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, 2020

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, 2020, 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, 2020) was approximately $1.3 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 shareholdings of our officers, directors and principal stockholders is included or incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

The number of shares of Registrant's Common Stock outstanding as of February 22, 2021 was 34,842,744.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2021 Annual Meeting of Stockholders 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, 2020.

Table of Contents

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. Factors that might cause such a difference include, but are not limited to the following:

- 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;
- 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 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;
- the loss of key scientific or management personnel;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our 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.

These factors, which are discussed in more detail throughout this Annual Report on Form 10-K, including in Part I, Item 1-A – Risk Factors, 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.

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.

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 ("M5 catheter") is a five-emitter catheter 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.

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 the S4 catheter is CE-marked. We commenced a full commercial launch of our S4 catheter in the second half of 2019 in select approved geographies and we have completed a limited market evaluation of our S4 catheter to test its performance in the heavily calcified and challenging BTK environment.

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 ("PMA") of our C2 catheters, which was approved by the FDA in February 2021.

Our differentiated range of 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.

Importantly, during 2020 we were engaged in the following clinical trials:

- DISRUPT CAD III: This global study was designed to support our U.S. 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 anticipate submitting CAD III and CAD IV data to support our Shonin submission in the first half of 2021, with the subsequent launch of our C2 catheters in Japan planned for the first half of 2022, subject to applicable regulatory approvals.

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. Additional registry data demonstrates 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.

A development program and initial clinical work are 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”).

Although we believe that, from a technological or medical perspective, there are no material disadvantages to the use of our products in comparison to other commercially available alternative products, our products are relatively new, we currently have limited commercialization, sales and marketing experience, and our products compete against alternative products that are well-established and are widely accepted by physicians, patients, and third-party payors. Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. Our success will depend in part on our ability to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, maintain existing reimbursement, and obtain reimbursement where it does not currently exist, and develop new products or add new features to our existing products.

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 PAD population in the United States has been estimated to be at least eight million people, according to the National Institutes of Health. The global PAD device market size for treatment of occlusive disease is estimated at approximately $2.9 billion and is expected to grow approximately 3% annually due to the fundamental drivers of an aging population and increasing prevalence of diabetes. The “calcium” segment of the PAD market represents a significant percentage of the market, with 50% or more of the population having moderate-to-severe calcium in their vessels, according to our estimates. Current technologies are often not able to safely and effectively treat heavily calcified vessels. Accordingly, we believe our IVL System to treat PAD has a total addressable market opportunity of over $1.7 billion.

The global device market in coronary intervention for CAD is estimated to be nearly $10 billion, according to Millennium Research Group, Inc. (“MRG”). The most common treatment for patients is percutaneous coronary intervention (“PCI”). This involves a suite of devices to facilitate successful angioplasty and stenting, the most commonly used device being drug-eluting stents (“DES”). Moreover, there are nearly four million PCI procedures performed globally every year, and the number of PCI procedures is growing at a rate of more than 5% annually. We believe our IVL System can help grow

this market through the improved treatment of patients undergoing PCI in whom the currently available solutions pose a higher degree of clinical risk, as well as through increased adoption of IVL by cardiologists compared to currently available plaque modification devices. A study published in the American Journal of Cardiology in 2014 demonstrated that more than 30% of patients undergoing PCI have 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 disease. Despite significant under-penetration of the market, these devices still represented a market of nearly $100 million in 2018 within the United States alone, according to MRG; 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 $2 billion total addressable market opportunity for our IVL System to treat CAD.

The global market for aortic valve replacement (“AVR”), the main treatment for AS, is growing rapidly, and is dominated by the emergence of transcatheter AVR (“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 is over 125,000 procedures performed worldwide in 2018 and is expected to grow to nearly 300,000 by 2025. 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 developing an IVL catheter which we believe can safely and effectively treat patients with AS. If successful, 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.

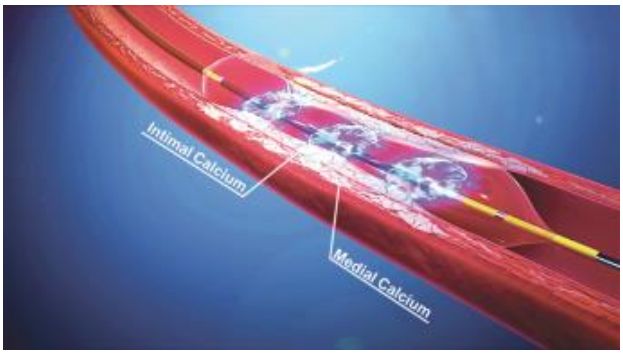
Plaque modification devices (including atherectomy and specialty balloons) have enhanced the treatment of some moderately calcified cardiovascular lesions by improving the ability of stent and balloon therapies to effectively expand in the vessel. Atherectomy devices are designed to break or remove superficial 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 angioplasty 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 aortic stenosis 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 with an effective pressure of up to 50 atmospheres (“atm”) (a unit of pressure) 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 with the goal to expand and improve upon our existing product offerings. Our research and development expenses totaled $32.9 million and $36.9 million for the years ended December 31, 2019 and 2020, respectively.

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 at our facility in Santa Clara, California.

Manufacturing

The manufacturing of our IVL catheters is done at our facilities in Santa Clara, California. 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. 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. 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 logistic 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, and Switzerland on a consignment basis from our third-party logistic provider located in the Netherlands. As of December 31, 2020, we had approximately 148 operations and manufacturing employees.

Our rigorous quality control management programs have earned us a number of quality-related manufacturing designations. Our manufacturing facilities are EN ISO 13485 compliant with ISO 13485:2016 edition certification achieved in 2017. In 2014, we achieved compliance with the applicable standards set forth in the European Union's Medical Device Directive (93/42/EEC) (the "MDD"). We use annual internal audits, combined with external audits by regulatory agencies, 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.

Sales & 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, and Switzerland, 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. 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. 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 M5 catheters and S4 catheters) and CE Mark in Europe for our IVL System using our C2 catheters. In August 2020, we submitted a PMA application with the FDA relating to our C2 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 172 professionals as of December 31, 2020.

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 U.S., 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.

Outside the U.S., 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 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., 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.

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, 2020, we owned 45 issued U.S. patents and 59 issued foreign patents, 18 pending U.S. non-provisional patent applications and 21 pending foreign patent applications (including four Patent Cooperation Treaty ("PCT") applications). This portfolio includes 19 issued U.S. patents, 24 issued foreign patents, six pending U.S. non-provisional patent applications and nine pending foreign patent applications relating to our current IVL Technology.

U.S. Pat. Nos. 9,642,673, 8,956,371 and 8,728,091, which are three of our issued U.S. patents relating to our current IVL Technology, are the subject of inter partes review ("IPR") proceedings filed by Cardiovascular Systems, Inc., one of our competitors. For more information regarding these proceedings, please see Part I, Item 3 of this Annual Report on Form 10-K.

These issued patents, and any patents granted from such applications, are expected to expire between 2029 and 2040, 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. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that any patent applications we have filed, or may file in the future, will result in issued patents. We can give no assurance that any patents that have been issued or may be issued in the future will protect our current or future products, will provide us with any competitive advantage, and will not be challenged, invalidated, or circumvented.

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

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 one or more of our products or us to a variety of sanctions, such as loss of product approvals/clearances/certifications, issuance of warning letters, import detentions, and civil monetary penalties or judicial sanctions, such as product seizures, injunctions, and 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 is exempt, or a premarket approval ("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 each 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 premarket notification 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 assure 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 ("MDUFA") performance goals 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, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or different technological characteristics and the information in the premarket notification demonstrates 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)s: traditional, special and abbreviated. Special 510(k)s are typically for devices that are modified 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.

