments that we are not able to predict, including the duration, spread and severity of the outbreak, the availability and effectiveness of vaccines against COVID-19, continued mutations of the virus and the impact on 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. The COVID-19 pandemic and containment measures have contributed to, among other things:

- adverse impacts on our daily business operations and our colleagues' ability to perform necessary business functions, including as a result of illness or restrictions on movement;
- increased challenges in managing clinical trials and product development;
- decreased sales of our products as our hospital customers allocate resources to care of patients with COVID-19 and defer treatment of procedures utilizing our products;

- decreased utilization of our products as patients elect to defer treatment for procedures utilizing our products due to real or perceived concerns about the potential spread of COVID-19 in hospital settings;
- increased challenges in growing our customer base due to limitations on travel and in-person meetings due to shelter-in-place measures and demands on hospital customers in managing COVID-19 concerns;
- diversion of time among our executive team on planning efforts to (i) manage the impacts of the COVID-19 pandemic on our employees, including changes health and safety protocols at our manufacturing facilities, and efforts to better manage telecommuting among employees able to do so, (ii) avoid or minimize supply-chain disruptions, and (iii) preserve liquidity, which could impact a variety of business operations;
- increased spending on our business continuity efforts for our headquarters and manufacturing operations, our supply chain, and readiness efforts for returning to our offices, which may in turn require that we further cut or defer costs and investments in other areas;
- increased risk of an information or cyber-security incident, fraud, a failure to maintain the uninterrupted operation of our information systems due to, among other things, an increase in remote work;
- material disruption of our supply of product components or ability to distribute our products, despite our efforts to manage potential supply-chain disruption;
- increased prices for components and materials used in the production of our products due to inflation and supply-chain issues;
- material business and manufacturing disruption caused by an outbreak at our headquarters and manufacturing facility for a sustained period of time; and
- delays and disruptions of our research and development and product approval processes.

All of these factors may have far reaching impacts on our business, operations, and financial results and condition, including without limitation impacts on the health of our management and employees, manufacturing, distribution, marketing and sales operations, customer and patient behaviors, and economic and social conditions generally. The scope and nature of these impacts, most of which are beyond our control, continue to evolve and the outcomes are uncertain, and such impacts could exist for an extended period of time even after any cessation of the pandemic.

We have limited commercial experience.

We were incorporated in 2009 and began commercializing our Shockwave M5 intravascular lithotripsy ("IVL") catheter ("M5 catheter") for treating peripheral artery disease ("PAD") in the United States and Europe in 2018 and our Shockwave C2 IVL catheter ("C2 catheter") for treating coronary artery disease ("CAD") in Europe in 2018. We initiated a limited launch of our Shockwave S4 IVL catheter ("S4 catheter") in the first half of 2019 and commenced a full commercial launch in select approved geographies in the second half of 2019. We submitted our application for U.S. pre-market approval ("PMA") with the U.S. Food and Drug Administration (the "FDA") relating to our C2 catheters in August of 2020 and we received FDA approval for our C2 catheters in February 2021. We are currently initiating a limited market release in the United States and select international locations of our Shockwave M5+ IVL catheter ("M5+ catheters"), which was CE-Marked in November 2020 and cleared by the FDA in April 2021. Our limited commercialization experience and limited number of approved or cleared products make 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 history of net losses, and we may continue to incur losses. We may not be able to sustain profitability.

We have incurred net losses since our inception and although we were profitable in the third and fourth quarters of 2021, we incurred a net loss for all of 2021 and we may continue to incur net losses in the future. For the years ended

December 31, 2021 and 2020, we had net losses of $9.1 million and $65.7 million, respectively. As a result of these losses, as of December 31, 2021, we had an accumulated deficit of approximately $252.8 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, obtain 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 the third and fourth quarters of 2021, we cannot be sure that we will remain profitable for any substantial period of time. 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 in future periods. As a result, we may continue to generate losses. We cannot ensure that we will achieve profitability in the future or that, if we do become 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 approved products, 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 products, if approved, and potential future products that 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;

- future accounting pronouncements or changes in our accounting policies; and
- the continued impact of the COVID-19 pandemic on our operations and financial results.

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.

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

As of December 31, 2021, we had net operating loss ("NOL") carryforwards of approximately $351.0 million for federal income tax purposes, and $54.0 million for California and $160.6 million for other state income tax purposes. These federal NOLs (generated prior to 2018) begin expiring in 2030, the California NOLs begin expiring in 2031 and other state NOL carryforwards begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Some of these NOLs could expire unused and be unavailable to offset our future income tax liabilities. To the extent available, we intend to use these NOL and credit carryforwards to offset future taxable income and/or income tax liabilities associated with our operations. There can be no assurance that we will generate sufficient taxable income in the carryforward period to utilize the remaining tax attributes before they expire. As well, there are a variety of federal rules and regulations that may impact our ability to use our NOLs, including:

- *Section 382*. Under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future results of operations by effectively increasing our future tax obligations.
- *The TCJA*. Under the Tax Cuts and Jobs Act, enacted on December 22, 2017 ("TCJA"), federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income.
- *The CARES Act*. In response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted on March 27, 2020, to provide aid and economic stimulus to the economy. Among other provisions, the CARES Act eliminates the 80% NOL limitation for tax years 2018, 2019, and 2020, and allows NOLs generated in those years to be carried back for five years. We believe that any impact of the CARES Act provisions is not significant to our financial position, results of operations or cash flows.

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. In addition, it is uncertain if and to what extent various states will conform to the TCJA or any newly enacted federal tax legislation. 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 eliminates the option to immediately deduct research and development expenditures and requires taxpayers to amortize domestic expenditures over five years and foreign expenditures over 15 years. While it is possible that Congress may defer, modify, or repeal this provision, we have no assurance that this provision will be deferred, modified or repealed and even if Congress makes any such decision, it may not be retroactive to January 1, 2022, and could still therefore result in an impact on cash from operating activities and on the balance of our deferred taxes.

These and other changes resulting from the TCJA or future tax reform legislation 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 U.S. 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.

Since our inception, we have incurred significant net losses and, although we had net income in the third and fourth quarters of 2021, 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, 2021, we had $201.0 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $252.8 million. Based on our current planned operations, we expect that our cash, cash equivalents and short-term investments will enable us to fund our cash requirements, including capital expenditures and working capital, for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We have a number of ongoing clinical trials and expect to continue to make substantial investments in these trials and in additional clinical trials that are designed to provide clinical evidence of the safety and efficacy of our products. We have made and we plan to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives and expanding our international marketing programs to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in research and development, regulatory affairs, and clinical studies to develop future generations of our products, support regulatory submissions and demonstrate the clinical efficacy of our products. Moreover, we expect to continue to incur expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, we may continue to 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 impact of the COVID-19 pandemic on our business;
- 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; 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.

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 acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. 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 and/or 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 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 Securities and Exchange Commission (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 these 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.

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 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. 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, because we are no longer an emerging growth company, 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. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of 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. Hiring and retention may also be impacted by the continuing COVID-19 pandemic. 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, 2021, we had 657 full-time employees worldwide, compared to 449 full-time employees as of December 31, 2020. 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 also rapidly expand other 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 existing Loan and Security Agreement with Silicon Valley Bank (the "Loan and Security Agreement") restricts our ability to pursue certain mergers, acquisitions, amalgamations, or consolidations and this would need to be addressed, if possible, in order to enter into any such transactions;
- 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, 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.

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 limited our rights, control, or decision-making authority in a manner that is not in our best interest;
- any delay or termination of a Collaboration related to our products could delay the development and commercialization of our products and reduce their competitiveness if they reach the market;
- counterparties in any Collaboration may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals;
- conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights, which may result in litigation or arbitration which would increase our expenses and divert the attention of our management; and

- we may be required to incur non-recurring and other charges, increase our near and long-term expenditures, or issue securities that dilute our existing stockholders and disrupt our management and business.

For example, in March 2021, we entered into a joint venture with Genesis MedTech International Private Limited ("Genesis") to establish a long-term strategic partnership to develop, manufacture and commercialize certain of our interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau ("China"). Under the joint venture agreement, Genesis Shockwave Private Ltd. was formed under the laws of Singapore to serve as a joint venture between us and Genesis for the purpose of establishing and managing such a strategic partnership. The termination of our joint venture with Genesis would disrupt our ability to commercialize our products in China.

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

Our participation in the joint venture with Genesis in China is subject to general, as well as industry-specific, economic, political 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, rules and policies in China. Because many laws and regulations are relatively new, the interpretations of many laws, regulations and rules 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 Loan and Security Agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Our Loan and Security Agreement initially provided for a $2.0 million revolving line of credit and a $15.0 million term loan.

On February 11, 2020, we entered into the First Amendment to the Loan and Security Agreement with Silicon Valley Bank (the "Amended Credit Facility"), to refinance our existing term loan. The Amended Credit Facility provided us with a supplemental term loan in the amount of $16.5 million. After repayment of the outstanding amount of the term loan, we received net proceeds of $3.3 million, which reflected an additional $4.3 million in principal as of the date of the modification less the final balloon payment fee of $1.0 million. In addition, the Amended Credit Facility terminated our revolving line of credit.

The supplemental term loan is secured by all of our assets, excluding intellectual property and certain other assets. Subject to the terms of the Amended Credit Facility, the supplemental term loan can be repaid at any time, subject to certain penalty payments, prior to the December 1, 2023 maturity date, at which time all amounts borrowed will be due and payable. The supplemental term loan is not subject to any financial covenants but is subject to customary affirmative and restrictive covenants, including with respect to our ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to our holders, make investments, merge or consolidate with any other person or engage in transactions with our affiliates. If we fail to comply with the covenants or payments in connection with

the supplemental term loan, Silicon Valley Bank could declare an event of default, which would give it the right to terminate its commitment 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, Silicon Valley Bank 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 using 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, compliance, purchasing and inventory management. Our information systems require an ongoing commitment of significant resources designed to maintain, protect, and enhance our existing systems, however, a number of issues could impact the integrity of our systems including:

- Technology risks ("Technology Risks"), including failures during the process of upgrading or replacing software, databases, or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures, and user errors.
- Data- and cyber-security threats ("Cyber Risks"), 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.

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. As well, because of the nature 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. In addition, a greater number of our employees working remotely during the COVID-19 pandemic has exposed us, and may continue to expose us, to increased Cyber Risks. Although we have expended, and will likely continue to need to expend, significant resources and make significant capital investment in efforts designed to protect against security breaches or to mitigate the impact of any such breaches, we realize that Cyber Risks are a threat, and there can be no assurance of our efforts will prevent information security breaches that would 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 such 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.

In connection with various facets of our business, we collect and use personal data, such as name, mailing address, email addresses, mobile phone number, medical and location information, the collection and use of which is regulated by a variety of privacy and security laws, rules and regulations. We also receive personal data from third parties for similar purposes and subject to legal obligations. Any violations of these rules by us could lead to civil and criminal penalties as well as adverse publicity that could harm our ability to initiate and complete clinical trials. In addition, when conducting clinical trials, we must collect and manage all clinical trial data in a manner consistent with applicable laws and regulations, including the Common Rule, Good Clinical Practice ("GCP") guidelines, and FDA human subject protection regulations. 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 data from the Cyber and Technology Risks discussed above with appropriate security measures. Privacy and data protection laws, rules and regulations evolve frequently, and their scope may continually change through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another.

Any failure by us or any of our third-party service providers to follow such laws, regardless of fault, could result in significant liability under various state, federal and international privacy, data protection and other laws, including, the laws listed below. In addition to the liability related to failing to comply with data security obligations, we may also face liability under state, federal, and internal privacy laws if we handle individual personal information in violation of such applicable laws. 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, including recently enacted laws in all jurisdictions where we operate:

- The Federal Trade Commission (the "FTC") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (the "FTC Act"). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.
- California's recently adopted California Consumer Privacy Act (the "CCPA") and will be modified by the successful 2020 ballot initiative titled the California Privacy Rights Act (the "CPRA"), coming into effect in January 2023 (with a look back to January 2022). The CCPA establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California consumers (as defined by the law). In November 2020, California voters approved the CPRA ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (the "CPPA"). New implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive

relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages. The uncertainty, ambiguity, complexity and potential inconsistency surrounding the implementation and interpretation of the CCPA and other enacted or potential laws in other states exemplify the vulnerability of our business to the evolving regulatory environment related to the privacy, security and confidentiality of personal information. Other states have followed California's lead, such as Virginia and Colorado, each of whom have passed similar legislation that will go into effect in 2023. As of January 2022, fourteen states have pending consumer privacy legislation under review, which if enacted would add additional costs and expense of resources to maintain compliance.

- The European Union (the "EU") General Data Protection Regulation ("GDPR") which applies extraterritorially and imposes several strict requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals regarding the processing of their personal data and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and use of information, increased requirements pertaining to the processing of special categories of personal data and pseudonymized (i.e., key-coded) data, additional obligations regarding the sharing of personal data with third parties, and security breach notification obligations, including reporting of personal data breaches to the supervisory authority without undue delay. The GDPR, as well as law in the United Kingdom (the "UK") and Switzerland, also prohibits the international transfer of personal data from the EEA/UK/Switzerland to countries outside of those jurisdictions unless made to a country deemed to have adequate data privacy laws by the European Commission or where a data transfer mechanism has been put in place. On June 4, 2021, the European Commission adopted new SCCs to apply to international transfers to such countries, like the United States, who have not been deemed to have adequate privacy laws. We will have until December 27, 2022 to update any existing agreements, or any new agreements executed before September 27, 2021, that rely on the former SCCs. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our operations, and we may find it necessary to establish systems in the EEA, Switzerland, and the UK to maintain personal data originating from the EEA and the UK, which may involve substantial expense and distraction from other aspects of our business. Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, 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 (approximately $22.6 million) or 4 percent of the annual global revenues of the noncompliant company, whichever is greater. The departure of the UK from the EU as of January 31, 2020 has added increased compliance efforts specifically relating to the UK and these UK-specific compliance efforts may become greater as time passes requiring more attention to the collection, use, disclosure, transfer, and protection of personal information; failure to adhere to the UK's incorporation of GDPR into UK national law provides for comparable penalties, such as the ability to separately fine up to the greater of £17.5 million (approximately $23.7 million) or 4 percent of global turnover.
- 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. (Japan also has additional sectorial laws governing the medical sector and the handling of personal information.) The APPI applies 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; some extra-territorial provisions exist for offshore PICs in certain situations. PICs are subject to disclosure requirements governing their collection, use, and disclosure of personal information, as well as restrictions on the transfer of data outside of Japan comparable to the GDPR's approach to countries not deemed to have adequate data protection measures. Data subjects also have the right to access, rectify, correct, amend, or delete their personal data, and to request the cessation of use of their personal data if it is used for a purpose other than the one originally stated, or if it was acquired by fraudulent or other unlawful means. PICs have legal obligations to secure personal information and report losses to the Japanese government. These rights are enforced by the Personal Information Protection Commission, which has the power to issue orders for "improvement" in response to violations of privacy law by PICs. Beginning on April 1, 2022, new amendments taking effect will provide that a PIC's noncompliance with an order for improvement would be grounds for harsher penalties than were previously in place, including criminal imprisonment for up to one year or a criminal

fine of up to JPY 1 million (approximately $8,700) for an individual who is the PIC or who is the director or employee of the PIC entity responsible for the breach, and a criminal fine of up to JPY 100 million (approximately $870,000) for the PIC as an entity.

We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (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 personally identifiable information resulting from Technology 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 data 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 and other similar non-U.S. law; 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. For example, the COVID-19 pandemic has caused extreme volatility and disruptions in the global capital and credit markets. A severe or prolonged economic downturn, could result in a variety of risks to our business, including driving hospitals to tighten budgets and curtail spending, which would negatively impact our sales and business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition, and results of operations.