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, FDA's requirement for review days is 150 rather than 90 days. This process is, however, quicker and less expensive than the PMA pathway. 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. A PMA is based on a determination by FDA that the PMA application contains sufficient valid scientific evidence to assure 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 important to 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 assure the validity of the data and compliance with the FDA's applicable clinical study 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.

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 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 institutional review boards, or 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 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 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 or Class III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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, will require 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, 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.

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.

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 or 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.

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, subject to certain safe harbors set forth in the Anti-Kickback Statute and its implementing regulations, 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 Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. 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. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 ("Affordable Care Act"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Affordable Care Act provides that the government may assert that 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 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 U.S. federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim to, or the knowing use of false statements to obtain payment from or approval by, the federal government. Suits filed under the federal civil 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 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 a case brought under the federal civil False Claim Act. If an entity is

determined to have violated the federal civil 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 federal civil 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 knows, or should know, is 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 a covered device that provides payment or other transfer of value to a physician or teaching hospital, or to a third party at the request of a physician or teaching hospital, must submit to CMS information about the payment or other transfer of value annually, with the reported information made public on a searchable website. Similar laws have been enacted in various U.S. states and in foreign jurisdictions, including France.

Health Insurance Portability and Accountability Act of 1996. The federal Health Insurance Portability and Accountability Act ("HIPAA") created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits 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.

The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included an expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Among other things, HITECH created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

We are also subject to other federal, state, and local laws, and regulations relating to safe working conditions, laboratory, and manufacturing practices.

International

General. 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. In addition, our international operations, distribution and sales require us to comply with: the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions; 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.

European Union. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Our products are regulated in the European Union as medical devices per the MDD. Conformity with the MDD is indicated by the CE mark, which is issued by the applicable Notified Body following the successful satisfaction of a variety of requirements, which depend on the class of the product, but normally involve a combination of: (a) submission 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 or evidence of current, valid QMS certificate from a recognized Notified Body evidencing compliance with ISO 13485; and (d) review of the design dossier, which may include safety and technical information, by the Notified Body. The CE mark is contingent upon continued compliance with the applicable regulations, including compliance with ISO 13485 and applicable vigilance and post-market surveillance.

The new European Union Medical Devices Regulation (the "MDR"), which was published in May 2017 with a transition period of three years (extended to four years in light of the COVID-19 pandemic), replaces the MDD and will expand and modify the pre-market and post-market obligations of the MDD. Starting May 2021, the new MDR will apply and no new applications under the previous directives will be permitted. We are in the process of updating our technical documentation and other quality management system processes to meet the new MDR requirements. Under the new MDR requirements, CE certificates issued under the MDD prior to May 2021 will remain valid in accordance with their term, beyond the expiration of the transition period, however certain limitations set forth in the MDR, such as the need to use classifications that are different from the previous directives, as well as post-market requirements would apply. We do not expect such limitations to have any material impact on our ability to supply our products to the countries covered by the MDR.

In addition, we anticipate that in the future our compliance obligations under UK law will continue to increase and change following the departure of the United Kingdom from the European Union as of January 1, 2021.

Regulatory Inspections

We are subject to periodic inspections by the FDA and other regulatory entities, such as a 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 inspectors 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.

Human Capital Resources

As of December 31, 2020, we had 449 full-time employees worldwide, of which 290 were located at our headquarters in Santa Clara, California, and 19 were located outside of the U.S. None of our U.S. employees are represented by a collective bargaining agreement with respect to their employment by us, however, in certain countries outside of the U.S. 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:

- Our employee relations are good.
- Our employees are a key factor in achieving our goals of developing and commercializing products intended to transform the way calcified cardiovascular disease is treated and of establishing a new standard of care for medical device treatment of atherosclerosis.
- Our future success largely depends upon our continued ability to attract and retain highly skilled employees.

In order to continue to attract new employees and to retain our current employees, we have a number of employee-focused policies and procedures, including the following:

- 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.
- We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth, and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning, and paid time off.
- 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.

Legal Proceedings

We may be subject to other legal proceedings and claims in the ordinary course of 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. For information with respect to Legal Proceedings, see Part I, Item 3 of this Annual Report on Form 10-K.

Corporate Information

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

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

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 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.

Risk Factors Summary

The following is a summary of the principal risks to which our business is subject. Each of these risks is more fully described in the individual risk factors immediately following this summary.

- 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 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 operating results 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. 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 continuing U.S. Food and Drug Administration (“FDA”) regulatory requirements.
- Our products may be subject to recalls after receiving 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.
- The market price of our common stock has been and may continue to be highly volatile.
- 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.
- An active trading market for our common stock may not be sustained.
- 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.

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 12 months ended December 31, 2020 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, any 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 as a result of 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 the elimination of 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 to manufacturing facilities, and efforts to better manage telecommuting among those employees able to do so, (ii) attempt to avoid 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.

In addition to potentially amplifying the foregoing and the other risk factors described in this Annual Report on Form 10-K, a prolonged or recurrent COVID-19 pandemic could result in the following, which would materially and adversely impact our business operations and financial results:

- Material disruption of our supply of product components or ability to distribute our products, despite our efforts to manage potential supply-chain disruption.

- Material business and manufacturing disruption caused by an outbreak at our headquarters and manufacturing facility for a sustained period of time.
- 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, directly and indirectly, including without limitation impacts on the health of our management and employees, manufacturing, distribution, marketing and sales operations, customer and patient behaviors, and on the overall economy 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 the pandemic might end.

We have limited commercial experience.

We were incorporated in 2009 and began commercializing our M5 intravascular lithotripsy ("IVL") catheter ("M5 catheter") for treating peripheral artery disease ("PAD") in the United States and Europe in 2018 and our C2 IVL catheter ("C2 catheter") for treating coronary artery disease ("CAD") in Europe in 2018. We initiated a limited launch of our 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 pre-market approval ("PMA") with the U.S. Food and Drug Administration relating to our C2 catheters in August of 2020 and we received FDA approval for our C2 catheters in February of 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 our DISRUPT CAD IV clinical trial, transcatheter aortic valve replacement ("TAVR") feasibility clinical trial, and other clinical trials we may undertake in the future, (ii) successfully commercialize our C2 catheter for the treatment of CAD in the United States, 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 expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. For the years ended December 31, 2020 and 2019, we reported net losses of $65.7 million and $51.1 million, respectively. As a result of these losses, as of December 31, 2020, we had an accumulated deficit of approximately $243.7 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. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. 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 future partners;
- 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;
- 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, regulatory approval, and commercialization activities 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; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results 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 operating results 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.

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.

Since our inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future, and our operations have been financed primarily by net proceeds from the sale of our equity securities and, to a lesser extent, product revenue. As of December 31, 2020, we had $202.4 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $243.7 million. Based on our current planned operations, we expect our cash, cash equivalents and short-term investments will enable us to fund our operating expenses 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 expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing, and distribution capabilities;

- the terms and timing of any other collaborative, licensing, and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current and potential products;
- the degree of success we experience in commercializing our products;
- the emergence of competing or complementary technologies;
- the cost of preparing, filing, prosecuting, maintaining, defending, and enforcing any patent claims and other intellectual property rights; 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.

We anticipate that we will 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 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. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists, and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, 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 and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. 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 operating results may be adversely affected.

As of December 31, 2020, we had 449 full-time employees worldwide. We have significantly expanded the size of our organization over the past three years, particularly in the number of sales and marketing personnel, and expect to do so in the future. As our sales and marketing strategies develop and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- 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.

Our future financial performance and our ability to successfully market and sell our products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We have grown and expect to grow our sales force in anticipation of additional product approvals or clearances and increased entry into new markets. 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 successfully implement the tasks necessary to further develop and commercialize our products and, accordingly, may not achieve our research, 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 complementary companies, products or technologies that we believe fit within our business model and can address the needs of our customers and potential customers. In the future, we may not be able to acquire and integrate other companies, products, or technologies in a successful manner. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, 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. 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.

Future acquisitions 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 pay cash, incur debt, or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, one-time charges and can 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 items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize, or such strategic alliance, joint venture or acquisition may be prohibited. In February 2018, we entered into the Loan and Security Agreement with Silicon Valley Bank (the “Loan and Security Agreement”). The Loan and Security Agreement restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

We may seek strategic alliances or enter into licensing arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to

our products and any planned or future products that we may develop. For example, in December 2018, we entered into a collaboration with Abiomed pursuant to which we are working with Abiomed to integrate our products into Abiomed's physician training and education programs. We may not be successful in our efforts to establish such collaborations for our products. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products could delay the commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our products, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our products, could delay the development and commercialization of our products and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

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. In connection with the Loan and Security Agreement, Silicon Valley Bank was concurrently issued a common stock warrant that entitled Silicon Valley Bank to purchase up to 34,440 shares of our common stock with an exercise price of $4.026 per share, with a term of ten years. In April 2019 this warrant was net exercised into 29,887 shares of our common stock.

On February 11, 2020, we entered into the First Amendment (the "Amendment") to the Loan and Security Agreement, to refinance our existing term loan. The Amendment 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 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. In addition, the Amendment 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 Amendment, 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 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, but is not subject to any financial covenants. 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. See the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Debt obligations*."

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

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing

and inventory management. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, 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, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. We address these data security concerns in more detail below. Technological interruptions would disrupt 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. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. 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. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

If we experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, or if customers, patients and other partners are reluctant to use our devices because of concerns about the privacy or security of their data, we may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our platform and business disruption.

In connection with various facets of our business, we collect and use a variety of personal data, such as name, mailing address, email addresses, mobile phone number, location information and clinical trial information. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our data or consumers' personal data could result in significant liability under state (e.g., state breach notification laws, the California Consumer Privacy Act ("CCPA"), which became effective in January 2020, and the California Public Records Act ("CPRA"), which will become effective in January 2023), federal (e.g., the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH Act")) and international law (e.g., the European Union's General Data Protection Regulation ("GDPR")). Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users and potentially disrupt our business. We may also rely on third-party service providers to host or otherwise process some of our data and that of users, and any failure by such third party to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us.

Because the techniques used to obtain unauthorized access, disable, or degrade service or sabotage systems 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 adequate preventative measures. Our servers and platforms may be vulnerable to computer viruses or physical or electronic break-ins that our security measures may not detect. Individuals able to circumvent our security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers, or otherwise damage our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. If we are unable to prevent or mitigate the impact of such security breaches, our ability to attract and retain new customers, patients and other partners could be harmed, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to 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.

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as the Common Rule, GCP guidelines, or FDA human subject protection regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal data or prevent use of their accounts. Data breaches could result in a violation of applicable U.S. and international privacy, data protection and other laws, and 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, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business. For example, in the United States, California recently adopted the CCPA, which came into effect in January 2020 and the CPRA, which will come into effect in January 2023. These laws will, among other things, require new disclosures to California consumers and afford such consumers new abilities to opt out of certain sales of personal information, in addition to severely limiting our ability to use their information. It remains unclear how various provisions of the CCPA and the CPRA will be interpreted and enforced. The effects of the CCPA and the CPRA are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

In addition, the GDPR, which became effective in May 2018, applies extraterritorially and imposes several stringent 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 and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR provides that European Union (“EU”) member states may make their own laws and regulations limiting the (i) processing of personal data, including special categories of data (e.g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and (ii) profiling and automated individual decision-making of individuals, which could limit our ability to use and share personal data or other data and could cause our costs to increase, harming our business and financial condition. Non-compliance with GDPR is subject to significant penalties, including fines of up to €20 million or 4% of total worldwide revenue. The interpretations of the GDPR by local data protection authorities in EU member states, along with the complexity of the new data protection regime itself, will leave the interpretation and enforcement of the law unclear in the near term, with potential inconsistencies across the EU member states. The implementation and enforcement of the GDPR may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected. In addition, the departure of the UK from the EU as of January 1, 2021 has added increased compliance efforts specifically relating to the UK and these UK-specific compliance efforts may become greater as time passes. As well, other jurisdictions outside the EU are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws.

Additionally, we are subject to laws and regulations regarding cross-border transfers of personal data, including laws relating to transfer of personal data outside of the European Economic Area (“EEA”). We rely on transfer mechanisms permitted under these laws, including EU Standard Contract Clauses. Such mechanisms have received heightened regulatory and judicial scrutiny in recent years. If we cannot rely on existing mechanisms for transferring personal data from the EEA, the United Kingdom or other jurisdictions, we could be prevented from transferring personal data of users or employees in those regions. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

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 similar 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; or (iv) 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 and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These

laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, 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.

We have adopted a code of business conduct and ethics, 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. 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.

Economic conditions may adversely affect our business.

Adverse worldwide economic conditions may negatively impact our 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.

Our operations and one or more markets in which we operate, could be subject to earthquakes, fires, medical epidemics and pandemics (including expectations about them), 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. As well, we rely on: (i) third-party manufacturers to produce various components that are integrated into our products; (ii) third-party distributors to distribute our products; and (iii) hospitals to purchase our products. 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, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown at this time.

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 for the treatment of above-the-knee PAD in the United States, Europe and other international markets, S4 catheters for the treatment of below-the knee PAD in the United States, Europe and other international markets, and C2 catheters for the treatment of CAD in the United States, Europe, and other international markets.

Therefore, we are dependent on widespread market adoption of these products and we will continue to be dependent on the success of these products for the foreseeable future. There can be no assurance that our products will gain a substantial degree of market acceptance among specialty physicians, patients, or healthcare providers. Our failure to successfully

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

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 right to products and technologies on terms that are acceptable to us.

Any product we identify, license, or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. All products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

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 catheters and S^4 catheters for the treatment of calcified plaque in patients with PAD in the United States, Europe and other international markets, 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.

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

The PMA process typically is more costly, lengthy, and stringent than either the 510(k) process or the de novo classification process. Unlike a 510(k) review, which determines “substantial equivalence,” a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human 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. The FDA requires device manufacturers to make and document a determination of whether a modification requires 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. 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 on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

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 a particular product or indication and fail to capitalize on products or indications 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, indications and discovery programs. As a result, we may forgo or delay pursuit of other opportunities with others 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. If we do not accurately evaluate the commercial potential or target market for a particular potential product, we may relinquish valuable rights to that potential product 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 potential product.

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 would be expensive and time-consuming. 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, 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 federal civil False Claims Act for which it might impose significant civil fines and even pursue criminal action. In those possible events, our reputation could be damaged, and adoption of the products would be impaired.

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 or misuse 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.

Material modifications to our products may require new 510(k) clearances or pre-market approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications that could significantly affect the safety and effectiveness of our approved or cleared products, such as changes to the intended use or technological characteristics of our products, will require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval, or clearance; however, the FDA can review a manufacturer's decision. 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 products, changes that affect safety and effectiveness will require the submission and approval of a PMA supplement.

We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, 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. 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 disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions.

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 addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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 the EU, on May 25, 2017 the new Medical Devices Regulation (the "MDR") was adopted. Following its entry into application on May 26, 2021, the MDR will introduce substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure.

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 or modifications of existing products, including new indications for existing products, including:

- Risks relating to clinical trial approvals:
  - there may be 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
  - the 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:
  - we may experience 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;
  - enrollment in our clinical trials may be slower than we anticipate, we may experience high screen failure rates in our clinical trials, or we may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials;
  - we may experience lower than anticipated retention rates of patients and volunteers in clinical trials or we may have difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
  - we may experience 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 Good Clinical Practice ("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:
  - our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical 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 in different ways than we do.