Disasters and other business disruptions 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.

In addition, 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 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.

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 M5 catheters and M5+ catheters for the treatment of above-the-knee PAD, S4 catheters for the treatment of below-the knee PAD, and C2

catheters for the treatment of CAD, each of which is available in the United States, Europe, and other international markets. 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.

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.

We currently market and sell our M^{5} and M^{5+} catheters and S^{4} catheters for the treatment of calcified plaque in patients with PAD and our C^{2} catheters for the treatment of calcified plaque in patients with CAD in the United States, Europe and other international markets. However, our 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 discover 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 use, 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 in 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, including single source component suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers to provide us with a portion of our demand for one of our products as well as 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. 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.

We depend on our suppliers to provide us with materials or products in a timely manner that meet our quality, quantity, and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, including as a result of the ongoing COVID-19 pandemic, any of which could delay or impede their ability to meet our demand. These suppliers 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 exist for all materials, components and services necessary to manufacture our products, establishing additional or replacement suppliers 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, 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 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 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.

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 procure materials from alternate suppliers or 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 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 or failure to obtain additional suppliers 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.

We and our 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 suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our products or component suppliers comply or will continue to comply with all regulatory requirements. The failure by us or one of our suppliers 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 has been identified and evaluated. Our or any product or component supplier'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 to satisfy our business requirements, we can locate new suppliers 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.

We depend on a third party to manufacture a portion of the demand for certain of our products and we may engage additional third-party manufacturers in the future. If any of these manufacturers fail to meet our requirements and strict regulatory standards, we may be unable to develop, commercialize or market our products.

We depend on one third-party to manufacture a certain portion of the demand for one of our products and we may in the future need to depend upon additional third parties to manufacture our products. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreement by the third party because of our breach of the manufacturing agreement or based on its own business priorities.

Any of these factors could cause delay or suspension of clinical trials, regulatory submissions, required approvals, commercialization or marketing of our products or cause us to incur higher costs. Furthermore, 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. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products on the timeline and in the quantities required, could have a material adverse effect on our business. It may take a significant amount of time and resources, including costs, to establish an alternative source of supply for our products and to have any such new source approved by the FDA.

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.

We are at an early stage in our growth and we must build effective sales and marketing capabilities for our products.

We are at an early stage in our growth and have only recently launched our products for commercial use. For example, we launched our M^5 catheters for the treatment of PAD in the United States, Europe and select other countries in 2018, and we launched our C^2 catheters for the treatment of CAD in Europe in 2018, and in the United States in February 2021. We initiated a limited launch of our S^4 catheter in the first half of 2019 and commenced a full commercial launch in select approved geographies in the second half of 2019. We initiated a limited launch of our M^{5+} catheters in the United States and Europe in late 2021. We had revenue of $237.1 million and $67.8 million for the years ended December 31, 2021 and 2020, respectively.

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 U.S. 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, on applicable federal and state laws and regulations and on our internal policies and procedures, requires significant time, expense, and attention and it can take significant time before our sales representatives are fully trained and productive.

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.

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 treatment outcomes. We believe that focusing on calcified plaque is a paradigm shift in the treatment of these 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.

For example, in July 2018, we initiated and subsequently completed a voluntary recall of our S4 catheters after seeing a higher instance of leaks in the balloon, which prevented the balloon from staying inflated at four atmospheres ("atm") for the full course of lithotripsy application. Although there were no patient safety issues reported and no reports of adverse clinical events related to this issue, and the issue has been corrected, customer satisfaction problems early in a product's launch can have lasting negative impact on our ability to sell such product. We proceeded with a full commercial launch of our S4 catheter in select approved geographies in the second half of 2019. However, we cannot guarantee that issues with our S4 catheters will not resurface. Any future government or voluntary recalls of our S4 catheter could divert managerial and financial resources, harm our reputation, and adversely affect our business.

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.

We may be unable to compete successfully with larger companies in our highly competitive industry.

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 by other companies, including Boston Scientific Corporation, Cardiovascular Systems, Inc. ("CSI"), Medtronic plc and Philips N.V. 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 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. We compete primarily on the basis that our products 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.

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.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

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 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.

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 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 21% of our revenue for the year ended December 31, 2021. 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 abroad;
- 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, 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, 2021, we have contracted with distributors who are actively selling our products in over 50 countries in North and South America, Europe, the UK, the Middle East, Asia, Africa, and Australia/New Zealand. For the year ended December 31, 2021, approximately 21% 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. For example, before a new medical device, or a new intended use for an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance, De Novo authorization or approval of a PMA from the FDA, unless an exemption applies. 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. 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. 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;
- unanticipated expenditures to address or defend such actions;
- 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; or
- criminal prosecution.

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.

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 510(k) clearance to market our M5, M5+, and S4 catheters and PMA approval for our C2 catheters, our 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.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting recalls and certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. Our C2 catheter 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.

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. Such reviews and investigations may result in civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and could result in substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may 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.

Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems, and processes to comply with these legal and regulatory requirements.

Although we have obtained regulatory clearance for our M5, M5+, and S4 catheters for the treatment of PAD and our C2 catheter for the treatment of CAD in the United States and in certain non-U.S. jurisdictions, they will remain subject to extensive regulatory scrutiny.

Although our M5, M5+ and S4 catheters have obtained regulatory clearance in the United States and in certain non-U.S. jurisdictions for the treatment of PAD, and our C2 catheters have obtained regulatory clearance in the United States and certain non-U.S. jurisdictions for the treatment of CAD, 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 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. In July 2018, for example, we initiated and subsequently completed a voluntary recall of our S4 catheters after seeing a higher instance of leaks in the balloon, which prevented the balloon from staying inflated at four atm for the full course of lithotripsy application. While there were no patient safety issues reported and no reports of adverse clinical events related to this issue and the issue has been corrected, we believe it was prudent to suspend utilization of the device and recall the product while we determined the cause of the leak. 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 our demand for our M5 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 repeal or replace them or to alter their interpretation and implementation, and there may be additional challenges and amendments to the ACA in the future. For example, legislation affecting the implementation of certain taxes under the ACA have 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." Further, the Bipartisan Budget Act of 2018 ("BBA"), among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, a United States District Court Judge for the Northern District of Texas ruled that (i) the "individual mandate" was unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the TCJA; and (ii) the individual mandate is not severable from the rest of the ACA, and as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional but remanded the case to the district court to reconsider the severability question. In March 2020, the U.S. Supreme Court agreed to hear the case and oral arguments before the U.S. Supreme Court took place on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to further judicial or Congressional challenges in the future. It is unclear how any such efforts to repeal, replace, amend or invalidate the ACA or its implementing regulations, or portions thereof, and the healthcare reform measures of the Biden administration will impact the ACA or our business.

In addition, other healthcare reform legislative changes have been proposed and adopted since the ACA was enacted. 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, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 (with the exception of a temporary suspension from May 1, 2020 through May 31, 2022, due to the COVID-19 pandemic). The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. 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.
- ***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.
- ***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 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. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance, including failure to respond to official actions within prescribed time limits, non-payment of fees or failure to properly legalize and submit formal documents, can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology.
- ***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 the section titled "*—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 the section titled "*—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 be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review ("IPR"), or interference proceedings 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 interference proceedings declared by the USPTO to determine priority of invention or 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. Nos. 9,642,673, 8,956,371 and 8,728,091, which are three of our issued U.S. patents that relate to our current IVL Technology, were filed in December 2018 at the USPTO's Patent Trial and Appeal Board (the "PTAB") by Cardiovascular Systems, Inc., one of our competitors. The PTAB instituted IPR proceedings for all three patents. The PTAB held oral hearings on April 15-16, 2020. On July 8, 2020, the PTAB ruled that one claim ("Claim 5") in U.S. Pat No. 8,956,371 (the "'371 patent") is valid and ruled that all other claims in the '371 patent are invalid and that all claims of U.S. Pat No. 8,728,091 (the "'091 patent") are invalid. On July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 (the "'673 patent") are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB judge in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB decision in the '371 patent proceeding. In addition, the PTAB judge reset the time for

commencement of an appeal in the ’371 patent proceeding pending the entry of a final decision after the requested briefing. On October 13, 2020, we submitted the last of the requested briefing, and the PTAB decision is pending. Subject to the final PTAB decision regarding the ’371 patent proceeding, we anticipate appealing this ruling to the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”).

We appealed the rulings in the IPR proceedings for the ’091 patent and the ’673 patent to the Federal Circuit. On January 18, 2022, the Federal Circuit issued two short opinions affirming the decisions of the PTAB, finding that the claims of the ’091 patent and the ’673 patent are unpatentable (the “Rulings”). These Rulings conclude the IPR proceedings initiated by CSI for these two patents and resulted in the loss in scope of the ’091 patent and the ’673 patent, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

IPR proceedings relating to the ’371 patent remain pending before the PTAB on rehearing and have not yet been addressed by the Federal Circuit. Claim 5 of the ’371 patent was found to be valid and all other claims remain valid and enforceable until a final decision is obtained from the PTAB and any 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 is a high one requiring 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 were we 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 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 propriety 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, 2021 through December 31, 2021, the closing price of our common stock has ranged from $92.73 per share to $241.83 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, some 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 or those that we have not 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;
- 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; and
- other events or factors, many of which are beyond our control.

In addition, the trading prices for common stock of other medical device companies have been highly volatile, due in part to the COVID-19 pandemic, which continues to rapidly evolve. The extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

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, 2021, our executive officers, directors and 5% stockholders beneficially owned approximately 37% of the outstanding shares of capital stock. As of December 31, 2021, we had 35,444,472 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, 2021, our executive officers and directors held options to purchase an aggregate of 906,047 shares of our common stock at a weighted-average exercise price of $4.82 per share and 218,491 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.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. In recent years, medical device companies have experienced significant stock price volatility. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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 and 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, 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. We believe that our facilities in Santa Clara meet our current and future anticipated needs.

Item 3. Legal Proceedings.

Petitions for *inter partes* review ("IPR") of U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091, 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.

The PTAB held oral hearings on April 15-16, 2020. On July 8, 2020, the PTAB ruled that one claim ("Claim 5") in U.S. Pat No. 8,956,371 (the "'371 patent") is valid and ruled that all other claims in the '371 patent are invalid and that all claims of U.S. Pat No. 8,728,091 (the "'091 patent") are invalid. On July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 (the "'673 patent") are invalid. On August 27, 2020, further briefing by the parties was requested by the PTAB judge in the '371 patent proceeding to assess whether recent guidance from the USPTO relating to "applicant admitted prior art" impacted the PTAB decision in the '371 patent proceeding. In addition, the PTAB judge reset the time for commencement of an appeal in the '371 patent proceeding pending the entry of a final decision after the requested briefing. On October 13, 2020, we submitted the last of the requested briefing, and the PTAB decision is pending. Subject to the final PTAB decision regarding the '371 patent proceeding, we anticipate appealing this ruling to the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit").

We appealed the rulings in the IPR proceedings for the '091 patent and the '673 patent to the Federal Circuit. On January 18, 2022, the Federal Circuit issued two short opinions affirming the decisions of the PTAB, finding that the claims of the '091 patent and the '673 patent are unpatentable (the "Rulings"). The Rulings conclude the IPR proceedings initiated by CSI for these two patents and resulted in the loss in scope of the '091 patent and the '673 patent, which may limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

IPR proceedings relating to the '371 patent remain pending before the PTAB on rehearing and have not yet been addressed by the Federal Circuit. Claim 5 of the '371 patent was found to be valid and all other claims remain valid and enforceable until a final decision is obtained from the PTAB and any 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.

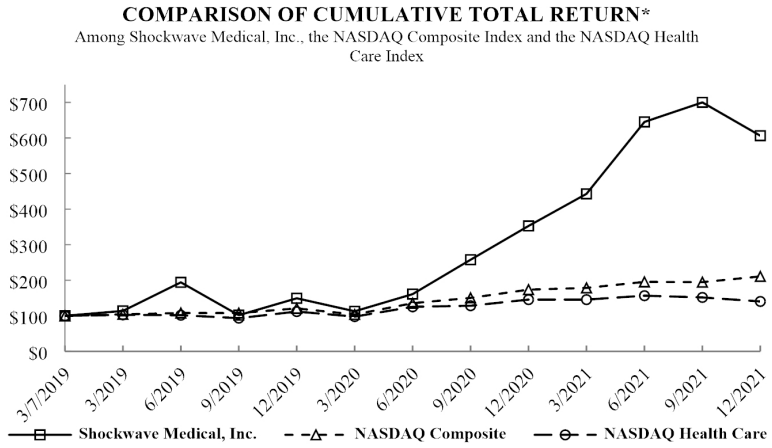
Holders of Record

As of February 18, 2022, there were 20 holders 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.



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

Item 6. Reserved.

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

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

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

Overview

We are a medical device company focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for medical device treatment of atherosclerotic cardiovascular disease ("atherosclerosis") through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, 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 significantly improve patient outcomes. 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 M5 IVL catheter (the "M5 catheter") and M5+ IVL catheter ("M5+ catheter") are five-emitter catheters for use in our IVL System in "medium" vessels for the treatment of above-the-knee PAD. The M5 catheter was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018. The M5+ catheter, for which we are currently initiating a limited market release in the United States and select international locations, was CE-Marked in November 2020 and cleared by the FDA in April 2021.
- Our Shockwave S4 IVL catheter ("S4 catheter") is a four-emitter catheter for use in our IVL System in small vessels for the treatment of below-the-knee PAD. The second version of our S4 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.

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

- Our Shockwave C2 IVL catheter ("C2 catheter") is a two-emitter catheter for use in our IVL System for the treatment of CAD. The C2 catheter was CE-Marked in June 2018. In August 2019, we received the Breakthrough Device Designation from the FDA for our C2 catheters using our IVL System for the treatment of CAD. In August of 2020, we submitted an application to the FDA for U.S. pre-market approval of our C2 catheters, which was approved by the FDA in February 2021.

Our differentiated range of M5 and M5+ catheters, S4 catheters and C2 catheters enables delivery of IVL therapy of 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 initial studies have consistently shown low rates of complications regardless of which vessel was being

studied. In addition to gaining regulatory approvals or clearances, the data from our clinical studies strengthen our ability to drive adoption of 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 also have ongoing clinical programs across several products and indications, which, if successful, will allow us to expand commercialization of our products into new geographies and indications. For a discussion of our current clinical trials, refer see the section titled "*Business – Company Overview – Our Products and Product Pipeline.*"

The first two indications we are targeting with our IVL System 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 to the cardiovascular field with the aim of creating what we believe can become the safest, most effective means of addressing the growing challenge of cardiovascular calcification. Lithotripsy has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years. 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 calcium in the medial layer of the artery, not just at the superficial most intimal layer. The shockwaves crack this calcium and enable the narrowed artery to expand at low pressures, thereby minimizing complications inherent to traditional balloon dilations, such as dissections or tears. Preparing the vessel with IVL facilitates optimal outcomes with other therapies, including stents and drug-eluting technologies. Using IVL also avoids complications associated with atherectomy devices such as dissection, perforation, and embolism. When followed by an anti-proliferative therapy such as a drug-coated balloons or drug-eluting stents, the micro-fractures may enable better drug penetration into the arterial wall and improve drug uptake, thereby improving the effectiveness of the combination treatment.

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, and the United Kingdom, and we are working to build out our direct sales team in Japan in anticipation of the launch of our C^2 catheters, for which we anticipate Japanese regulatory approvals in the first half of 2022. We have complemented our direct sales capability with distributors actively selling our products in over 50 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. We are actively expanding our international field presence through new distributors, as well as additional sales and clinical personnel. In addition, we are continuing to add new U.S. sales territories.