- Risks related to investigation devices used in the clinical trial:
  - 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 stock options 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 begin 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, such as GCP guidelines, the Common Rule, and FDA human subject protection regulations. 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 our maintaining 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.

Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under "*Risks Related to Government Regulation and Our Industry*."

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.

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, our production processes and assembly methods may have to change 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.

Since we produce all of our IVL catheters at one facility, any contamination of the controlled environment, equipment malfunction or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can 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 can 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 suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers to provide us with certain components of our products. We rely on single source suppliers for certain components of our products. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our suppliers, including single source suppliers. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. These suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us.

Any supply interruption from our suppliers or failure to obtain additional suppliers for 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 component 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 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, 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 component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. The failure by us or one of our component 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, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our 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 ("ISO") certifications to sell our products and must undergo periodic inspections by notified bodies, including the 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 may need to depend on third parties to manufacture our products. If these manufacturers fail to meet our requirements and strict regulatory standards, we may be unable to develop, commercialize or market our products.

We may in the future need to depend upon third parties to manufacture our products. Reliance on a third-party manufacturer entails risks to which we would not be subject if we manufactured products ourselves, 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 at the times and in the quantities we need, 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 following:

- 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;
- achieving and maintaining 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 Good Manufacturing Practices ("cGMP") and the Quality System Regulation ("QSR"); and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities 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 user 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 launched our M5 catheters for the treatment of PAD in the United States, Europe and select other countries in 2018, we launched our C2 catheters for the treatment of CAD in Europe in 2018, and following receipt of FDA approval, in the United States in February 2021. We initiated a limited launch of our S4 catheter in the first half of 2019 and commenced a full commercial launch in select approved geographies in the second half of 2019. Our sales were $67.8 million and $42.9 million for the years ended December 31, 2020 and 2019, 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 US 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 our leadership team to manage;
- 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 to have our sales force meet required productivity levels within a reasonable period of time, we may not be able to realize the expected benefits of this investment 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 doctors, patients, practitioners, third-party payors, and regulators could adversely affect our ability to grow the 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, or market 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, they may not gain market acceptance, as 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 technology.

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 tests 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 population 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 have an adverse impact on our business.

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. Third-party payors 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 manufacture by other companies, including Boston Scientific Corporation, Cardiovascular Systems, Inc., Medtronic plc and Philips. 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 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. Our continued success depends on our ability to:

- develop innovative, proprietary products that can cost-effectively address significant clinical needs;
- 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;
- apply our 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.

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 respond quickly to medical and other changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that our new product development efforts will result in any commercially successful products.

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 goods 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. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition and results of operations.

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 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 currently 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 doctors 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 limited data and experience regarding the safety and efficacy of our products. 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 PAD and CAD, we have performed clinical trials only with limited patient populations. The long-term effects of using our products in a large number of patients have not been studied and the results of short-term clinical use of such products 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 and ongoing or future studies and trials of our current, planned or future products 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 clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier 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.

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.

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.

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 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 image, 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.

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 European Union and certain other international markets for the treatment of PAD and CAD, and international sales comprised 45% of our revenue for the year ended December 31, 2020. Sales of our products outside of the United States are and will be subject to foreign regulatory requirements governing clinical trials and marketing approval. We will incur substantial expenses in connection with our international expansion. Additional risks related to operating in foreign countries include:

- differing regulatory requirements in foreign countries;

- differing reimbursement regimes in foreign countries, including price controls;
- 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;
- 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 United Kingdom's departure from the European Union;
- 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; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our planned and future products in foreign markets. We are not permitted to market or promote any of our planned or future products before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our planned or future products. 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. If we obtain regulatory approval of our products and ultimately commercialize our planned or future products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of medical devices in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;

- unexpected changes in tariffs, trade barriers and 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 currency fluctuations, which could result in increased operating expenses, reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

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, 2020 have contracted with distributors who are actively selling our products in over 50 countries in North and South America, Europe, the Middle East, Asia, Africa, and Australia/New Zealand. For the year ended December 31, 2020, approximately 45% 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 operating results. In addition, failure by our foreign distributors to comply with 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, in which 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 U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes 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 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, 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 or 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 federal healthcare Anti-Kickback Statute ("Anti-Kickback Statute") and federal civil 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 following:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that 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 Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device 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. Our practices, such as the loan, consignment, or purchase of certain components of our IVL System to customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability. In October 2019, the federal government published two proposed regulations that would create new safe harbors for (among other things) certain value-based arrangements and patient engagement tools, and modify and clarify the scope of existing safe harbors for warranties and personal service agreements. These regulations were finalized in December 2020, and the impact of these regulations on our operations is not yet clear.

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. 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. Actions under the federal civil False Claims Act may be brought by the government or as a *qui tam* action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil 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. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations through settlement for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.
- HIPAA, which imposes criminal and civil liability for, among other actions, 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 a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to 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. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- 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 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; and 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.

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, federal civil 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, 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 federal civil 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 federal civil 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 agencies regulate our products as medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, 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 or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies 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 and S4 catheters, our clearance 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 certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA. Our C^2 catheter for the treatment of CAD is designated as a Class III product and will follow the PMA process. As a Company, we do not have prior experience in obtaining PMA approval.

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 the 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 our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies; and result in our incurring 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, which may also impact our business, and which could have a material adverse effect on our business, financial condition and results of operations.

Although we have obtained regulatory clearance for our M^5 and S^4 catheters for the treatment of PAD in the United States and in certain non-U.S. jurisdictions, and our C^2 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 M^5 and S^4 catheters have obtained regulatory clearance in the United States and in certain non-U.S. jurisdictions for the treatment of PAD, and our C^2 catheters have obtained regulatory clearance in the U.S. 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 the products' cleared or approved labeling. 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. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use, known as "off-label uses." However, physicians may use our products for off-label purposes and are allowed to do so when, in the physician's independent professional medical judgment, he or she deems it appropriate. If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, or that our internal policies and procedures are inadequate to prevent such off-label uses, it could subject us to regulatory or enforcement actions as discussed below.

If a regulatory agency discovers previously unknown problems with a product, 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 a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, 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 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.

Our products may be subject to recalls after receiving FDA or foreign approval or clearance, 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. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation, and adversely affect our business.

If we initiate a 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 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 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.

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. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can 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.

If we or our suppliers fail to comply with the FDA's Quality System Regulation or any applicable state or country equivalent, our operations could be interrupted, and our potential product sales and operating results could suffer.

Our manufacturing processes and those of our third-party suppliers are required to 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 overseas. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic announced or unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we experience an unsuccessful Quality System inspection, our operations could be disrupted, and our manufacturing could be interrupted. Failure to take adequate corrective action in response to an adverse Quality System 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 product 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 ("CDHS"). We anticipate that we and certain of our third-party component suppliers will be subject to FDA and CDHS inspections.

We completed the move of our production of our IVL catheters from our prior Fremont, California facility to our facility in Santa Clara, California in the second half of 2019. We produce all 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 85,200 square feet. Our Santa Clara facility has been inspected by the FDA and by the British Standards Institution ("BSI"). We can provide no assurance that the FDA or other inspecting bodies will continue to find us to be in compliance with QSR. If our 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 produce 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 produce 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 the 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 the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under FDA and other applicable international medical device reporting regulations, medical device manufacturers are required to report that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported within the required timeframes, or at all, the applicable regulatory agency could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, 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.

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 by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act ("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 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. For example, former President Trump signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law, including the Tax Cuts and Jobs Act, enacted on December 22, 2017 ("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 (i) that 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 Supreme Court took place on November 10, 2020. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace, or invalidate the ACA or its implementing regulations, or portions thereof, will affect the ACA or our business.

In addition, other 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 2029 unless additional Congressional action is taken. 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.

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 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, and remediation of, as well as 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 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 effective patent claims that cover, and other intellectual property with respect to, such products, their manufacturing processes and their intended methods of use and enforcing those patent claims once granted as well as our other intellectual property. In some cases, we may not be able to obtain issued claims covering our technologies which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent and other intellectual property protection with respect to our IVL products and technologies or other aspects of our business could have a material adverse effect on our business, financial condition, and results of operations.

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. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

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. 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. In addition, 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. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. 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. 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. 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. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This

uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products. 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. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products. Furthermore, even if they are unchallenged, our patents may not adequately protect our products, provide exclusivity for our products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products.

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. Various extensions may be available; however, 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, 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. Any patents that we own may be challenged, narrowed, circumvented or invalidated by third parties. 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.

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. Any of the foregoing could have a material adverse effect on our business, financial condition, 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 U.S. Patent and Trademark Office (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 (the "IPR Patents"), 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 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 are invalid, and on July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 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. In the meantime, we have appealed the rulings in the other two IPR proceedings. All claims of the IPR Patents remain valid and enforceable until such appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could limit our ability to stop others from using or commercializing products and technology similar or identical to ours.

Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

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. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. 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. There are situations, however, in which non-compliance 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, which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our 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 or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be adversely affected.

Changes in U.S. 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. 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.

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. The confidentiality 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. 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 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 we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. 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 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.

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.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-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. In addition, with respect to any patents we may in the future co-own with third parties, we may require licenses to such co-owners' interest to such patents. 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. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. 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. 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, 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.

Our employees, consultants and scientific advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. 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. 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, 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.

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.

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, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations.

Our use of "open-source" software could subject our proprietary software to general release, adversely affect our ability to sell our products and subject us to possible litigation.

A portion of the products or technologies licensed, developed and/or distributed by us incorporate so-called "open-source" software and we may incorporate open-source software into other products in the future. Such open-source software is generally licensed by its authors or other third parties under open-source licenses. Some open-source licenses contain requirements that we disclose source code for modifications we make to the open-source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open-source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products that use particular open-source software at no cost to the user. We monitor our use of open-source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open-source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open-source software into their products have, in the past, faced claims seeking enforcement of open-source license provisions and claims asserting ownership of open-source software incorporated into their product. If an author or other third party that distributes such open-source software were to allege that we had not complied with the conditions of an open-source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open-source software in certain ways, under some open-source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could have a material adverse effect on 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. Since our initial public offering which occurred in March 2019 through February 25, 2021, the closing price of our common stock has ranged from $29.40 per share to $142.05 per share. The market price for our common stock may be influenced by many factors, including:

- the sales level for 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 patent protection 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 stock market 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. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

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

Our common stock is currently listed on the Nasdaq Global Select Market under the symbol "SWAV" and trades on that market. 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, operating results, 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 ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had net operating loss ("NOL") carryforwards of approximately $301.9 million for federal income tax purposes, and $52.4 million for California and $123.7 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. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), 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 operating results by effectively increasing our future tax obligations. In addition, under the 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

The TCJA enacted many significant changes to the U.S. tax laws, and we are still awaiting guidance from the IRS and other tax authorities on some of the TCJA changes that may affect us. 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 contained in 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. The foregoing items, as well as any future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the TCJA or any newly enacted federal tax legislation.

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, 2020, our executive officers, directors and 5% stockholders beneficially owned approximately 53.1% of the outstanding shares of capital stock. As of December 31, 2020, we had 34,684,337 shares of common stock outstanding. Of these shares, the 11,364,048 shares of common stock sold in our IPO, November 2019 follow-on offering and June 2020 offering are freely tradeable.

As of December 31, 2020, our executive officers and directors held options to purchase an aggregate of 1,311,773 shares of our common stock at a weighted-average exercise price of $5.56 per share and 186,278 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 restricted stock and upon exercise or settlement of any other equity incentives we may grant in the future, for public resale under the Securities Act. Accordingly, these shares may be freely sold in the public market upon issuance as permitted by any applicable vesting requirements. Furthermore, as of December 31, 2020, holders of approximately 1,459,807 shares of our common stock have certain rights with respect to the registration of such shares under the Securities Act.

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which requires, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”), as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market 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 more 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. We are in the process of designing and implementing our internal control over financial reporting in which the process will be time-consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply

with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, once required, 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 the stock exchange on which our securities are listed, 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 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. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. 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. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our stock price and trading volume could decline.

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. A limited number of analysts are currently covering our company. 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 you might otherwise receive a premium for your 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. See the section titled "Description of Capital Stock."

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, 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. The choice of forum provision 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. 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In May 2018 we entered into a lease agreement for a stand-alone building located at 5403 Betsy Ross Drive in Santa Clara, California, consisting of approximately 35,000 square feet, utilized by us for our corporate offices as well as laboratory and manufacturing space. In December 2019, we entered into a new lease agreement to extend the May 2018 lease and to add an adjacent stand-alone building located at 5353 Betsy Ross Drive in Santa Clara, which increased our total leased space from approximately 35,000 square feet to approximately 85,200 square feet. The May 2018 lease will continue under its existing terms (and with no changes to its terms, including its base rent) until its expiration on August 31, 2022, at which point the leased space under the May 2018 lease will become subject to the terms of the December 2019 lease. The initial term of the December 2019 lease is for 96 months, and we have the option to extend for an additional five years on one or both of the buildings.

Our corporate offices are located at the Santa Clara location. In addition, we produce our IVL catheters in-house at our facilities in Santa Clara. We believe that the above Santa Clara facilities 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 (the "IPR Patents"), 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 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 are invalid, and on July 20, 2020, the PTAB ruled that all claims of U.S. Pat. No. 9,642,673 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. In the meantime, we have appealed the rulings in the other two IPR proceedings. All claims of the IPR Patents remain valid and enforceable until such appeals have been exhausted. Upon the conclusion of such appeals, if we are unsuccessful in whole or in part, the IPR proceedings could result in the loss or narrowing in scope of the IPR Patents, which could 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, please see the section of this Annual Report on Form 10-K entitled “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. Public trading of our common stock began on March 7, 2019. Prior to that, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock on the Nasdaq Global Select Market:

	Low	High
Fiscal year ending December 31, 2020		
First quarter	$ 22.01	$ 48.74
Second quarter	26.33	48.52
Third quarter	41.77	76.95
Fourth quarter	66.09	105.09
Fiscal year ending December 31, 2019		
First quarter (beginning March 7, 2019)	$ 24.58	$ 43.39
Second quarter	28.80	68.39
Third quarter	28.93	59.72
Fourth quarter	28.31	45.57

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, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

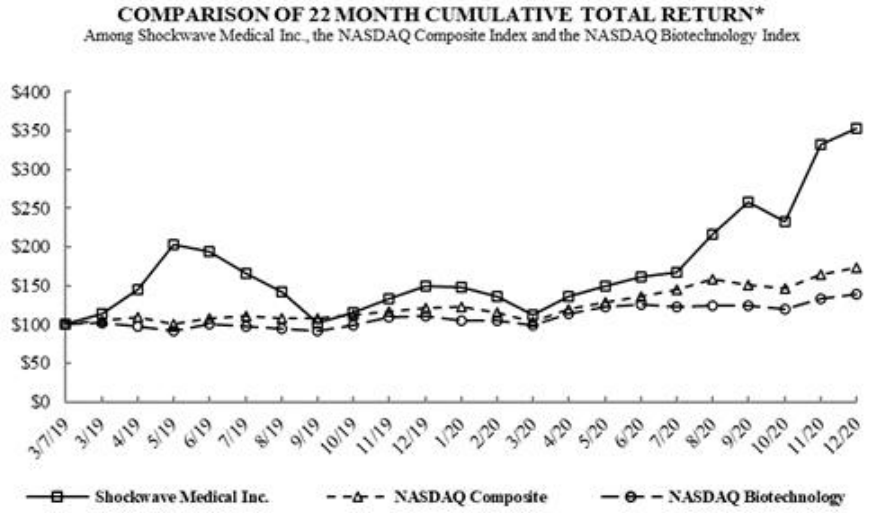
Stockholders

As of February 22, 2021, there were 22 holders of record of our common stock, including The Depository Trust Company, which holds shares of our common stock on behalf of an indeterminate number of beneficial owners.