For the years ended December 31, 2021, 2020 and 2019, we generated revenue of $237.1 million, $67.8 million and $42.9 million, respectively, and incurred net losses of $9.1 million, $65.7 million and $51.1 million, respectively. For the years ended December 31, 2021, 2020 and 2019, 21%, 45% and 47%, 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.

Since inception, we have incurred significant net losses. Although we had positive net income for the quarters ended September 30, 2021, and December 31, 2021, we had a net loss for the year ended December 31, 2021. We may continue to incur 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, 2021, we had positive cash flows from operations of $15.0 million. As of December 31, 2021, we had $201.0 million in cash, cash equivalents and short-term investments and an accumulated deficit of $252.8 million.

Impact of the COVID-19 pandemic

The global COVID-19 pandemic presents significant risks to us and has had, and continues to have, far reaching impacts on our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on: the health of our management and employees; our manufacturing, distribution, marketing and sales operations; our research and development activities, including clinical activities; and customer and patient behaviors.

Access to many hospitals and other customer sites may be or may periodically be, depending on the current COVID-19 infection rates in the applicable location, restricted to essential personnel, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and other therapeutic centers have in the past suspended, and may suspend or continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers are located.

Quarantines, shelter-in-place and similar government orders have also impacted and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

In addition, we have recently seen some 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 and, in certain cases, requiring us to procure materials from alternate suppliers or incur higher logistical expenses. We are continuing to work closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand. However, we have not experienced material disruptions in our supply chain to date.

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in manufacturing and limited support functions continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our other employees and their families from potential exposure to COVID-19, until recently all other staff in our Santa Clara headquarters were required to work from home. Certain of these other employees had begun to return to our headquarters full or part-time during the second quarter of 2021, although we continue to review the impact of the omicron variant of COVID-19 on employee safety. We continue to limit travel to protect the health and safety of our employees and customers.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that we consider prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, including the ability of various regions to effectively manage COVID-19, the extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19, including the current omicron variant, and the ability of various economies and supply-chains to recover from the COVID-19 pandemic. Most of these developments and factors are outside of our control and could exist for an extended period of time even after any cessation of the pandemic.

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. We must continue to successfully compete 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.
- ***COVID-19 pandemic.*** The COVID-19 pandemic and measures taken in response thereto, which have negatively affected, and we expect will continue to negatively affect, our revenues and results of operations. Due to these impacts and measures, we may experience significant and unpredictable fluctuations in demand for certain of our products as hospital customers re-prioritize the treatment of patients and distributors adjust their operations to support the current demand level.
- ***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 also anticipate that we may in the future experience 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; and fluctuations in foreign currency exchange 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 derived 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 certain customers that purchase stocking orders in the United States, 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 costs of 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 generators used in our IVL System that we provide to our hospital customers, often on a cost-free loan basis to facilitate the use of our IVL catheters in their procedures. We depreciate the generators 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, head count and cost-reduction strategies. 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, gross margin percentage 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:

- 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 approval.

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 include marketing and promotional activities, including trade shows and market research, and cost of outside consultants. We expect to continue to grow our sales force and increase marketing efforts as we continue commercializing products based on our IVL Technology.

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 include professional services fees, including legal,

audit and tax fees, insurance costs, cost of outside consultants 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.

Share in net loss of equity method investment

Share in net loss of equity method investment, represents our proportionate share of the underlying income or loss incurred in connection with our joint venture with Genesis MedTech International Private Limited ("Genesis").

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.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020:

	Year Ended December 31,		Change	Change
	2021	2020	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 237,146	$ 67,789	$ 169,357	250%
Cost of revenue:				
Cost of product revenue	41,438	20,991	20,447	97%
Gross profit	195,708	46,798	148,910	318%
Operating expenses:				
Research and development	50,544	36,926	13,618	37%
Sales and marketing	111,288	51,672	59,616	115%
General and administrative	34,747	23,863	10,884	46%
Total operating expenses	196,579	112,461	84,118	75%
Loss from operations	(871)	(65,663)	64,792	(99)%
Share in net loss of equity method investment	(6,286)	—	(6,286)	100%
Interest expense	(1,096)	(1,212)	116	(10)%
Other income (expense), net	(582)	1,256	(1,838)	(146)%
Net loss before taxes	(8,835)	(65,619)	56,784	(87)%
Income tax provision	301	80	221	276%
Net loss	$ (9,136)	$ (65,699)	$ 56,563	(86)%

Product revenue. Product revenue increased by $169.4 million, or 250%, from $67.8 million in 2020 to $237.1 million in 2021, 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
	2021	2020	$	%
	(in thousands, except percentages)			
Coronary	$ 161,463	$ 24,586	$ 136,877	557%
Peripheral	74,064	41,994	32,070	76%
Other	1,619	1,209	410	34%
Product revenue	$ 237,146	$ 67,789	$ 169,357	250%

Coronary product revenue increased by $136.9 million, or 557%, from $24.6 million in 2020 to $161.5 million in 2021. In February 2021, we received FDA approval for our C2 catheters. The increase in coronary product revenue was due to the commencement of sales in the United States, increased adoption of our products internationally, and continued recovery from

the COVID-19 pandemic impact in the prior year. All coronary product revenue was from international customers for the year ended December 31, 2020.

Peripheral product revenue increased by $32.1 million, or 76%, from $42.0 million in 2020 to $74.1 million in 2021. The change was due to an increase in the number of our M5 and S4 IVL catheters sold within the United States and internationally driven by increased adoption of our products and recovery from the COVID-19 pandemic impact in the prior year.

Other product revenue increased by $0.4 million, or 34%, from $1.2 million in 2020 to $1.6 million in 2021. 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 2021 compared to 2020. Product revenue, classified by the major geographic areas in which our products are shipped, was $186.3 million within the United States and $50.8 million for all other countries in 2021 compared to $37.1 million within the United States and $30.7 million for all other countries in 2020.

Cost of product revenue and gross margin percentage. Cost of product revenue increased by $20.4 million, or 97%, from $21.0 million in 2020 to $41.4 million in 2021. The increase was driven by higher product sales volume compared to the prior year. Gross margin percentage improved to 83% in 2021, compared to 69% in 2020. This change in gross margin percentage was primarily due to higher average selling price and lower fixed costs per unit from increased production volume of our IVL catheters and increased manufacturing 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,			
	2021	2020	Change $	Change %
	(in thousands, except percentages)			
Compensation and personnel-related costs	$ 29,051	$ 17,097	$ 11,954	70%
Clinical-related costs	8,586	10,268	(1,682)	(16)%
Material and supplies	3,382	2,984	398	13%
Facilities and other allocated costs	5,547	2,941	2,606	89%
Outside consultants	3,022	1,868	1,154	62%
Other research and development costs	956	1,768	(812)	(46)%
Total research and development expenses	$ 50,544	$ 36,926	$ 13,618	37%

Research and development expenses increased by $13.6 million, or 37%, from $36.9 million in 2020 to $50.5 million in 2021. The increase was primarily due to a $12.0 million increase in compensation and personnel-related costs due to an increase in head count to support research and development activities. There was also a $2.6 million increase in facilities and other allocated costs due to increased information technology, rent and building expenditures, a $1.2 million increase for outside consultants, and a $0.4 million increase in materials and supplies. These increases were partially offset by a $1.7 million decrease in clinical-related costs primarily due to the timing of completion of patient enrollment for certain clinical trials and the timing of commencement of new clinical trials, and a $0.8 million decrease in other research and development costs due to software license costs in the prior year not incurred in the current year.

Sales and marketing expenses. Sales and marketing expenses increased by $59.6 million, or 115%, from $51.7 million in 2020 to $111.3 million in 2021. The increase was primarily due to a $45.2 million increase in compensation and personnel-related costs, as a result of a higher head count and increased revenue for the year-ended December 31, 2021. Marketing and promotional expenses increased by $5.2 million to support the continued commercialization of our products. There was also a $4.3 million increase due to travel-related costs driven by higher head count and continued recovery from the COVID-19 pandemic impact in the prior year, a $2.4 million increase in facilities and other allocated costs, due to increased information technology, rent and building expenditures, a $1.9 million increase due to consulting and general corporate expenses, a $0.5 million increase in materials and supplies, and a $0.1 million increase due to recruiting and training fees.

General and administrative expenses. General and administrative expenses increased by $10.9 million, or 46%, from $23.9 million in 2020 to $34.7 million in 2021. The change was primarily due to a $7.7 million increase in compensation and personnel-related costs due to an increase in head count, $2.1 million increase in consulting, professional services and general corporate expenses, and a $1.1 million increase in recruiting, training, information technology and facilities costs.

Share in net loss of equity method investment. The share in net loss of equity method investment of $6.3 million in 2021 was due to our 45% ownership in the joint venture which was acquired in March 2021.

Interest expense. Interest expense of $1.1 million was related to our outstanding term loan which matures in December 2023. The term loan requires monthly repayments of principal starting in July 2022.

Other income (expense), net. Other income (expense), net decreased by $1.8 million, or 146%, from $1.3 million in other income, net in 2020 to $0.6 million in other expense, net in 2021. The decrease in other income was primarily due to a decrease in interest income attributable to the decreased interest rate environment in the comparable period and the timing of the maturities of marketable securities. Also included in other income (expense), net are the net impact of foreign exchange gains and losses.

Comparison of the Years Ended December 31, 2020 and 2019

For a discussion regarding our financial condition and our results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019, 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, 2020, filed with the SEC on February 26, 2021.

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 Credit Facility”) to refinance our existing term loan, which was accounted for as a modification. The Amended Credit Facility 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 matures on December 1, 2023. The Amended Credit Facility provides an interest-only payment through June 30, 2022.

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 positive net income for the quarters ended September 30, 2021, and December 31, 2021, we had a net loss for the year ended December 31, 2021 and we may incur net losses and have negative cash flows from operations in the future.

As of December 31, 2021, we have $201.0 million in cash, cash equivalents and short-term investments and an accumulated deficit of $252.8 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;
- 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. 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

Our debt, principal and interest commitments consist of our debt obligations under the Amended Credit Facility. As of December 31, 2021, we had debt, principal, and interest commitments of $17.1 million, of which $6.0 million is expected to be paid within the next twelve months.

Manufacturing Purchase Obligations

We have fixed commitments with a contract manufacturer of approximately $12.7 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. During the year ended 2021, we entered into a lease amendment and executed a lease for an additional facility. Our total operating lease commitments as of December 31, 2021 are approximately $56.2 million, of which $3.5 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,		
	2021	2020	2019
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ 15,036	$ (71,184)	$ (48,107)
Investing activities	26,416	(107,473)	(59,543)
Financing activities	(2,451)	90,035	208,052
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 39,001	$ (88,622)	$ 100,402

Operating activities

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 share in net loss of equity method investment, $3.6 million in depreciation and amortization, $2.0 million in amortization of right-of-use assets, $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.

In 2020, cash used in operating activities was $71.2 million, attributable to a net loss of $65.7 million and a net change in our net operating assets and liabilities of $20.3 million, partially offset by non-cash charges of $14.8 million. Non-cash charges primarily consisted of $10.4 million in stock-based compensation, $1.9 million in depreciation and amortization, $1.5 million in amortization of right-of-use assets, $0.6 million in amortization of debt issuance costs, $0.3 million in accretion of discount on available-for-sale securities and $0.2 million of a loss due to the write down of fixed assets. The change in our net operating assets and liabilities was primarily due to a $17.1 million increase in inventory and $4.3 million increase in accounts receivable due to an increase in sales, a $0.5 million increase in prepaid expenses and other current assets, a $0.3 million increase in other assets, a $1.4 million decrease in accounts payable and a $0.8 million decrease in lease liabilities. These changes were partially offset by a $4.0 million increase in accrued and other current liabilities resulting primarily from the expansion in our operating activities, leasehold improvements associated with our Santa Clara office and laboratory premises, and accrued bonuses and commissions.

Investing activities

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.

In 2020, cash used in investing activities was $107.5 million, attributable to the purchase of available-for-sale securities of $168.0 million and the purchase of property and equipment of $11.5 million, partially offset by proceeds from the maturity of available-for-sale investments of $72.0 million.

Financing activities

In 2021, cash used in financing activities was $2.5 million, attributable to $8.3 million of payment of taxes withheld on net settled vesting of restricted stock units (“RSUs”), 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.

In 2020, cash provided by financing activities was $90.0 million, attributable to $83.4 million from the public offering of our common stock, $3.3 million from borrowings under the Amended Credit Facility, proceeds of $4.3 million from stock

option exercises and proceeds of $1.8 million from the issuance of shares under our employee stock purchase plan. These changes were offset by payment of taxes withheld on net settled vesting of RSUs of $1.4 million, principal payments on our term loan of $1.1 million and payment of public offering costs of $0.2 million.

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 appearing elsewhere in 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 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 certain customers that purchase stocking orders in the United States, 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.

Under agreements with our customers, we may provide for the use of an IVL generator and connector cable at no charge to facilitate the use of our IVL catheters. These agreements 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.

On March 19, 2021, we entered into the Joint Venture Deed (the "JV Agreement") with Genesis to establish a long-term strategic partnership to develop, manufacture and commercialize certain of our interventional products in the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau. Under the JV Agreement, Genesis Shockwave Private Ltd. (the "JV") was formed under the laws of Singapore to serve as a joint venture with Genesis for the purpose of establishing and managing such a 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, 2021, 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.

Equity Method Investment

Entities which we have significant influence over the activities, 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 sheet. We record our proportionate share of the underlying income or loss which is recognized in share in net loss of equity method investment. For the year ended December 31, 2021, our share in the losses incurred by the equity method investee was $6.3 million. We eliminate any intra-entity profits to the extent of our beneficial interest.

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 evidenced 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.

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, 2021 consist of $201.0 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, 2021, we had $17.1 million in variable rate debt outstanding, consisting of the supplemental term loan under our Amended Credit Facility. The supplemental term loan requires monthly repayments of principal starting on July 2022. The supplemental term loan matures on December 1, 2023 and accrues interest at a floating per annum rate equal to the greater of the prime rate minus 1.25% and 3.5%. The interest rate was 3.5% as of December 31, 2021.

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, 2021 and 2020, approximately 12% and 26% 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, 2021, we incurred $0.8 million in foreign exchange losses, primarily driven by Euro denominated accounts receivable and the strengthening of the U.S. Dollar relative to the Euro during the period. A 10% change in exchange rates could result in a change in fair value of $2.1 million and $0.6 million in foreign currency cash and accounts receivable as of December 31, 2021 and 2020, 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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Shockwave Medical, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 25, 2022 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 critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which they relate.

Revenue recognition

Description of the Matter	The Company recorded product revenue of $237.1 million for the year ended December 31, 2021. 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. For consignment inventory, control is transferred at the time the catheters are consumed in a surgical procedure. Auditing the Company’s revenue recognition was challenging given the volume of transactions and the timing of revenue recognition varies by customer, including consideration of the appropriate recognition of revenue for consigned inventory.

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 Jose, California
February 25, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 89,209	$ 50,423
Short-term investments	111,772	151,931
Accounts receivable, net	37,435	11,689
Inventory	42,978	29,859
Prepaid expenses and other current assets	4,508	2,398
Total current assets	285,902	246,300
Operating lease right-of-use assets	27,496	7,568
Property and equipment, net	24,361	16,362
Equity method investment	5,987	—
Other assets	1,936	1,812
TOTAL ASSETS	$ 345,682	$ 272,042
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,520	$ 1,466
Term notes, current portion	5,500	3,300
Accrued liabilities	40,870	19,942
Lease liability, current portion	1,738	873
Total current liabilities	51,628	25,581
Lease liability, noncurrent portion	28,321	7,488
Term notes, noncurrent portion	11,630	13,319
Related party contract liability, noncurrent portion	12,273	—
TOTAL LIABILITIES	103,852	46,388
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, 2021 and 2020	—	—
Common stock, $0.001 par value; 281,274,838 shares authorized; 35,444,472 and 34,684,337 issued and outstanding as of December 31, 2021 and 2020	35	35
Additional paid-in capital	494,806	469,283
Accumulated other comprehensive income (loss)	(202)	9
Accumulated deficit	(252,809)	(243,673)
TOTAL STOCKHOLDERS' EQUITY	241,830	225,654
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 345,682	$ 272,042

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

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenue:			
Product revenue	$ 237,146	$ 67,789	$ 42,927
Cost of revenue:			
Cost of product revenue	41,438	20,991	17,159
Gross profit	195,708	46,798	25,768
Operating expenses:			
Research and development	50,544	36,926	32,853
Sales and marketing	111,288	51,672	30,620
General and administrative	34,747	23,863	14,134
Total operating expenses	196,579	112,461	77,607
Loss from operations	(871)	(65,663)	(51,839)
Interest expense	(1,096)	(1,212)	(944)
Change in fair value of warrant liability	—	—	(609)
Share in net loss of equity method investment	(6,286)	—	—
Other income (expense), net	(582)	1,256	2,345
Net loss before taxes	(8,835)	(65,619)	(51,047)
Income tax provision	301	80	62
Net loss	$ (9,136)	$ (65,699)	$ (51,109)
Unrealized gain (loss) on available-for-sale securities	(211)	(5)	35
Adjustment for net gain realized and included in other income, net	—	(21)	—
Total comprehensive loss	$ (9,347)	$ (65,725)	$ (51,074)
Net loss per share, basic and diluted	$ (0.26)	$ (1.99)	$ (2.14)
Shares used in computing net loss per share, basic and diluted	35,098,130	33,088,095	23,904,828

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

SHOCKWAVE MEDICAL, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance — December 31, 2018	18,670,328	$ 152,806	1,824,852	$ 2	$ 4,275	$ —	$ (126,865)	$ (122,588)
Exercise of common stock warrants for cash	—	—	50,331	—	110	—	—	110
Issuance of common stock upon net exercise of warrants	—	—	180,952	—	133	—	—	133
Conversion of preferred stock to common stock upon initial public offering	(18,670,328)	(152,806)	18,670,328	18	152,788	—	—	152,806
Conversion of Series A-1 warrants to common stock warrants upon initial public offering	—	—	—	—	789	—	—	789
Issuance of common stock in connection with initial public offering, net of issuance costs of $11.5 million	—	—	6,555,000	7	99,917	—	—	99,924
Issuance of common stock in connection with private placement	—	—	588,235	1	9,999	—	—	10,000
Issuance of common stock in connection with public offering, net of issuance costs of $6.8 million	—	—	2,854,048	3	96,674	—	—	96,677
Exercise of stock options	—	—	723,155	—	2,206	—	—	2,206
Vesting of early exercised options	—	—	—	—	27	—	—	27
Stock-based compensation	—	—	—	—	3,646	—	—	3,646
Adjustment for fractional shares resulting from reverse stock split	—	—	(114)	—	(3)	—	—	(3)
Unrealized gain on available-for-sale securities	—	—	—	—	—	35	—	35
Net loss	—	—	—	—	—	—	(51,109)	(51,109)
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

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,		
	2021	**2020**	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (9,136)	$ (65,699)	$ (51,109)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,579	1,863	1,337
Share in net loss of equity method investment	6,286	—	—
Stock-based compensation	27,257	10,350	3,646
Amortization of right-of-use assets	1,957	1,483	944
Accretion of discount on available-for-sale securities	1,093	300	(543)
Loss on write down of fixed assets	7	187	67
Change in fair value of warrant liability	—	—	609
Amortization of debt issuance costs	511	646	436
Changes in operating assets and liabilities:			
Accounts receivable	(25,746)	(4,312)	(4,527)
Inventory	(12,073)	(17,056)	(6,824)
Prepaid expenses and other current assets	(2,110)	(501)	(785)
Other assets	91	(306)	41
Accounts payable	1,870	(1,392)	1,272
Accrued and other current liabilities	21,637	4,017	8,339
Lease liabilities	(187)	(764)	(1,010)
Net cash provided by (used in) operating activities	15,036	(71,184)	(48,107)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of available-for-sale securities	(117,245)	(167,953)	(119,476)
Proceeds from maturities of available-for-sale securities	156,100	72,000	63,750
Purchase of property and equipment	(12,439)	(11,520)	(3,817)
Net cash provided by (used in) investing activities	26,416	(107,473)	(59,543)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	—	—	100,547
Proceeds from issuance of common stock in private placement	—	—	10,000
Proceeds from issuance of common stock in public offering, net of issuance costs paid	—	83,368	96,856
Payments of taxes withheld on net settled vesting of restricted stock units	(8,337)	(1,420)	—
Proceeds from term loans	—	3,265	—
Payment of deferred offering costs	—	(179)	—
Proceeds from stock option exercises	3,049	4,317	2,206
Proceeds from issuance of common stock under employee stock purchase plan	2,837	1,795	—
Proceeds from warrant exercises	—	—	110
Principal payment of term loan	—	(1,111)	(1,667)
Net cash provided by (used in) financing activities	(2,451)	90,035	208,052
Net increase (decrease) in cash, cash equivalents and restricted cash	39,001	(88,622)	100,402
Cash, cash equivalents and restricted cash at beginning of period	51,873	140,495	40,093
Cash, cash equivalents and restricted cash equivalents at end of period	$ 90,874	$ 51,873	$ 140,495
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 586	$ 549	$ 534
Income tax paid	$ 143	$ 22	$ 120
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Common stock issued on conversion of convertible preferred stock	$ —	$ —	$ 152,806
Offering cost included in account payable and accrued liabilities	$ —	$ —	$ 179
Common stock warrants issued on conversion of preferred stock warrants and the reclassification of the warrant liability	$ —	$ —	$ 789
Right-of-use asset obtained in exchange for lease liability	$ 21,885	$ 226	$ 6,948
Property and equipment purchases included in accounts payable and accrued liabilities	$ 1,923	$ 2,448	$ 52
Equity method investment obtained in exchange for related party contract liability	$ 12,273	$ —	$ —
Transfer of fixed assets to inventory	$ 329	$ 413	$ 119

The accompanying notes are an integral part of these 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 subsidiaries in Germany, the United Kingdom, Japan and France.

As of December 31, 2021, the Company had cash, cash equivalents and short-term investments of $201.0 million, which are available to fund future operations. The Company believes that its cash, cash equivalents, and short-term investments as of December 31, 2021, 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 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,	
	2021	2020
	(in thousands)	
Cash and cash equivalents	$ 89,209	$ 50,423
Restricted cash	1,665	1,450
Total cash, cash equivalents, and restricted cash	$ 90,874	$ 51,873

Restricted cash as of December 31, 2021 and 2020 relates to letters of credit established for real property leases relating to buildings housing the Company's corporate offices and manufacturing facilities, 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.

Equity Method Investments

Entities which the Company has significant influence over 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*. 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 share in net loss of equity method investment. For the year ended December 31, 2021, the Company's share in the losses incurred by the equity method investee was $6.3 million. The Company eliminates any intra-entity profits to the extent of the Company's beneficial interest.

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, 2021, 2020 and 2019 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, 2021. One customer accounted for 15% of the Company's accounts receivable as of December 31, 2020.

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. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historic accounting prior to the adoption of ASU 2016-13.

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,		
	2021	2020	2019
	(in thousands)		
Beginning balance	$ 380	$ 194	$ 76
Amounts charged (reversed) to costs and expenses	(12)	205	121
Write-offs	(18)	(19)	(3)
Ending balance	$ 350	$ 380	$ 194

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 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 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 year ended December 31, 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. The Company accounts for forfeitures as they occur.

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. Variable lease payments include lease operating expenses.

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 $2.5 million and $1.1 million for the years ended December 31, 2021 and 2020, respectively. The Company did not make such contributions for the year ended December 31, 2019.

Comprehensive Loss

Comprehensive 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 $0.8 million for the year ended December 31, 2021. There were

net foreign currency transaction gains of $0.3 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration of potential dilutive shares of common stock. Because the Company was in a loss position for the period presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

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

	December 31,		
	2021	**2020**	**2019**
Common stock options issued and outstanding	1,524,985	2,087,202	3,315,001
Restricted stock units	1,156,683	859,577	280,904
Employee stock purchase plan	10,028	15,251	16,420
Total	2,691,696	2,962,030	3,612,325

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. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. 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.

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, 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

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 126,363	$ —	$ —	$ 126,363
Money market funds	35,053	—	—	35,053
Commercial paper	—	31,968	—	31,968
Total assets	$ 161,416	$ 31,968	$ —	$ 193,384

4. Cash Equivalents and Short-Term Investments

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

	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

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 126,354	$ 11	$ (2)	$ 126,363
Money market funds	35,053	—	—	35,053
Commercial paper	31,968	—	—	31,968
Total	$ 193,375	$ 11	$ (2)	$ 193,384
Reported as:				
Cash equivalents				$ 41,453
Short-term investments				151,931
Total				$ 193,384

As of December 31, 2021, the fair value of the Company's available-for-sale securities, by remaining contractual maturities, were as follows (in thousands):

One year or less	$	113,330
Greater than one year and less than two years		45,983
Total	$	159,313

For the years ended December 31, 2021 and 2019, the Company recognized no material realized gains or losses on cash equivalents and short-term investments. For the year ended December 31, 2020, the Company recognized $21,000 in realized gains on cash equivalents and short-term investments.

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	December 31,	
	2021	2020
	(in thousands)	
Raw material	$ 7,685	$ 4,995
Work in progress	13,315	6,051
Finished goods	20,326	16,952
Consigned inventory	1,652	1,861
Total inventory	$ 42,978	$ 29,859

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2021	2020
	(in thousands)	
Equipment	$ 6,234	$ 3,794
Equipment on loan to customers	1,714	1,756
Office furniture	549	157
Software	742	175
Leasehold improvements	17,742	5,808
Construction in progress	3,544	7,800
Property and equipment, gross	30,525	19,490
Less: accumulated depreciation and amortization	(6,164)	(3,128)
Total property and equipment, net	$ 24,361	$ 16,362

Depreciation and amortization expense amounted to $3.6 million, $1.9 million and $1.3 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2021	2020
	(in thousands)	
Accrued employee compensation	$ 25,749	$ 10,885
Accrued research and development costs	4,605	3,057
Accrued asset purchases	4,101	2,527
Accrued professional services	2,636	1,325
Other	3,779	2,148
Total accrued liabilities	$ 40,870	$ 19,942

6. Commitments and Contingencies

Operating Leases

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

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") will continue 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 will become 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, 2021, the Company is not reasonably certain it will exercise these extension options.

The weighted average remaining lease term and discount rate used to measure the Company's operating lease liabilities were 9.9 years and 5.0%, respectively. The Company estimated the discount rate using the incremental borrowing rate as the rate implicit in the lease was not readily determinable.

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, 2021, the Company has no material finance leases.

Operating lease cost was $2.9 million, $2.2 million and $1.2 million, for the years ended December 31, 2021, 2020, and 2019, respectively.

The following are minimum future rental payments owed under lease agreements which have commenced as of December 31, 2021:

	(in thousands)
2022	$ 3,204
2023	4,194
2024	4,289
2025	4,415
2026	4,545
Thereafter	24,664
Total minimum lease payments	$ 45,311
Less: imputed interest and adjustments	(15,252)
Total lease liability	$ 30,059

The total minimum future rental payments owed for the 5403 Betsy Ross facility under the terms of the Lease Amendment which has not yet commenced as of December 31, 2021 is $10.8 million.

7. Term Notes

Loan and Security Agreement

In February 2018, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the "Loan and Security Agreement"). The terms of the Loan and Security Agreement included a term loan of $15.0 million and a revolving line of credit of $2.0 million.

The term loan accrued interest at a floating per annum rate equal to the greater of (a) the Wall Street Journal prime rate minus 1.75% and (b) 2.75%. There was a final payment equal to 6.75% of the original aggregate principal amount, or $1.0 million, of the term loan advances, which was being accrued over the term of the loan using the effective-interest method.

In connection with the execution of the Loan and Security Agreement, the Company issued warrants to purchase 34,440 shares of the Company's common stock. Upon issuance, the fair value of the warrants of $0.1 million was recorded as a debt issuance cost. The debt issuance cost will be amortized to interest expense, net over the term of the loan.

In February 2020, the Company entered into a First Amendment to the Loan and Security Agreement (the "Amended Credit Facility") to, among other things, refinance its existing term loan, which is accounted for as a modification of the Loan and Security Agreement. Under the Amended Credit Facility, the existing revolving line of credit of $2.0 million was terminated and the termination fee of less than $0.1 million was waived. The Amended Credit Facility provides the Company with a supplemental term loan in the amount of $16.5 million. After repayment of the outstanding amount of the term loan, the Company 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 principal amount outstanding under the supplemental term loan accrues interest at a floating per annum rate equal to the greater of (a) the prime rate minus 1.25% and (b) 3.5%. The interest rate was 3.5% as of December 31, 2021.

The supplemental term loan matures on December 1, 2023. The Amended Credit Facility provides an interest-only payment period through June 30, 2022.

The additional final payment for the Amended Credit Facility is $1.6 million, which is currently being accrued over the term of the supplemental term loan using an effective interest rate that reflects the revised cash flows of the modified term loan.

The Company recorded interest expense of $1.1 million, $1.2 million and $0.9 million, for the years ended December 31, 2021, 2020 and 2019, respectively.

The supplemental term loan is secured by all of the Company's assets, excluding intellectual property and certain other assets. The loan contains customary affirmative and restrictive covenants, including with respect to the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments, merge or consolidate with any other person or engage in transactions with the Company's affiliates, but does not include any financial covenants.

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

	December 31,	
	2021	2020
	(in thousands)	
Principal amount of term note	$ 16,500	$ 16,500
Net premium associated with accretion of final payment, and other debt issuance costs	630	119
Term note, current and noncurrent	17,130	16,619
Less: term note, current portion	(5,500)	(3,300)
Term note, noncurrent portion	$ 11,630	$ 13,319

Future minimum payments of principal and estimated payments of interest on the Company's outstanding variable rate borrowings as of December 31, 2021 are as follows:

Year ending December 31:	(in thousands)
2022	6,045
2023	12,779
Total future payments	18,824
Less: amounts representing interest	(756)
Less: final payment	(1,568)
Total principal amount of term note payments	$ 16,500

8. Stock-Based Compensation

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Cost of product revenue	$ 1,153	$ 496	$ 268
Research and development	6,240	2,464	943
Sales and marketing	11,043	3,478	972
General and administrative	8,821	3,912	1,463
Total stock-based compensation	$ 27,257	$ 10,350	$ 3,646

Stock-based compensation of $717,000 and $316,000 was capitalized into inventory for the years ended December 31, 2021 and 2020, respectively. No material stock-based compensation was capitalized into inventory for the year ended December 31, 2019. Stock-based compensation capitalized into inventory is recognized as cost of product revenue when the related product is sold.

Determination of Fair Value

The estimated grant-date fair value of all the Company's stock-based awards was calculated using the Black-Scholes option pricing model, based on the following assumptions:

	Year Ended December 31, 2019
Expected term (in years)	6.08
Expected volatility	42.4%-42.9%
Risk-free interest rate	2.4%-2.6%
Expected dividend yield	0%

The fair value of each stock option grant was determined by the Company using 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—Since the Company has limited trading history for its common stock due to its short trading history, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

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 has elected to recognize forfeitures of share-based payment awards as they occur.