Stock Performance Graph

The following shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or 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 Biotechnology Index. The graph assumes $100 was invested in each of the Company's common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology 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. Selected Financial Data.

Not required.

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 this report in Part I, Item 1A — "Risk Factors," and elsewhere in this report. 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 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. We are currently selling the following products in a number of countries around the world where we have applicable regulatory approvals:

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

- Our Shockwave M5 IVL catheter ("M5 catheter"), which was CE-Marked in April 2018 and cleared by the U.S. Food and Drug Administration ("FDA") in July 2018 for use in our IVL System for the treatment of PAD.
- The second version of our Shockwave S4 IVL catheter ("S4 catheter"), for the treatment of below the knee PAD, which was cleared by the FDA in August 2019, and accepted by our EU notified body in May 2020.

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

- Our Shockwave C2 IVL catheter ("C2 catheter") was CE-Marked in June 2018 and cleared by the FDA in February 2021 for use in our IVL System for the treatment of CAD.

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. Importantly, in October 2020, we announced the results of our DISRUPT CAD III global study. The data from DISRUPT CAD III supported our pre-market application ("PMA") in the United States for our C2 catheters, and is intended to support a Shonin submission in Japan for our C2 catheters. In addition, we began enrollment in the DISRUPT CAD IV Japan study in 2019 and completed enrollment in April 2020. We anticipate submitting CAD III and CAD IV data to support Shonin approval, with subsequent Japan launch planned for the first half of 2022, subject to applicable regulatory approvals.

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 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 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 and Switzerland, which we have complemented 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 adding new U.S. sales territories.

For the years ended December 31, 2020, 2019 and 2018, we generated product revenue of $67.8 million, $42.9 million and $12.3 million, respectively, and a $65.7 million, $51.8 million and $41.2 million loss from operations, respectively. For the years ended December 31, 2020, 2019 and 2018, 45%, 47% and 43%, 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 and expect to continue to incur net losses for the foreseeable future. To date, our principal sources of liquidity have been the net proceeds we received through the sale of our common stock in our initial public offering, private sales of equity securities and payments received from customers using our products. As of December 31, 2020, we had $202.4 million in cash, cash equivalents and short-term investments and an accumulated deficit of $243.7 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 continues to be 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.

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 have continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our employees and their families from potential exposure to COVID-19, all other staff in our Santa Clara headquarters have been required to work from home. We have restricted non-essential 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. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

Public Offerings of Common Stock

On March 11, 2019, we closed on our initial public offering ("IPO") of 6,555,000 shares of common stock at an offering price of $17.00 per share, which included the full exercise of the underwriters' over-allotment option to purchase 855,000 additional shares of our common stock. We raised a total of $111.4 million in gross proceeds from the IPO, or approximately $99.9 million in net proceeds after deducting underwriters' discounts and commissions of $7.1 million and offering costs of $4.4 million. Concurrent with the IPO, we issued 588,235 shares of common stock in a private placement (the "Private Placement") for net proceeds of $10.0 million.

On November 15, 2019, we completed a follow-on offering of 2,854,048 shares of our common stock, including 372,267 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares at a public offering price of $36.25 per share. Upon completion of our follow-on offering, we received net proceeds of $96.7 million, after deducting underwriters' discounts and commissions and offering expenses. On June 19, 2020, we completed an offering of 1,955,000 shares of our common stock, including 255,000 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares at a public offering price of $45.75 per share. Upon completion of the June 2020 offering, we received net proceeds of $83.4 million, after deducting underwriting discounts and commissions and offering expenses.

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.
- ***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 profit/loss 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 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 equipment 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 equipment over a three-year period. We expect cost of product revenue to increase in absolute terms as our revenue grows.

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

Research and development expenses

Research and development ("R&D") expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D 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 ("CROs") and site payments;
- materials and supplies used for internal R&D 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.

R&D costs are expensed as incurred. In the future, we expect R&D 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 SEC compliance and investor relations.

Interest expense

Interest expense consists of interest on our debt and amortization of associated debt discount. In February 2018, we entered into a Loan and Security Agreement with Silicon Valley Bank for a term loan and a revolving line of credit. In June 2018 and December 2018, we drew an aggregate of $15.0 million in borrowings under the term loan facility.

On February 11, 2020, we entered into the First Amendment (the "Amended Credit Facility") to the Loan and Security Agreement, to refinance the 2018 term loan. The Amendment 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 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. In addition, the Amendment terminated our revolving line of credit. As of December 31, 2020, we had $16.6 million outstanding under the Amended Credit Facility.

Other income, net

Other income consists primarily of interest earned on our cash equivalents and short-term investments.

Income tax provision

Income tax provision consists primarily of income taxes in certain foreign jurisdictions in which we conduct business. We have a full valuation allowance for deferred tax assets, including net operating loss carryforwards and tax credits related primarily to R&D.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019:

	Year Ended December 31,		Change	Change
	2020	2019	$	%
	(in thousands, except percentages)			
Revenue:				
Product revenue	$ 67,789	$ 42,927	$ 24,862	58%
Cost of revenue:				
Cost of product revenue	20,991	17,159	3,832	22%
Gross profit	46,798	25,768	21,030	82%
Operating expenses:				
Research and development	36,926	32,853	4,073	12%
Sales and marketing	51,672	30,620	21,052	69%
General and administrative	23,863	14,134	9,729	69%
Total operating expenses	112,461	77,607	34,854	45%
Loss from operations	(65,663)	(51,839)	(13,824)	27%
Interest expense	(1,212)	(944)	(268)	28%
Change in fair value of warrant liability	—	(609)	609	(100)%
Other income, net	1,256	2,345	(1,089)	(46)%
Net loss before taxes	(65,619)	(51,047)	(14,572)	29%
Income tax provision	80	62	18	29%
Net loss	$ (65,699)	$ (51,109)	$ (14,590)	29%

Product revenue. Product revenue increased by $24.9 million, or 58%, from $42.9 million in 2019 to $67.8 million in 2020, driven primarily by peripheral and coronary product revenues, as further described below.

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

	Year Ended December 31,		Change	Change
	2020	2019	$	%
	(in thousands, except percentages)			
Peripheral	$ 41,994	$ 26,325	$ 15,669	60%
Coronary	24,586	15,621	$ 8,965	57%
Other	1,209	981	$ 228	23%
Product revenue	$ 67,789	$ 42,927	$ 24,862	58%

Peripheral product revenue increased by $15.7 million, or 60% from $26.3 million in 2019 to $42.0 million in 2020. The change was due to an increase in purchase volume of our M5 and S4 IVL catheters within the United States and internationally.

Coronary product revenue increased by $9.0 million, or 57% from $15.6 million in 2019 to $24.6 million in 2020. The change was due to an increase in purchase volume of our C2 IVL catheter. All coronary product revenue was international for the years ended December 31, 2020 and 2019.

Other product revenue increased by $0.2 million, or 23% from $1.0 million in 2019 to $1.2 million in 2020. 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 2020 compared to 2019. Product revenue, classified by the major geographic areas in which our products are shipped, was $37.1 million within the United States and $30.7 million for all other countries in 2020 compared to $22.7 million within the United States and $20.2 million for all other countries in 2019.