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, 2021, the Company had reserved 3,745,216 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, 2018	392,299	3,636,358	$ 3.54	7.79	$ 11,267
Awards authorized	2,000,430	—			
Options expired	(287,600)	—			
Options granted	(442,858)	442,858	14.69		
Options exercised	—	(722,242)	3.10		
Options cancelled	41,973	(41,973)	3.85		
Balance, December 31, 2019	1,704,244	3,315,001	$ 5.08	7.28	$ 128,744
Awards authorized	943,345	—			
Options exercised	—	(1,185,764)	3.64		
Options cancelled	42,035	(42,035)	4.45		
Balance, December 31, 2020	2,689,624	2,087,202	$ 5.92	6.77	$ 204,137
Awards authorized	1,040,530	—			
Options exercised	—	(547,155)	5.57		
Options cancelled	15,062	(15,062)	9.33		
Balance, December 31, 2021	3,745,216	1,524,985	$ 6.01	5.76	$ 262,793
Vested and exercisable, December 31, 2021		1,295,974	$ 5.12	5.55	$ 224,475
Vested and expected to vest, December 31, 2021		1,524,985	$ 6.01	5.76	$ 262,793

There were no options granted during the years ended December 31, 2021 and 2020. The weighted-average grant date fair value of options granted during the year ended December 31, 2019, was $6.58. The total grant date fair value of options vested was $1.6 million, $2.3 million and $1.9 million for the years ended December 31, 2021, 2020, and 2019, respectively.

As of December 31, 2021, total unrecognized stock-based compensation related to unvested stock options was $1.0 million, which the Company expects to recognize over a remaining weighted-average period of 0.8 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. The Company's RSUs generally vest over a four-year period with a 25% one-year cliff or over a three-year period in equal amounts on a semi-annual basis, 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.

RSU activity under the 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2018	—	$ —
RSUs granted	288,170	38.28
RSUs forfeited	(5,600)	40.01
RSUs vested	(1,666)	59.79
Balance, December 31, 2019	280,904	$ 38.12
RSUs granted	687,223	51.34
RSUs forfeited	(38,650)	41.55
RSUs vested	(69,900)	38.46
Balance, December 31, 2020	859,577	$ 48.50
RSUs granted	588,305	138.52
RSUs forfeited	(51,986)	77.13
RSUs vested	(239,213)	47.18
Balance, December 31, 2021	1,156,683	$ 93.27

The total grant date fair value of RSUs vested was $11.3 million, $2.7 million, and $0.1 million, for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, there was $87.6 million of unrecognized stock-based compensation expense related to RSUs to be recognized over a weighted-average period of 2.7 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 30, 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. The Company recorded $1.3 million, $0.8 million and $0.3 million of stock-based compensation expense related to the ESPP for the years ended December 31, 2021, 2020 and 2019, respectively.

	Years Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.5	0.5	0.5
Expected volatility	48.9%-64.8%	44.3%-74.0%	76.9%
Risk-free interest rate	0.1%	0.1%-0.3%	1.9%
Expected dividend yield	0%	0%	0%

9. Income Taxes

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

	December 31,		
	2021	2020	2019
	(in thousands)		
Domestic	$ (9,388)	$ (65,957)	$ (51,179)
Foreign	553	338	132
Total loss before income taxes	$ (8,835)	$ (65,619)	$ (51,047)

Current income tax provision consists of the following:

	December 31,		
	2021	2020	2019
	(in thousands)		
Domestic	$ 84	$ 3	$ —
Foreign	217	77	62
Total current income tax provision	$ 301	$ 80	$ 62

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

	December 31,	
	2021	2020
	(in thousands)	
Deferred tax assets:		
Net operating loss carryovers	$ 85,764	$ 73,453
Fixed and intangible assets	512	718
Accruals and reserves	7,603	2,245
Stock-based compensation	5,523	2,060
Research and development credits	4,698	3,379
Contributions	42	42
Lease liability	7,398	2,004
Total deferred tax assets	111,540	83,901
Less valuation allowance	(104,773)	(82,087)
Gross deferred tax assets	6,767	1,814
Deferred tax liabilities:		
Right-of-use-assets	(6,767)	(1,814)
Gross deferred tax liabilities	(6,767)	(1,814)
Total net deferred tax assets	$ —	$ —

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

	December 31,		
	2021	2020	2019
	(in thousands)		
Income tax benefit at federal statutory rate	$ (1,856)	$ (13,780)	$ (10,720)
State and local income taxes net of federal tax benefit	36	(9)	(9)
Foreign tax rate differential	101	6	35
Change in valuation allowance	19,027	27,990	14,470
Stock-based compensation	(17,968)	(13,425)	(3,403)
Research and development credits	(808)	(611)	(354)
Section 382 limitation	575	—	—
Equity method investment	1,320	—	—
Other	(126)	(91)	43
Total current income tax provision	$ 301	$ 80	$ 62

Due to the uncertainties surrounding the realization of deferred assets through future taxable income, the Company has provided a full valuation allowance and, therefore, no benefit has been recognized for the net operating loss ("NOL") and other deferred tax assets. The valuation allowance increased by $22.7 million, $27.0 million and $22.8 million during the years ended December 31, 2021, 2020 and 2019, respectively.

As of December 31, 2021, the Company had NOL carryforwards available to reduce future federal, California and other state income of $351.0 million, $54.0 million and $160.6 million, respectively. The federal NOL carryforwards of $78.4 million and $272.6 million begin expiring in 2030 and never expire respectively, the California NOL carryforwards begin expiring in 2031 and other state NOL carryforwards begin expiring in various years, starting in 2029.

As of December 31, 2021, the Company had research and development credit carryforwards of $5.5 million for federal income tax purposes and $5.0 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 NOL carryforward may be subject to an annual limitation due to the ownership change provided by the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions. The annual limitation may result in the expiration of the NOL before utilization. The Company has completed a study under Section 382 of the Code through December 31, 2020, and determined there was a $2.4 million loss of federal NOLs and a $0.1 million loss of federal research and development credits as a result of ownership changes. Utilization of the NOL or tax credit carryforwards to offset future taxable income and taxes, respectively, are subject to an annual limitation under the Code and similar state provisions, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments such as built-in gain or built-in loss, as required. Any limitation may result in expiration of all or a portion of its NOLs losses and or tax credit carryforwards before utilization.

Uncertain Tax Positions

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

	December 31,		
	2021	2020	2019
	(in thousands)		
Beginning balance	$ 3,746	$ 2,586	$ 1,896
Additions (Reductions) based on tax positions related to prior years	(79)	(3)	—
Additions based on tax positions related to current years	1,554	1,163	690
Balance at end of year	$ 5,221	$ 3,746	$ 2,586

If recognized, gross unrecognized tax benefits would not have an impact on the Company's effective tax rate due to the Company's full valuation allowance position. While it is often difficult to predict the final outcome of any particular uncertain tax position, the Company does not believe that the amount of gross unrecognized tax benefits will change significantly in the next twelve months.

The Company is subject to taxation in the United States, Germany, the United Kingdom (the "UK"), Japan and France. The Company is subject to examination of its income tax returns since inception by U.S. federal and certain state tax authorities due to its NOLs. The income tax returns of the German entity are open to examination for the tax years 2017 and forward. The income tax returns for the entities in Japan, the UK and France are open to examination for the tax years starting 2020, 2021 and 2021, respectively. 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. The federal and California statute of limitations remains open for three and four years, respectively, from the date of utilization of any NOL or credits.

10. Revenue

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

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Coronary	$ 161,463	$ 24,586	$ 15,621
Peripheral	74,064	41,994	26,325
Other	1,619	1,209	981
Product revenue	$ 237,146	$ 67,789	$ 42,927

Peripheral product revenue encompasses sales of the Company's M5 and S4 IVL catheters. Coronary product revenue encompasses sales of the Company's C2 catheters. 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,		
	2021	2020	2019
	(in thousands)		
United States	$ 186,324	$ 37,121	$ 22,699
Europe	38,571	23,456	17,499
All other countries	12,251	7,212	2,729
Product revenue	$ 237,146	$ 67,789	$ 42,927

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 ("China"). 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 such a 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 total equity of the JV, to Genesis in exchange for a cash contribution of $15.0 million, of which 50% was paid upon signing and the remaining 50% will be due within one year of signing, and (ii) 45,000 ordinary shares which represents 45% of total equity, to the Company as consideration for the Shockwave License Agreement (or "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 China and is entitled to receive royalties on the sales of the licensed products in China. Further, the Company entered into a Distribution Agreement, pursuant to which the Company has agreed to sell certain Company-manufactured products to the JV and/or a to-be formed Chinese subsidiary of the JV for commercialization and distribution in China.

The Company has accounted for its investment in the JV under the equity method of accounting. As of December 31, 2021, the carrying value of the Company's investment in the JV was $6.0 million. The Company's share of losses generated by the JV for the year ended December 31, 2021 was $6.3 million which was recorded in share in net loss of equity method investment. The JV has not generated any revenues to date.

The following table summarizes the unaudited balance sheet for the JV:

	December 31, 2021
Balance sheet:	(in thousands)
Current assets	$ 14,854
Current liabilities	(1,539)
Net assets	$ 13,315

The following table summarizes the unaudited results of operations for the JV:

	For the Year Ended December 31, 2021
	(in thousands)
Revenues	$ —
Loss from operations	14,043
Net loss	$ 14,043

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 which were issued at the formation of the JV.

For the year ended December 31, 2021, the Company sold approximately $184,000 in product to the JV for use in ongoing clinical trials. As of December 31, 2021, approximately $138,000 was owed by the JV to the Company for the sale of the product.

As of December 31, 2021, the associated manufacturing technology transfer to the JV had not yet been completed. The Company maintains a related party contract liability, noncurrent, of $12.3 million for the outstanding performance obligation. The Company expects to satisfy the outstanding performance obligation upon the completion of training provided by the Company to the JV, and successful regulatory approval from the China National Medical Products Administration.

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, 2021 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, 2021. The effectiveness of our internal control over financial reporting as of December 31, 2021 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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and our report dated February 25, 2022 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 Jose, California
February 25, 2022

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 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021 (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
3.1	Restated Certificate of Incorporation	8-K	001-38829	3.3	March 12, 2019
3.2	Amended and Restated Bylaws	8-K	001-38829	3.4	March 12, 2019
4.1	Specimen 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				
10.7†	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†	Separation Pay Agreement with Douglas Godshall	10-Q	001-38829	10.1	November 8, 2019
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†	Form of Separation Pay Agreement for Executive Officers (other than CEO)	10-Q	001-38829	10.2	November 8, 2019

10.14*	Amended and Restated Non-Employee Director Compensation Policy				
10.15	Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated February 26, 2018	S-1	333-229590	10.10	February 8, 2019
10.16	First Amendment to Loan and Security Agreement	10-K	001-38829	10.15	March 12, 2020
10.17	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
10.18	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
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, 2021 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 25, 2022

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 25, 2022
/s/ Dan Puckett Dan Puckett	Chief Financial Officer (principal financial officer)	February 25, 2022
/s/ Trinh Phung Trinh Phung	Vice President of Finance (principal accounting officer)	February 25, 2022
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman & Director	February 25, 2022
/s/ F.T. “Jay” Watkins F.T. Watkins	Director	February 25, 2022
/s/ Antoine Papiernik Antoine Papiernik	Director	February 25, 2022
/s/ Sara Toyloy Sara Toyloy	Director	February 25, 2022
/s/ Frederic Moll, M.D. Frederic Moll	Director	February 25, 2022
/s/ Maria Sainz Maria Sainz	Director	February 25, 2022
/s/ Laura Francis Laura Francis	Director	February 25, 2022

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, Shockwave Medical, Inc. ("we," "us," or "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our restated certificate of incorporation, our amended and restated bylaws, the amended and restated investor rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, amended and restated bylaws and amended and restated investor rights agreement, copies of which are filed as exhibits to this Annual Report on Form 10-K and incorporated herein by reference.

General

Our authorized capital stock consists of 281,274,838 shares of common stock, par value $0.001 per share, and 5,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Common Stock

As of December 31, 2021, there were 35,444,472 shares of our common stock issued and outstanding, held by 20 stockholders of record. All outstanding shares of common stock are fully paid and non-assessable.

Voting rights. The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders.

Dividend rights. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors, out of funds legally available therefor.

Rights upon liquidation. In the event of liquidation, dissolution or winding up of the company, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding.

Other rights. The holders of our common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

As of December 31, 2021, no shares of preferred stock are outstanding. Under our restated certificate of incorporation, our board of directors has the authority to issue undesignated preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any series or the designation of such series, without further vote or action by the stockholders.

The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock.

Common Stock Options

As of December 31, 2021, we had outstanding options to purchase an aggregate of 1,524,985 shares of our common stock, with a weighted-average exercise price of $6.01 per share, under our 2009 Equity Incentive Plan and 2019 Equity Incentive Plan ("2019 Plan").

Restricted Stock Units

As of December 31, 2021, we had outstanding restricted stock units that may be settled for an aggregate of 1,156,683 shares of our common stock granted pursuant to our 2019 Plan.

Registration Rights

Certain holders of our common stock, or their permitted transferees, are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (the "Securities Act") pursuant to our amended and restated investor rights agreement as described in additional detail below ("registrable securities"). In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

- *Demand Registration Rights.* Certain holders of our common stock are entitled to demand registration rights. The holders of at least 40% of the registrable securities have the right to require us, on not more than two occasions, to file a registration statement under the Securities Act in order to register the resale of their shares of common stock, *provided* that such registration of shares would result in aggregate proceeds (after deducting the estimated underwriting discounts and expenses related to the issuance) of at least $10.0 million. We may, in certain circumstances, defer such registrations and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

- *Piggyback Registration Rights.* If we propose to register the offer and sale of any of our securities under the Securities Act, in connection with the public offering of such securities certain holders of our common stock are entitled to certain "piggyback" registration rights, allowing the holders to include their shares in such registration, subject to certain limitations. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

- *S-3 Registration Rights.* We are required to use commercially reasonable efforts to qualify for registration on Form S-3. After we are qualified for registration on Form S-3, certain holders of our common stock may make a written request that we register the offer and sale of their shares on Form S-3, *provided* that such registration of shares would result in an aggregate price to the public of not less than $2,000,000 and we have not effected two such registrations in the last 12 months. We may, in certain circumstances, defer such registrations and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

Expenses. Subject to specified conditions and limitations, we are required to pay all expenses, other than underwriting discounts and commissions and stock transfer taxes, incurred in connection with any exercise of these registration rights.

Indemnification. Our amended and restated investor rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling holders of registrable securities in the event of either material misstatements or omissions in the applicable registration statement attributable to us or our violation of the Securities Act, and the selling stockholders are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them, subject to certain limitations.

Termination. The registration rights terminate upon the earliest of: (i) such date on which all shares of registrable securities may be sold during any 90 day period pursuant to Rule 144 of the Securities Act, (ii) the fifth anniversary of the completion of our initial public offering, (iii) the occurrence of a deemed liquidation event or (iv) the date that no registrable securities remain outstanding that have not previously been sold to the public pursuant to a registration or in reliance on Rule 144 of the Securities Act.

Anti-Takeover Effects of our Certificate of Incorporation and our Bylaws

Election and Removal of Directors. Our board of directors consists of eight directors. The exact number of directors will be fixed from time to time by resolution of the board. No director may be removed except for cause, and directors may be removed for cause by an affirmative vote of shares representing a majority of the shares then entitled to vote at an election of directors. Any vacancy occurring on the board of directors and any newly created directorship may be filled only by a majority of the remaining directors in office.

Staggered Board. Our board of directors is divided into three classes serving staggered three-year terms. At each annual meeting of stockholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our board of directors could have the effect of increasing the length of time necessary to change the composition of a majority of the board of directors. In general, at least two annual meetings of stockholders will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

Limits on Written Consents. Our restated certificate of incorporation and our amended and restated bylaws provide that holders of our common stock will not be able to act by written consent without a meeting, unless such consent is unanimous.

Stockholder Meetings. Our restated certificate of incorporation and our amended and restated bylaws provide that special meetings of our stockholders may be called only by the chairman of our board of directors or a majority of the directors. Our restated certificate of incorporation and amended and restated bylaws specifically deny any power of any other person to call a special meeting.

Amendment of Certificate of Incorporation. The provisions of our restated certificate of incorporation described under “Election and Removal of Directors,” “Stockholder Meetings” and “Limits on Written Consents” may be amended only by the affirmative vote of holders of at least 75% of the voting power of our outstanding shares of voting stock, voting together as a single class. The affirmative vote of holders of at least a majority of the voting power of our outstanding shares of stock are generally required to amend other provisions of our restated certificate of incorporation.

Amendment of Bylaws. Our amended and restated bylaws may generally be altered, amended or repealed, and new bylaws may be adopted, with:

- the affirmative vote of a majority of directors present at any regular or special meeting of the board of directors called for that purpose, provided that any alteration, amendment or repeal of, or adoption of any bylaw inconsistent with, specified provisions of the bylaws, including those related to special and annual meetings of stockholders, action of stockholders by written consent, classification of the board of directors, nomination of directors, special meetings of directors, removal of directors, committees of the board of directors and indemnification of directors and officers, requires the affirmative vote of at least 75% of all directors in office at a meeting called for that purpose; or

- the affirmative vote of holders of 75% of the voting power of our outstanding shares of voting stock, voting together as a single class.

Other Limitations on Stockholder Actions. Our amended and restated bylaws also impose some procedural requirements on stockholders who wish to:

- make nominations in the election of directors;

- propose that a director be removed;

- propose any repeal or change in our bylaws; or

- propose any other business to be brought before an annual or special meeting of stockholders.

Under these procedural requirements, in order to bring a proposal before a meeting of stockholders, a stockholder must deliver timely notice of a proposal pertaining to a proper subject for presentation at the meeting to our corporate secretary along with the following:

- a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;

- the stockholder’s name and address;

- any material interest of the stockholder in the proposal;

- the number of shares beneficially owned by the stockholder and evidence of such ownership; and

- the names and addresses of all persons with whom the stockholder is acting in concert and a description of all arrangements and understandings with those persons, and the number of shares such persons beneficially own.

To be timely, a stockholder must generally deliver notice:

- in connection with an annual meeting of stockholders, not less than 120 nor more than 180 days prior to the date on which the annual meeting of stockholders was held in the immediately preceding year, but in the event that the date of the annual meeting is more than 30 days before or more than 60 days after the anniversary date of the preceding annual meeting of stockholders, a

stockholder notice will be timely if received by us no earlier than 120 days prior to the annual meeting and no later than the 10th day following the day on which we first publicly announce the date of the annual meeting; or

- in connection with the election of a director at a special meeting of stockholders, not less than 40 nor more than 60 days prior to the date of the special meeting, but in the event that less than 55 days' notice or prior public disclosure of the date of the special meeting of the stockholders is given or made to the stockholders, a stockholder notice will be timely if received by us not later than the close of business on the 10th day following the day on which a notice of the date of the special meeting was mailed to the stockholders or the public disclosure of that date was made.

In order to submit a nomination for our board of directors, a stockholder must also submit any information with respect to the nominee that we would be required to include in a proxy statement, as well as some other information. If a stockholder fails to follow the required procedures, the stockholder's proposal or nominee will be ineligible and will not be voted on by our stockholders.

Limitation of Liability of Directors and Officers. Our restated certificate of incorporation provides that we may indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

Forum Selection. The Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the company to the company or the company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the company shall be deemed to have notice of and consented to the foregoing forum selection provisions. The provision would not apply to suits brought to enforce a duty or liability created by the Securities Act and the Securities Exchange Act of 1934, as amended. In addition, our amended and restated bylaws provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Delaware Business Combination Statute. We have elected to be subject to Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. Section 203 prevents an "interested stockholder," which is defined generally as a person owning 15% or more of a corporation's voting stock, or any affiliate or associate of that person, from engaging in a broad range of "business combinations" with the corporation for three years after becoming an interested stockholder unless:

- the board of directors of the corporation had previously approved either the business combination or the transaction that resulted in the stockholder's becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder's becoming an interested stockholder, that person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, other than statutorily excluded shares; or

- following the transaction in which that person became an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specific business combinations proposed by an interested stockholder following the announcement or notification of designated extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors, if such extraordinary transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors.

Section 203 may make it more difficult for a person who would be an interested stockholder to effect various business combinations with a corporation for a three-year period. Section 203 also may have the effect of preventing changes in our management and could make it more difficult to accomplish transactions that our stockholders may otherwise deem to be in their best interests.

Anti-Takeover Effects of Some Provisions. Some provisions of our restated certificate of incorporation and amended and restated bylaws could make the following more difficult:

- acquisition of control of us by means of a proxy contest or otherwise, or
- removal of our incumbent officers and directors.

These provisions, as well as our ability to issue preferred stock, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection give us the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, and that the benefits of this increased protection outweigh the disadvantages of discouraging those proposals, because negotiation of those proposals could result in an improvement of their terms.

Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for the common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall St., Canton, Massachusetts 02021.

Exhibit 10.5

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN

NOTICE OF RESTRICTED STOCK UNIT AWARD

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

Name:
Address:

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

Number of Restricted Stock Units:	
Date of Grant:	
Dividend Equivalents:	**Not Included**
Vesting Commencement Date:	
Vesting Schedule:	Subject to Section 2 of the Agreement, the Award will vest in accordance with the following schedule:

[Twenty-five percent (25%) of the Restricted Stock Units subject to the Award shall vest on each of the first four (4) anniversaries of the Vesting Commencement Date, subject to Participant continuing to be a Service Provider through each such date.]

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN
GLOBAL RESTRICTED STOCK UNIT AWARD AGREEMENT

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

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

2. **Vesting Schedule.** Subject to Section 1, the Award shall vest pursuant to the Vesting Schedule set forth in the Notice.

3. **Termination of Service**. In the event of Participant's Termination of Service for any reason, any Restricted Stock Units that are not vested as of the date of such Termination of Service will be forfeited and Participant will have no right to the forfeited Restricted Stock Units or the underlying Shares.

4. **Change in Control**. In the event of a merger or Change in Control, the Restricted Stock Units will be treated in accordance with Section 15(c) of the Plan.

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

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

7. **Distribution of Shares**. Subject to the provisions of this Agreement, upon the vesting of any of the Restricted Stock Units, the Company shall deliver to Participant, as soon as reasonably practicable (and in no event later than 30 days) after the applicable Vesting Date, one Share for each vested Restricted Stock Unit; *provided that*, if a valid deferral election is in effect with respect to this Award pursuant to an Administrator-approved deferred compensation plan, the delivery of shares shall occur at such time or times as set forth in such election. Upon the delivery of Shares pursuant to this Agreement, the Shares delivered shall be fully assignable, alienable, saleable and transferrable by Participant; *provided* that any such assignment, alienation, sale, transfer or other alienation with respect to such Shares shall be in accordance with applicable securities laws and any applicable Company policy.

8. **Responsibility for Taxes**.

(a) Participant acknowledges that, regardless of any action taken by the Company or if different, Participant's employer (the "**Employer**"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items related to Participant's participation in the Plan and legally

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

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

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

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

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

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

(c) Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates in the relevant Participant jurisdiction(s), in which case Participant will receive a refund of any over-withheld amount in cash and will have no entitlement to the Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, Participant is deemed to have been issued the full number of Shares subject to the vested Restricted Stock Units, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items. The Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

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

number of Shares withheld (or sold on Participant's behalf) shall not exceed the number of Shares that equals the liability for Tax-Related Items.

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

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

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

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

(d) Participant is voluntarily participating in the Plan;

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

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

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

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

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the Restricted Stock Units resulting from Participant's Termination of Service (for any reason whatsoever and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) and, in consideration of the grant of the Restricted Stock Units to which Participant is otherwise not entitled, Participant irrevocably agrees never to institute any such claim against the Company, the Employer, or any Subsidiary, waives his or her ability, if any, to bring any such claim, and releases the Company, the Employer, and any Subsidiary from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, Participant shall be deemed irrevocably to have agreed not to pursue such claim and agrees to execute any and all documents necessary to request dismissal or withdrawal of such claim;

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

discretion to determine when Participant is no longer actively providing services for purposes of the Restricted Stock Units (including whether Participant may still be considered to be providing services while on a leave of absence); and

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

11. **Data Privacy Information and Consent**.

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

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

(c) International Data Transfers. The Company and its service providers are based in the United States. Participant's country or jurisdiction may have different data privacy laws and protections than the United States. The Company's legal basis, where required, for the transfer of Data is the Company's legitimate business interest of providing discretionary benefits under the Plan to Participant.

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

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

(f) Data Subject Rights. Participant may have a number of rights under data privacy laws in Participant's jurisdiction. Depending on where Participant is based, such rights may include the right to (i) request access or copies of Data the Company processes, (ii) rectification of incorrect Data, (iii) deletion of Data, (iv) restrictions on processing of Data, (v) portability of Data, (vi) lodge complaints with competent authorities in Participant's jurisdiction,

and/or (vii) receive a list with the names and addresses of any potential recipients of Data. To receive clarification regarding these rights or to exercise these rights, Participant can contact the Company's General Counsel, Haj Tada.

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

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

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

14. **No Guarantee of Continued Service**. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF THE AWARD PURSUANT TO THE VESTING SCHEDULE HEREOF IS EARNED ONLY BY CONTINUING AS A SERVICE PROVIDER AT THE WILL OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS AWARD OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) TO TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER AT ANY TIME, WITH OR WITHOUT CAUSE.

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

16. **No Advice Regarding Grant.** The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or

sale of the underlying Shares. Participant should consult with his or her own personal tax, legal and financial advisors regarding his or her participation in the Plan before taking any action related to the Plan.

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

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

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

20. **Lock-Up Agreement**.

(a) Participant hereby agrees that Participant shall not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Stock (or other securities) of the Company or enter into any swap, hedging or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Common Stock (or other securities) of the Company held by Participant (other than those included in the registration) for a period specified by the representative of the underwriters of Common Stock (or other securities) of the Company not to exceed one hundred and eighty (180) days following the effective date of any registration statement of the Company filed under the Securities Act (or such other period as may be requested by the Company or the underwriters to accommodate regulatory restrictions on (i) the publication or other distribution of research reports and (ii) analyst recommendations and opinions, including, but not limited to, the restrictions contained in NASD Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto).

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

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

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

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

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

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

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

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

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

29. **Entire Agreement.** This Agreement, the Plan, the Notice and any other agreements, schedules, exhibits and other documents referred to herein or therein constitute the entire agreement and understanding between the parties in respect of the subject matter hereof and supersede all prior and contemporaneous arrangements, undertakings, agreements

and understandings, both oral and written, whether in term sheets, presentations or otherwise, between the parties with respect to the subject matter hereof.

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

[Signature Page Follows]

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

PARTICIPANT

Signature

Print Name

Residence Address

Email Address

SHOCKWAVE MEDICAL, INC.

By: _____

Name: Daniel Puckett
Title: Chief Financial Officer

APPENDIX TO THE
SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN
RESTRICTED STOCK UNIT AWARD AGREEMENT

COUNTRY-SPECIFIC TERMS AND CONDITIONS

All capitalized terms used in this Appendix that are not defined herein have the meanings defined in the Plan and/or the Agreement. This Appendix constitutes part of the Agreement.

Terms and Conditions

This Appendix includes additional or different terms and conditions that govern the Award if Participant works or resides in one of the countries listed below. Participant understands that if Participant is a citizen or resident of a country other than the one in which he or she is currently working, transfers employment or residency after the Grant Date or is considered a resident of another country for local law purposes, the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to Participant.

Notifications

This Appendix also includes information regarding exchange controls and certain other issues of which Participant should be aware with respect to participation in the Plan. The information is based on the securities, exchange control and other laws in effect in the respective countries as of September 2021. Such laws are often complex and change frequently. As a result, Participant should not rely on the information in this Appendix as the only source of information relating to the consequences of participation in the Plan because the information may be out of date at the time the Restricted Stock Units vest or at the time Participant sells the Shares acquired pursuant to the Award.

In addition, the information contained herein is general in nature and may not apply to Participant's particular situation, and the Company is not in a position to assure Participant of a particular result. Accordingly, Participant should seek appropriate professional advice as to how the relevant laws in Participant's country may apply to his or her situation.

Finally, if Participant is a citizen or resident of a country other than the one in which he or she is currently working, transfers employment or residency after the Grant Date or is considered a resident of another country for local law purposes, the information contained herein may not apply to Participant.

AUSTRIA

Terms and Conditions

By accepting the Award and acceptance of this Agreement, Participant confirms having fully read and understood the documents related to the Award (the Plan and the Notice and this Agreement) which were provided in the English language. Participant expressly accepts the terms of these documents.

In particular, Participant understands that the Award according to the Plan, the Notice and the Agreement is a completely voluntary and discretionary benefit provided by the Company, no legal entitlement is created from the Plan, the Notice or this Agreement (*Unverbindlichkeitsvorbehalt)*, be it against the Company or the local employer entity, and that the Award is solely governed by the Plan, as it may be amended from time to time by the Company.

BELGIUM

Taxation, Withholding and Reporting

You will be subject to personal income tax (at the normal progressive income tax rates) on the fair market value of the Shares on the date of Vesting and on any Dividend Equivalents.

Your local employer is required to withhold income tax at the time of the taxable event and to report the taxable amount on your salary slip. You are always obliged and responsible to report the benefit in kind on your annual income tax return and to pay any taxes resulting from the acquisition of the Shares.

Your local employer will also withhold employee social security contributions (of 13.07% of the benefit in kind) from your monthly salary.

Sale of Shares

On the date(s) that you sell any Shares acquired, you generally will not be subject to taxation on any gain you realize from the sale.

However, you will be subject to a stock exchange tax at the time you sell the Shares. The stock exchange tax applies on the sale proceeds on a per transaction basis (subject to the applicable maximum threshold). You will be responsible for filing a stock exchange tax return and paying the tax due by the end of the second month following the month of the sale, except in the unlikely event that the financial intermediary involved in the sale of Company shares arranges to pay and/or remit the stock exchange tax on your behalf via a Belgian representative.

Dividends

Where Shares are acquired, dividends may be paid with respect to these Shares. The dividends received will be subject to income tax in Belgium (at a rate of 30%) and to U.S. federal income withholding tax. The employee may be entitled to reduce the U.S. federal income withholding tax rate provided that the appropriate certifications concerning domicile in Belgium are provided as required by the United States Internal Revenue Service.

Notifications

You are required to report any securities (e.g., Shares acquired under the Plan) held and bank accounts (including brokerage accounts) opened and maintained outside of Belgium on your annual tax return.

The first time you report the foreign security and/or bank account on your annual income tax return you will have to provide the National Bank of Belgium Central Contact Point with the account details of any such foreign accounts (including the account number, bank name and country in which such account was opened) in a separate form. This report, as well as information on how to complete it, can be found on the website of the National Bank of Belgium, www.nbb.be, under the Kredietcentrales / Centrales des crédits caption.