Cost of product revenue and gross margin percentage. Cost of product revenue increased by $3.8 million, or 22%, from $17.2 million in 2019 to $21.0 million in 2020. The increase was primarily due to growth in sales volume. Gross margin percentage improved to 69.0% in 2020, compared to 60.0% in 2019. This change in gross margin percentage was primarily due to 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 R&D expenses incurred during the periods presented:

	Year Ended December 31,			
	2020	2019	Change $	Change %
	(in thousands, except percentages)			
Compensation and personnel-related costs	$ 17,097	$ 13,302	$ 3,795	29%
Clinical-related costs	10,268	12,933	(2,665)	(21)%
Material and supplies	2,984	2,094	890	43%
Facilities and other allocated costs	2,941	2,252	689	31%
Outside consultants	1,868	1,449	419	29%
Other research and development costs	1,768	823	945	115%
Total research and development expenses	$ 36,926	$ 32,853	$ 4,073	12%

R&D expenses increased by $4.1 million, or 12%, from $32.9 million in 2019 to $36.9 million in 2020. The increase was primarily due to a $3.8 million increase in compensation and personnel-related costs due to an increase in head count to support quality assurance functions. There was also a $0.9 million increase in other R&D costs primarily driven by an increase in software license expense related to R&D, a $0.9 million increase in materials and supplies, a $0.7 million increase in facilities and other allocated costs due to increased rent and building expenditures and a $0.4 million increase for outside consultants. These increases were partially offset by a $2.7 million decrease in clinical-related costs primarily due to the completion of patient enrollment for the current clinical trials.

Sales and marketing expenses. Sales and marketing expenses increased by $21.1 million, or 69%, from $30.6 million in 2019 to $51.7 million in 2020. The increase was primarily due to a $17.0 million increase in compensation and personnel-related costs, which included a $4.7 million increase in commission expense, as a result of a higher head count and increased revenue for the year-ended December 31, 2020. Marketing and promotional expenses increased by $1.4 million to support the continued commercialization of our products. There was also a $0.9 million increase due to facilities and other allocated costs, due to increased rent and building expenditures, a $0.8 million increase due to consulting and general corporate expenses, a $0.7 million increase in materials and supplies, and a $0.3 million increase due to recruiting and training fees.

General and administrative expenses. General and administrative expenses increased by $9.8 million, or 69%, from $14.1 million in 2019 to $23.9 million in 2020. The change was primarily due to a $4.8 million increase in compensation and personnel-related costs due to an increase in head count, $4.2 million increase in consulting, professional services and general corporate expenses, and a $0.8 million increase in recruiting, training, and facilities.

Interest expense. Interest expense increased by $0.3 million, or 28%, from $0.9 million in 2019 to $1.2 million in 2020. The increase in interest expense was primarily due to increased loan principal amount to $16.5 million after the Company entered into the Amended Credit Facility in February 2020.

Change in fair value of warrant liability. The change in fair value of warrant liability was $0.6 million in 2019 due to the common stock warrants which were exercised in April 2019.

Other income, net. Other income, net decreased by $1.1 million, or 46%, from $2.3 million in 2019 to $1.3 million in 2020. The decrease was primarily driven by a decrease in the interest rate environment compared to the prior year.

Income tax provision. The income tax provision increased by $18,000, or 29%, from $62,000 in 2019 to $80,000 in 2020. This increase was primarily due to an increase in foreign income tax expense.

Comparison of the Years Ended December 31, 2019 and 2018

For a comparison of our results of operations for the fiscal years ended December 31, 2019 and 2018, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 12, 2020.

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 using our products and to a lesser extent proceeds from our debt financings. On March 11, 2019, we completed our initial public offering, including the underwriters' full exercise of their over-allotment option, selling 6,555,000 shares of our common stock at $17.00 per share. Upon completion of our initial public offering, we received net proceeds of $99.9 million, after deducting underwriting discounts and commissions and offering expenses. Concurrent with the initial public offering, we issued 588,235 shares of common stock in our Private Placement for net proceeds of $10.0 million. On November 15, 2019, we completed a follow-on offering of 2,854,048 shares of our common stock, including 372,267 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares at a public offering price of $36.25 per share. Upon completion of our follow-on offering, we received net proceeds of $96.7 million, after deducting underwriting discounts and commissions and offering expenses. On June 19, 2020, we completed an offering of 1,955,000 shares of our common stock, including 255,000 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares at a public offering price of $45.75 per share. Upon completion of the June 2020 offering, we received net proceeds of $83.4 million, after deducting underwriting discounts and commissions and offering expenses.

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 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 R&D, 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, we expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future.

Our future capital requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish including any contract manufacturing arrangements;
- the volume of product sales and the timing of receipt of the corresponding sales proceeds;
- 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.

We believe that our cash, cash equivalents and short-term investments as of December 31, 2020 will be sufficient to fund our operations for at least the next 12 months from the date the audited consolidated financial statements are filed with the SEC. As of December 31, 2020, we had $202.4 million in cash, cash equivalents and short-term investments and an accumulated deficit of $243.7 million.

Debt obligations

Loan and Security Agreement. In February 2018, we entered into our 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 was available in two tranches, of which the first tranche of $10.0 million was drawn down in June 2018 and the second tranche of $5.0 million was drawn down in December 2018. In connection with the execution of the Loan and Security Agreement, we issued Silicon Valley Bank a warrant to purchase 34,440 shares of our common stock, with a term of ten years. In April 2019 this warrant was net exercised into 29,887 shares of common stock.

On February 11, 2020, we entered into the Amended Credit Facility to the Loan and Security Agreement (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 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. In addition, the Amended Credit Facility terminated our revolving line of credit of $2.0 million and the termination fee of less than $0.1 million was waived.

The principal amount outstanding under the supplemental term loan accrues interest, payable monthly in arrears, at a floating per annum rate equal to the greater of (A) the Wall Street Journal prime rate minus 1.25% and (B) 3.50% (3.50% as of December 31, 2020). No principal payments are due on the supplemental term loan until June 30, 2021; provided that such interest only period shall be extended to December 31, 2021 if we achieve specified revenue milestones and shall be extended further to June 30, 2022 if we achieve specified revenue and regulatory milestones, as described in Note 7 (the date that such interest only period ends, the "Amortization Date").

Following the Amortization Date, the principal amount of the supplemental term loan shall be due in equal monthly installments through the maturity date, December 1, 2023. There is also a final payment equal to 9.5% of the original principal amount of the supplemental term loan, or $1.6 million, due at maturity (or any earlier date of optional pre-payment or acceleration of principal due to an event of default). We may, at our option, prepay the supplemental term loan in full, subject to an additional prepayment fee ranging between 0% and 3% of the original principal amount of the supplemental term loan. The prepayment fee would also be due and payable in the event of an acceleration of the principal amount of the supplemental term loan due to an event of default.

The supplemental term loan is secured by all of our assets, excluding intellectual property and certain other assets. The supplemental term loan 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 stockholders, make investments and merge or consolidate with any other person or engage in transactions with affiliates, but is not subject to any financial covenants.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Cash used in operating activities	$ (71,184)	$ (48,107)	$ (41,465)
Cash used in investing activities	(107,473)	(59,543)	(174)
Cash provided by financing activities	90,035	208,052	29,809
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (88,622)	$ 100,402	$ (11,830)

Operating activities

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, accrued bonuses and commissions.

In 2019, cash used in operating activities was $48.1 million, attributable to a net loss of $51.1 million and a net change in our net operating assets and liabilities of $3.5 million, partially offset by non-cash charges of $6.5 million. Non-cash charges primarily consisted of $3.6 million in stock-based compensation, $1.3 million in depreciation and amortization, $0.9 million in amortization of right-of-use assets, $0.6 million in the change in fair value of our warrant liability, $0.4 million in amortization of debt issuance costs and $0.1 million of a loss due to the write down of fixed assets, partially offset by $0.5 million in accretion of discount on available-for-sale securities. The change in our net operating assets and liabilities was primarily due to a $6.8 million increase in inventory and $4.5 million increase in accounts receivable due to an increase in sales, a $0.8 million increase in prepaid expenses and other current assets and a $1.0 million decrease in lease liabilities. These changes were partially offset by a $9.6 million increase in accrued and other current liabilities and accounts payable resulting primarily from the expansion in our operating activities and accrued bonuses and commissions.