Tax on securities accounts

You may be subject to a 0.15% tax on securities accounts with Belgian and foreign financial institutions if the total average annual value of the securities you hold in securities accounts exceeds EUR 1,000,000.

FRANCE

Terms and Conditions

Type of Award. The Restricted Stock Units are not granted as “French-qualified” awards and are not intended to qualify for the specific tax and social security treatment applicable to shares granted for no consideration under Sections L. 225-197 to L. 225-197-6 of the French Commercial Code, as amended.

Consent to Receive Information in English. By accepting the Award, Participant confirms having read and understood the documents related to the Award (the Plan and the Agreement) which were provided in the English language. Participant accepts the terms of these documents accordingly.

Consentement Relatif à l'Utilisation de la Langue Anglaise. *En acceptant l'Attribution, le Participant confirme avoir lu et compris les documents relatifs à cette Attribution (le Plan et le Contrat d'Attribution) qui ont été remis en langue anglaise. Le Participant accepte les termes de ces documents en conséquence.*

Notifications

Foreign Asset/Account Reporting Information. Participant is required to report all foreign accounts (whether open, current or closed) to the French tax authorities when filing his or her annual tax return.

GERMANY

Notifications

Exchange Control Information. Cross-border payments in excess of €12,500 must be reported electronically to the German Federal Bank (*Bundesbank*) on a monthly basis. The form of the report ("*Allgemeine Meldeportal Statistik*") can be accessed via the Bundesbank's website (www.bundesbank.de).

JAPAN

Notifications

Exchange Control Information. Cross-border payments in excess of JPY30,000,000 must be reported to the Bank of Japan on a transaction basis or a monthly basis. The form of the report ("Report on Payment or Receipt of Payment") can be accessed via the Bank of Japan's website (www.boj.or.jp).

Information on the Issuance and Acquisition of Securities. The Company must make a filing with the Bank of Japan if the total market value of the shares that it issues to Participant in Japan is 1 billion yen or more. Participant in Japan must make a similar filing if the consideration for the shares that the Company issues to Participant is 100 million yen or more. The form of the relevant report ("Report on Issuance or Offering of Securities" and "Report on Acquisition or Transfer of Securities") can be accessed via the Bank of Japan's website (www.boj.or.jp).

IRELAND

Responsibility for Taxes. The following provisions supplement Section 8 of the Agreement:

The references in the Plan and / or the Agreement to "tax" or "Tax-Related Items" includes any and all taxes, charges, levies and contributions in Ireland or elsewhere, to include, in particular, Universal Social Charge (USC) and Pay Related Social Insurance (PRSI) ("Taxes").

The Participant shall be accountable for any Taxes, which are chargeable on any assessable income deriving from the grant, exercise, purchase, or vesting of, or other dealing in, Awards or Shares issued pursuant to an Award. Neither the Company nor any Subsidiary shall become liable for any Taxes, as a result of the Participant's participation in the Plan. In respect of

such assessable income, the Participant shall indemnify the Company and (at the direction of the Company) any Subsidiary, which is or may be treated as the employer of the Participant in respect of the Taxes (the "Tax Liabilities").

Pursuant to the indemnity referred to above, where necessary, the Participant shall make such arrangements as the Company or any Subsidiary requires to meet the cost of the Tax Liabilities, including at the direction of the Company any of the following:

i. making a cash payment of an appropriate amount to the relevant company in the Company's group whether by check, banker's draft or deduction from salary in time to enable the relevant company to remit an appropriate amount of Taxes to the Irish Revenue Commissioners in accordance with its statutory requirements or as otherwise required by the Company; or

ii. appointing the Company as agent and / or attorney for the sale of sufficient Shares acquired pursuant to the grant, exercise, purchase or vesting of, or other dealing in, Awards or Shares issued pursuant to an Award to cover the Tax Liabilities and authorizing the payment to the relevant company of the appropriate amount (including all reasonable fees, commissions and expenses incurred by the relevant company in relation to such sale) out of the net proceeds of sale of the Shares.

Securities Law Information. Neither the grant of the Award of Restricted Stock Units, being non-transferable securities of the Company, to Participants in Ireland, nor the subsequent issuance of Shares on vesting of any such Restricted Stock Units, will trigger a requirement to produce a prospectus or other information or disclosure document under Irish securities law.

Termination Date. Unless otherwise determined by the Company, for the purposes of section 10 (j), a Participant's employment or service relationship will be considered terminated upon the giving of (written) notice of termination by either party to the other in accordance with the Participant's employment or service contract and/or in any event as of the date of termination, and "Termination Date" will be construed accordingly.

At Will Employment. The Company acknowledges that the concept of "at will" employment does not apply in Ireland. Accordingly, where the Plan refers to "at the will" of the Company in section 14, it should be read as though these words are deleted therefrom.

ITALY

Terms and Conditions

Plan Document Acknowledgement. By accepting the Award, Participant acknowledges that (a) Participant has received the Plan and the Agreement, including this Appendix; (b) Participant has reviewed those documents in their entirety and fully understands the contents thereof; and (c) Participant accepts all provisions of the Plan and the Agreement, including this Appendix. Participant further acknowledges that Participant has read and specifically and expressly approves, without limitation, the Notice and the following sections of the Agreement: "Grant of Award", "Vesting Schedule", "Change in Control", "Transferability"; "Termination of Service"; "Nature of Grant"; "No Advice Regarding Grant"; "Responsibility for Taxes"; "Governing Law and Choice of Venue"; "Data Privacy"; and "Imposition of Other Requirements" contained in the Agreement.

Notifications

Foreign Asset/Account Reporting Information. If, at any time during the fiscal year, Participant holds foreign financial assets (including cash and Shares) which may generate income taxable in Italy, Participant is required to report these assets on his or her annual tax return (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting obligations will also apply to Participant if Participant is the beneficial owner of foreign financial assets under Italian money laundering provisions.

PORTUGAL

Terms and Conditions

Plan Document Acknowledgment. Participant acknowledges that he or she has received the Notice, the Plan and the Agreement, including this Appendix, he or she has reviewed those documents in their entirety, he or she has had an opportunity to obtain a clarification of those aspects included in those documents which may warrant clarification and fully understands the contents thereof.

Notifications

Foreign Asset/Account Reporting Information. Participant is required to report foreign financial assets to the Portuguese Tax Authorities when filling his or her annual personal income tax return. Upon vesting a restricted stock unit, income tax is due by the Participant on the fair market value of the units.

SPAIN

Terms and Conditions

Plan Document Acknowledgement. By accepting the Award, Participant acknowledges that (a) Participant has received the Plan and the Agreement, including this Appendix; (b) Participant has reviewed those documents in their entirety and fully understands the contents thereof; and (c) Participant accepts all provisions of the Plan and the Agreement, including this Appendix.

Responsibility for Taxes: The following provisions would supplement the section 8 of the Agreement:

The Participant acknowledges that employment taxable income shall arise for him/her on the date of the delivery of the Shares derived from the Restricted Stock Units and this shall be determined on the fair market value of the Shares on that date.

Also, the Participant acknowledges that, irrespective of the withholding and reporting tax obligations of the Employer, he/she is responsible to report the benefit in kind derived from the delivery of the Shares acquired upon settlement of the Restricted Stock Units on his/her annual Personal Income Tax return and, when necessary, to pay any taxes resulting from such event. This Personal Income Tax Return should be generally submitted no later than June 30th of the correspondent following year.

The Participant is informed that current Personal Income Tax Law states the following tax benefits that may be applicable on the correspondent taxable income derived from the delivery of shares to employees:

- Annual 12,000 euros exemption

  In general terms, under current Personal Income Tax Law, an annual exemption of up to 12,000 euros can be applicable to the remuneration in kind derived from the delivery of shares of a company to its employees as a consequence of the participation in the company or other group company, if:

  iii. the offer is made in the same terms to all employees of the company in which the employee renders his services;

  iv. the employee does not sell the shares during the three years following the date on which he acquires them; and

  v. the employee, together with his spouse and their relatives to the second degree, does not have a direct or indirect interest of more than 5 per cent in the company or in any other group company.

As long as the Personal Income Tax Law requires that the delivery of shares has to be made to active employees, this exemption should not be applicable to members of the Board of Directors, or to individuals without an employment relationship (e.g. consultants, service providers, etc.).

- Reduction of 30 percent

  In general terms, a 30 percent reduction could be applicable on the employment income subject to taxation, in this case, derived from the delivery of the Shares, if:

  i. it has been generated over a period of more than two years (that could be understood as the elapsed period of time between the date of grant of the Restricted Stock Units and the date of settlement);

  ii. it is imputed in a single tax year;

  iii. and, in the previous five tax years, the individual has not received any other income generated in more than two years on which the mentioned reduction has been applied.

  The maximum amount that can benefit from the 30 percent reduction is limited to 300,000 euros.

The application of these tax benefits should be analysed in a case by case basis.

Transfer of the Shares

The transfer of the Shares acquired upon settlement of the Restricted Stock Units shall generate a capital gain or loss for the Participant to be calculated as the difference between the transfer price of the Shares and their market value on the date of delivery to the Participant.

The correspondent capital gains and losses derived from the transfer of the Shares shall be included in the saving tax base of the Personal Income Tax return of the Participant for the correspondent tax period. In general terms, gains and losses can be offset against each other in each tax period, resulting in a positive or negative balance.

In relation to the provisions of the section 8 (b) of this document, when a partial sale of the Shares is made in order to apply the correspondent withholding taxes, a capital gain or loss may arise for the Participant. If the Participant held Shares of the Company prior to the delivery of the Shares derived from this Plan, in order to calculate the taxable capital gain or loss, the acquisition price would be calculated by applying the FIFO (First In First Out) method, according to which the Shares transferred by the Participant shall be deemed to be those which he/she acquired in the first place, that is to say, those that were kept for longer in his/her assets.

Dividends

Dividends received from the Shares acquired will be reportable in the correspondent annual Personal Income Tax return and subject to taxation in the saving tax base of the Personal Income Tax of the Participant at a progressive tax scale currently ranging from 19 to 26 per cent.

Reporting obligations for the Participants

In addition to the correspondent tax reporting obligations for the Participants in the annual Personal Income Tax returns of the employment income derived from the delivery of the Shares, the capital gain or loss derived for any transfer of the Shares and the dividends received, the following reporting obligations may be applicable:

- Wealth tax return (Form 714)

  The Participants considered tax resident in Spain should take into consideration the value of the Shares for Spanish Net Wealth Tax ("**NWT**") purposes. In this regard, the NWT is levied on an individual's worldwide net worth as of December 31st each fiscal year.

Currently there is an annual obligation to file a NWT return for taxpayers who are in the following circumstances:

i. Their tax quote, determined according to the NWT rules, and once the appropriate tax credits or reliefs are applied (which may vary depending on the Autonomous Region of residence), results in tax payable, or

ii. where, the above circumstance not complies, the value of their assets or rights, determined according to the rules regulating NWT, is higher than 2,000,000 euros.

- Declaration of assets and rights located abroad (Form 720)

Participants considered tax residents should also file an informative declaration, reporting the foreign goods and assets (Form 720) held by December 31st of the correspondent tax year, which does not imply a tax liability.

As a summary, this reporting obligation involves to provide information about the following blocks of goods, rights and assets located outside Spain:

i. Accounts and deposits held at financial institutions situated abroad.

ii. Securities or rights representing the capital stock or assets of any entity or transfer to third parties of own capital, insurances and temporary or lifetime annuities located abroad; and

iii. Real estate assets and rights in those assets, situated abroad.

The obligation to file this declaration is determined by analysing each block, and arises, for the first time, when the value of the assets of at least one of these blocks exceeds the limit of 50,000 euros.

This declaration must be filed, generally, before the end of March of the correspondent following year.

Once the first declaration is submitted, it must only be submitted again when the joint value of all the assets and rights, of each of the aforementioned blocks, had increased more than 20,000 euros with respect to the value that determined the filing of the last declaration and, in any case, when the holders, representatives, authorized persons, beneficiaries, persons with powers of disposal or real owners no longer have such status over the assets and rights declared at December 31st of the corresponding tax year.

It should be noted that the inobservance of this reporting obligation may lead to substantial monetary fines.

SWITZERLAND

Notifications

Securities Law Information. The offer of the Restricted Stock Units is considered a private offering in Switzerland and is therefore not subject to securities registration in Switzerland. Neither this document nor any other materials relating to the Restricted Stock Units (i) constitutes a prospectus as such term is understood pursuant to article 652a of the Swiss Code of Obligations, (ii) may be publicly distributed or otherwise made publicly available in Switzerland or (iii) has been or will be filed with, approved, or supervised by any Swiss regulatory authority (in particular, the Swiss Financial Market Supervisory Authority (FINMA)).

UNITED KINGDOM

Terms and Conditions

Distribution of Shares. This provision supplements Section 7 of the Agreement:

Notwithstanding any discretion in the Plan, Restricted Stock Units granted to Participants in the United Kingdom shall be paid in Shares and not in cash or a combination of cash and Shares.

Responsibility for Taxes. The following provisions supplement Section 8 of the Agreement:

Participant agrees that he or she is liable for all Tax-Related Items and hereby covenants to pay all such Tax-Related Items, as and when requested by the Company or the Employer, or by Her Majesty's Revenue & Customs ("**HMRC**") (or any other tax authority or other relevant authority). Participant also hereby agrees to indemnify and keep indemnified the Company and the Employer against any Tax-Related Items that they are required to pay or withhold or have paid or will pay to HMRC (or any other tax authority or other relevant authority) on Participant's behalf.

Notwithstanding the foregoing, if Participant is an executive officer or director of the Company (within the meaning of Section 13(k) of the Exchange Act), the terms of the immediately foregoing provision will not apply. In the event Participant is an executive officer or director of the Company and the income tax is not collected from or paid by Participant within ninety (90) days of the end of the U.K. tax year in which an event giving rise to the indemnification described above occurs, the amount of any uncollected income tax may constitute a benefit to Participant on which additional income tax and National Insurance contributions may be payable. Participant acknowledges that Participant will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for paying the Company or the Employer (as applicable) for the value of any employee National Insurance contributions due on this additional benefit. Participant further acknowledges that the Company or the Employer may collect such amounts from Participant by any of the means referred to in Section 8 of the Agreement.

Joint Election. As a condition of Participant's participation in the Plan, Participant agrees to accept any liability for secondary Class 1 National Insurance contributions which may be payable by the Company and/or the Employer in connection with the Restricted Stock Units and any event giving rise to Tax-Related Items (the "**Employer's Liability**"). Without limitation to the foregoing, Participant agrees to execute the following joint election with the Company (the "**Joint Election**"), the form of such Joint Election being formally approved by HMRC, and to execute any other consents or elections required to accomplish the transfer of the Employer's Liability to Participant. Participant further agrees to execute such other joint elections as may be required between Participant and any successor to the Company and/or the Employer. Participant further agrees that the Company and/or the Employer may collect the Employer's Liability from him or her by any of the means set forth in Section 8 of the Agreement.

If Participant does not enter into the Joint Election prior to the vesting of the Restricted Stock Units or any other event giving rise to Tax-Related Items, he or she will not be entitled to vest in the Restricted Stock Units or receive any benefit in connection with the Restricted Stock Units unless and until he or she enters into the Joint Election and no Shares or other benefit pursuant to the Restricted Stock Units will be issued to Participant under the Plan, without any liability to the Company and/or the Employer; provided, however, that this provision shall not apply if Participant is a U.S. taxpayer and the application of this provision would cause the Restricted Stock Units to fail to qualify under an exemption from, or comply with, Section 409A of the Code.

Exhibit 10.6

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN
NOTICE OF PERFORMANCE-BASED RESTRICTED STOCK UNIT AWARD

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

Name:
Address:

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

Target Number of Performance-Based Restricted Stock Units ("Total Target PRSUs"):	
Date of Grant:	
Dividend Equivalents:	Not Included
Performance Conditions:	The actual number of Performance-Based Restricted Stock Units that may be earned will be between 0% and 200% of the Total Target PRSUs, based upon achievement of the performance conditions set forth in Annex A
Performance Measurement Period	With respect to 50% of the Total Target PRSUs, January 1, 2022 through December 31, 2023 (the "First Measurement Period") With respect to the remaining 50% of the of the Total Target PRSUs, January 1, 2022 through December 31, 2024 (the "Second Measurement Period", and together with the First Measurement Period, the "Measurement Periods")
Vesting Schedule:	The Award will vest in accordance with the schedule set forth in Annex A

SHOCKWAVE MEDICAL, INC. 2019 EQUITY INCENTIVE PLAN
GLOBAL PERFORMANCE-BASED RESTRICTED STOCK UNIT AWARD AGREEMENT

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

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

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

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

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

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

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

7. **Distribution of Shares**. Subject to the provisions of this Agreement, upon the vesting of any of the Performance-Based Restricted Stock Units, the Company shall deliver to Participant, as soon as reasonably practicable (and in no event later than 30 days) after the applicable vesting date, one Share for each vested Performance-Based Restricted Stock Unit. Upon the delivery of Shares pursuant to this Agreement, the Shares delivered shall be fully assignable, alienable, saleable and transferrable by Participant; *provided* that any such assignment, alienation, sale, transfer or other alienation with respect to such Shares shall be in accordance with applicable securities laws and any applicable Company policy.

8. **Responsibility for Taxes**.

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

Further, if Participant is subject to Tax-Related Items in more than one jurisdiction, Participant acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

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

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

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

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

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

(c) Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates in the relevant Participant jurisdiction(s), in which case Participant will receive a refund of any over-withheld amount in cash and will have no entitlement to the Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, Participant is deemed to have been issued the full number of Shares subject to the vested Performance-Based Restricted Stock Units, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items. The Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

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

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

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

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

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

(d) Participant is voluntarily participating in the Plan;

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

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

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

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

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the Performance-Based Restricted Stock Units resulting from Participant's Termination of Service (for any reason whatsoever and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where Participant is employed or the terms of Participant's employment agreement, if any) and, in consideration of the grant of the Performance-Based Restricted Stock Units to which Participant is otherwise not entitled, Participant irrevocably agrees never to institute any claim against the Company, the Employer, or any Subsidiary, waives his or her ability, if any, to bring any such claim, and releases the Company, the Employer, and any Subsidiary from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, Participant shall be deemed irrevocably to have agreed not to pursue such claim and agrees to execute any and all documents necessary to request dismissal or withdrawal of such claim;

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

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

11. **Data Privacy Information and Consent**.

(a) Data Collection and Usage. The Company or the Employer may collect, process and use certain personal information about Participant, including, but not limited to, Participant's name, home address and telephone number, office address (including department and employing entity) and telephone number, e-mail address, date of birth, citizenship, country of residence at the time of grant, work location country, system employee ID, employee local ID, employment status (including international status code), supervisor (if applicable), job code, job title, salary, bonus target and bonuses paid (if applicable), termination date and reason, tax payer's identification number, tax equalization code, US Green Card holder status, contract type (single/dual/multi), social insurance number, passport or other identification number (*e.g.*, resident registration number), nationality, any directorships held in the Company, any shares of stock held, details of

all Performance-Based Restricted Stock Units or any other equity awards granted, canceled, forfeited, exercised, vested, unvested or outstanding with respect to Participant, estimated tax withholding rate, brokerage account number (if applicable), and brokerage fees ("**Data**"), for the purposes of implementing, administering and managing the Plan. The legal basis, where required, for the processing of Data is the Company's legitimate business interest of providing discretionary benefits under the Plan to Participant.

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

(c) International Data Transfers. The Company and its service providers are based in the United States. Participant's country or jurisdiction may have different data privacy laws and protections than the United States. The Company's legal basis, where required, for the transfer of Data is the Company's legitimate business interest of providing discretionary benefits under the Plan to Participant.

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

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

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

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

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

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

14. **No Guarantee of Continued Service**. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF THE AWARD PURSUANT TO THE VESTING SCHEDULE HEREOF IS EARNED ONLY BY CONTINUING AS A SERVICE PROVIDER AT THE WILL OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS AWARD OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER

ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE COMPANY (OR THE PARENT OR SUBSIDIARY EMPLOYING OR RETAINING PARTICIPANT) TO TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER AT ANY TIME, WITH OR WITHOUT CAUSE.

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

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

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

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

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

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

21. **Lock-Up Agreement**.

(a) Participant hereby agrees that Participant shall not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Stock (or other securities) of the Company or enter into any swap, hedging or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Common Stock (or other securities) of the Company held by Participant (other than those included in the registration) for a period specified by the representative of the underwriters of Common Stock (or other securities) of the Company not to exceed one hundred and eighty (180) days following the effective date of any registration statement of the Company filed under the Securities Act (or such other period as may be requested by the Company or the underwriters to accommodate regulatory restrictions on (i) the publication or other distribution of research

reports and (ii) analyst recommendations and opinions, including, but not limited to, the restrictions contained in NASD Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto).

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

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

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

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

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

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

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

28. **Governing Law; Venue.** The Award as well as the terms and conditions set forth in the Plan and/or matters arising out of or relating to this Agreement and the transactions contemplated hereby, including its validity, interpretation, construction, performance and enforcement, shall be governed by and construed in accordance with the internal laws of the State of California, without giving effect to its principles of conflict of laws. For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to

the sole and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts.

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

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

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

[Signature Page Follows]

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

PARTICIPANT	SHOCKWAVE MEDICAL, INC.
Signature	By:
Print Name	Name: Title:
Residence Address	
Email Address	

ANNEX A
Performance Goals and Vesting Schedule

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

	Target Number of PRSUs	Relevant Dates of Measurement
First Measurement Period	50% of Total Target PRSUs	January 1, 2022 through December 31, 2023
Second Measurement Period	50% of Total Target PRSUs	January 1, 2022 through December 31, 2024

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

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

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

	Performance Goal		
	Threshold Performance (Achievement Percentage is 50%)	**Target Performance (Achievement Percentage is 100%)**	**Maximum Performance (Achievement Percentage is 200%)**
First Measurement Period	40% CAGR	50% CAGR	60% CAGR
Second Measurement Period	35% CAGR	40% CAGR	45% CAGR

If the achieved CAGR for a Measurement Period is less than the Threshold Performance amount, then the Achievement Percentage shall be zero for that Measurement Period; if the achieved CAGR for a Measurement Period is equal to the Threshold Performance amount, then the Achievement Percentage shall be 50% for that Measurement Period; if the achieved CAGR for a Measurement Period is equal to the Target Performance amount, then the Achievement Percentage shall be 100% for that Measurement Period; and if the achieved CAGR for a Measurement Period is equal to or greater than the Maximum Performance amount, then the Achievement Percentage shall be 200% for that Measurement Period. Notwithstanding the foregoing, there will be linear interpolation (rounded to two decimal places) to derive the Achievement Percentage for any achieved CAGR that is between the Threshold Performance level and the Target Performance level, or between the Target Performance level and the Maximum Performance level. Any fractional Shares resulting from the application of the Achievement Percentage will be rounded down to the nearest whole Share. In the event that the Threshold Performance level (as indicated in the table below) for any Measurement Period is not achieved, the number of Earned PRSUs for that Measurement Period will be zero.

2. **Determination Date and Vesting; Change in Control**. As soon as practicable after the end of each Measurement Period (but no later than February 25, 2024 for the First Measurement Period and February 25, 2025 for the Second Measurement Period), the Administrator shall determine the Company's CAGR for the applicable Measurement Period, the resulting Achievement Percentage for the applicable Measurement Period and the number of PRSUs that are earned and become PRSUs for the applicable Measurement Period (the date of the Administrator's determination (except as otherwise set forth in this Section 2), the "**Determination Date**"). The Earned PRSUs for the relevant Measurement Period shall vest on the corresponding Determination Date, subject to the Participant's continued employment through such Determination Date.

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

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

(A) the number of PRSUs that become Earned PRSUs for such Measurement Period shall be based on an Achievement Percentage of 100%;

(B) notwithstanding such determination of the Achievement Percentage and the number of PRSUs that become Earned PRSUs for such Measurement Period, (1) if such Measurement Period is the First Measurement Period, the Determination Date for such Measurement Period shall be deemed to occur on February 25, 2024; and (2) if such Measurement Period is the Second Measurement Period, the Determination Date for such Measurement Period shall be deemed to occur on February 25, 2025; and

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

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

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

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

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

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

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

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

SHOCKWAVE MEDICAL, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION PLAN

This Shockwave Medical, Inc. Amended and Restated Non-Employee Director Compensation Plan (this "Plan") was adopted by the Board of Directors (the "Board") of Shockwave Medical, Inc. (the "Company") on February 20, 2019, and became effective on February 20, 2019. As amended and restated below, this Plan was adopted by the Compensation Committee of the Board (the "Compensation Committee") on December 6, 2021 and became effective on such date.

1. Eligibility. Each member of the Board who is not a full- or part- time officer or employee of the Company (a "Non-Employee Director") is eligible to participate in this Plan during the period of the Non-Employee Director's service as a member of the Board.

2. Annual Cash Fees.
    a. *Annual Board Member Fee*. Each Non-Employee Director will earn cash compensation for service as member of the Board at an annual rate of $40,000 (such compensation, the "Annual Board Member Fee").
    b. *Annual Non-Executive Chair Fee*. Any Non-Employee Director serving as "Non-Executive Chair" of the Board will earn additional cash compensation for such service at an annual rate of $45,000 (such additional compensation, the "Annual Non-Executive Chair Fee").
    c. *Annual Committee Chair Fees*. Each Non-Employee Director serving as the chair of one or more of the following committees of the Board will earn cash compensation for such service at the annual rate set forth here (such compensation, the "Annual Committee Chair Fee"):
        i. $20,000 for the chair of the Audit Committee of the Board (the "Audit Committee");
        ii. $15,000 for the chair of the Compensation Committee; and
        iii. $10,000 for the chair of the Nominating and Corporate Governance Committee of the Board (the "Nominating and Corporate Governance Committee").
    d. *Annual Committee Member Fee*. Each Non-Employee Director serving as a non-chair member of one or more of the following committees of the Board will earn cash compensation for such service at the annual rate set forth here (such compensation, the "Annual Committee Member Fee"):
        i. $10,000 for each member of the Audit Committee;
        ii. $7,500 for each member of the Compensation Committee; and
        iii. $5,000 for each member of the Nominating and Corporate Governance Committee.
    e. *Payment*. The Annual Board Member Fee, Annual Non-Executive Chair Fee, Annual Committee Chair Fee and Annual Committee Member Fee (together, the "Annual Fees") earned by each Non-Employee Director will be paid quarterly in arrears on the last business day of each calendar quarter. In the event that a Non-Employee Director serves on the Board, as Non-Executive Chair or as a chair or member of a committee for less than an entire quarter, the portion of the applicable Annual Fees earned and payable for such quarter will be prorated based on the number of days in such quarter for which such Non-Employee Director provided such service.

3. Initial Equity-Based Compensation for New Non-Employee Directors. Upon the election of a Non-Employee Director to the Board who has not previously served on the Board, such director shall receive an

award (an "Initial Award") of restricted stock units ("RSUs") under the Shockwave Medical Inc., 2019 Equity Incentive Plan (the "Equity Plan"), with a value equal to $180,000, based on the grant date closing price of the Company's common stock, par value $0.001 per share (the "Common Stock"). The grant date of the Initial Award shall be the date of such director's election to the Board, or the earliest practicable date thereafter, as determined by the Company's Chief Executive Officer or Chief Financial Officer. The Initial Award shall vest in equal annual installments over three years from the date of grant, subject to the applicable director's continued service on the Board through the applicable vesting date. The Initial Award shall be granted pursuant to the Company's standard form RSU award agreement, and subject to the terms and conditions therein.

4. Annual Equity-Based Compensation for Non-Employee Directors. An annual grant of RSUs (an "Annual Award") shall be made under the Equity Plan to each Non-Employee Director following each annual meeting of stockholders of the Company. The Annual Award shall have a value equal to $120,000, based on the grant date closing price of the Common Stock. The grant date of the Annual Award shall be the date of such annual meeting of stockholders of the Company, or as the earliest practicable date thereafter, as determined by the Company's Chief Executive officer or Chief Financial Officer. The Annual Award shall vest in full on the earlier of (i) one year following the date of grant or (ii) the following year's annual meeting of stockholders, subject to the applicable director's continued service on the Board through the vesting date. The Annual Award shall be granted pursuant to the Company's standard form RSU award agreement, and subject to the terms and conditions therein.

5. Deferral of Compensation. Notwithstanding anything to the contrary in this Plan, any compensation under this Plan may be deferred pursuant to the terms of any deferred compensation program or plan implemented by the Compensation Committee.

6. Cash Equivalent for Equity Award. In each case where an Non-Employee Director is an equity partner or service provider of a private equity sponsor of the Company, and such sponsor has informed the Company in writing that it does not allow its equity partners or service providers, as the case may be, to accept awards of equity for compensation for services rendered to boards of directors of its portfolio companies, then such Non-Employee Director shall be eligible to receive a cash award in lieu of any Initial Award or Annual Award (each, a "Cash Equivalent Award") with a value equal to the designated value of the equity award that would otherwise be provided hereunder, but otherwise subject to the same terms and conditions applicable to such award.

7. Administration. This Plan will be administered by the Board, or if the Board so determines in its discretion, by the Compensation Committee. The Board (or the Compensation Committee, as the case may be) will have the power to construe this Plan, to determine all questions hereunder, and to adopt and amend such rules and regulations for the administration of this Plan as it may deem desirable. All decisions, determinations and interpretations of the Board (or the Compensation Committee, as the case may be) with respect to this Plan will be final and binding.

8. Transfer and Assignment. The right of a Non-Employee Director to receive the payment of all or a portion of an Annual Fee or to be granted an Initial Award or Annual Award may not be assigned, transferred, pledged or encumbered, other than by will or the laws of descent and distribution and any attempted assignment or transfer will be null and void.

9. Governing Law. This Plan will be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof.

10. Amendment and Termination. The Board (or the Compensation Committee, if so authorized by the Board) may amend, modify or terminate this Plan for any reason at any time; *provided*, that no amendment, modification or termination, without the consent of the applicable Non-Employee Director, will materially adversely affect any then issued and outstanding Initial Award or Annual Award held by such Non-Employee Director.

Exhibit 21.1

SHOCKWAVE MEDICAL, INC.

The following is a list of subsidiaries of the Company as of December 31, 2021:

Name	Jurisdiction of Incorporation
Shockwave Medical GmbH	Germany
Shockwave Medical UK Limited	United Kingdom
Shockwave Medical Japan KK	Japan
Shockwave Medical France SARL	France

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

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

of our reports dated February 25, 2022, with respect to the consolidated financial statements of Shockwave Medical, Inc. and the effectiveness of internal control over financial reporting of Shockwave Medical, Inc. included in this Annual Report (Form 10-K) of Shockwave Medical, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

San Jose, California
February 25, 2022

Exhibit 31.1

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

I, Douglas Godshall, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2022

By: /s/ Douglas Godshall
Douglas Godshall
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Dan Puckett, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2022

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Shockwave Medical, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 25, 2022

By: /s/ Douglas Godshall
Douglas Godshall
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Shockwave Medical, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 25, 2022

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer
(Principal Financial Officer)