Investing activities

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.

In 2019, cash used in investing activities was $59.5 million, attributable to the purchase of available-for-sale securities of $119.5 million and the purchase of property and equipment of $3.8 million, partially offset by proceeds from the maturity of available-for-sale investments of $63.8 million.

Financing activities

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

In 2019, cash provided by financing activities was $208.1 million, attributable to net proceeds of $100.5 million received in the IPO in March 2019, net proceeds of $96.9 million from our follow-on offering in November 2019, net proceeds of $10.0 million from the concurrent Private Placement in March 2019, and proceeds of $2.2 million from stock option exercises and $0.1 million from warrant exercises. These changes were offset by payments on our term loan of $1.7 million.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2020:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations(1)	$ 17,802	$ 1,946	$ 5,041	$ 5,330	$ 5,485
Debt, principal and interest(2)	19,116	3,861	15,255	—	—
Total	$ 36,918	$ 5,807	$ 20,296	$ 5,330	$ 5,485

(1) In December 2019, we entered into a lease for office and laboratory space in two buildings located in Santa Clara, California. The lease term for the first building began in December 2019 and the lease term for the second building will begin in September 2022. Operating lease obligations in the above table includes lease payments for both buildings.
(2) Consists of our debt obligations under the Amended Credit Facility.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

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 ("GAAP"). 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 recognition

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 significant 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.

Accrued research and development costs

We accrue liabilities for estimated costs of R&D activities conducted by our third-party service providers, which include the conduct of preclinical and clinical studies. We record the estimated costs of R&D 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 R&D 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.

Accounts receivable – allowance for doubtful accounts

We are exposed to credit losses through our receivables from customers. Our expected loss allowance methodology for receivables is developed using our historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of our 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 our assessment of expected credit losses for our receivables by aging category. Balances are written off when they are ultimately determined to be uncollectible. As of March 31, 2020, we considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and increased the overall reserve for credit losses by $0.2 million in response to an assessment of the evolving credit environment under the COVID-19 pandemic. We continued to monitor our customer collections and credit risk, however, no additional material changes to the allowance for doubtful accounts, subsequent to March 31, 2020, were recorded for the year-ended December 31, 2020. We will continue to monitor the impact of COVID-19 pandemic and we may need to make further adjustments to this estimate in future periods.

Inventories – expiration and existence risk

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. We produce our IVL catheters at our facilities in Santa Clara, California. At the time of manufacture, our IVL catheters generally have a two-year shelf life prior to expiration. We maintain finished goods inventory at our facilities in California, with our sales representatives, with our third-party logistics provider in the Netherlands, and on consignment at hospital locations. Each reporting period, we update provisions for excess and obsolete inventory based on our estimates of forecast demand and, where applicable, product expiration. As of March 31, 2020, we considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and increased the provision for excess and obsolete inventory by $0.2 million in response to an assessment of the evolving market environment under the COVID-19 pandemic. As of December 31, 2020, the substantial majority of our finished goods inventory had expiration dates in 2022 or later. We considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic, however, no additional material reserve, subsequent to March 31, 2020, was required for the year-ended December 31, 2020.We will continue to monitor the impact of COVID-19 pandemic and we may need to make further adjustments to this estimate in future periods.

The existence of physical inventory is verified through ongoing cycle counts, periodic physical counts of inventory with our sales representatives and consigned at hospital locations, and full physical counts at the end of the year at our facilities in California and significant third-party locations. For significant locations not counted at the end of the year, we reserved for estimated inventory losses that have likely occurred since the last physical inventory date to cost of product revenue. Historically, such reserve due to physical inventory shrinkage has not been material.

Recent Accounting Pronouncements

Please refer to Note 2 to our consolidated financial statements appearing under Part II, Item 8 for a discussion of new accounting standards updates that may impact us.

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

Interest rate risk

Our cash, cash equivalents and short-term investments as of December 31, 2020 consist of $202.4 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. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash, cash equivalents and short-term investments.

As of December 31, 2020, we had $16.6 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 as early as June 2021, subject to a contingent deferral if certain milestones are met. 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 3.50% as of December 31, 2020.

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, 2020 and 2019, approximately 26% and 27% of our product 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 is primarily in the United States. A 10% change in exchange rates could result in a change in fair value of $0.6 million and $1.2 million in foreign currency cash and accounts receivable as of December 31, 2020 and 2019, 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2021 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 Matters

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

Revenue recognition

Description of the Matter	The Company recorded product revenue of $67.8 million for the year ended December 31, 2020. 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 due to the Company’s limited history of product revenue and the growth of revenue in US and international markets. The revenue recognition process can be complex 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.

Inventory existence - consignment

Description of the Matter

As of December 31, 2020, the Company had inventory of $1.9 million at consignment locations. As noted in Note 5, the Company sells its products to hospitals through a consignment model under which inventory is maintained at hospitals.

Auditing the existence of the Company's inventory at the consignment locations was complex due to the number of consignment locations and varying limitations on the access to the consigned inventory to perform test counts, including limitations during the year ended December 31, 2020 related to the COVID-19 pandemic.

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 to determine physical inventory quantities at consignment locations.

To test the existence of inventory at the consignment locations, our audit procedures included, among others, confirming inventory quantities with a sample of consignment locations and testing a sample of inventory shipment and product sale transactions with selected consignment locations.

/s/ Ernst & Young LLP

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

San Jose, California
February 26, 2021

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

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 50,423	$ 139,045
Short-term investments	151,931	56,304
Accounts receivable, net	11,689	7,377
Inventory	29,859	12,074
Prepaid expenses and other current assets	2,398	1,897
Total current assets	246,300	216,697
Operating lease right-of-use assets	7,568	8,825
Property and equipment, net	16,362	4,910
Other assets	1,812	1,506
TOTAL ASSETS	$ 272,042	$ 231,938
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,466	$ 2,790
Term notes, current portion	3,300	6,667
Accrued liabilities	19,942	13,777
Lease liability, current portion	873	774
Total current liabilities	25,581	24,008
Lease liability, noncurrent portion	7,488	8,125
Term notes, noncurrent portion	13,319	7,152
TOTAL LIABILITIES	46,388	39,285
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, 2020 and 2019	—	—
Common stock, $0.001 par value; 281,274,838 shares authorized; 34,684,337 and 31,446,787 issued and outstanding as of December 31, 2020 and 2019	35	31
Additional paid-in capital	469,283	370,561
Accumulated other comprehensive income	9	35
Accumulated deficit	(243,673)	(177,974)
TOTAL STOCKHOLDERS' EQUITY	225,654	192,653
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 272,042	$ 231,938

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,		
	2020	**2019**	**2018**
Revenue:			
Product revenue	$ 67,789	$ 42,927	$ 12,263
Cost of revenue:			
Cost of product revenue	20,991	17,159	7,250
Gross profit	46,798	25,768	5,013
Operating expenses:			
Research and development	36,926	32,853	22,698
Sales and marketing	51,672	30,620	17,536
General and administrative	23,863	14,134	5,979
Total operating expenses	112,461	77,607	46,213
Loss from operations	(65,663)	(51,839)	(41,200)
Interest expense	(1,212)	(944)	(401)
Change in fair value of warrant liability	—	(609)	(52)
Other income, net	1,256	2,345	589
Net loss before taxes	(65,619)	(51,047)	(41,064)
Income tax provision	80	62	38
Net loss	$ (65,699)	$ (51,109)	$ (41,102)
Unrealized gain (loss) on available-for-sale securities	(5)	35	1
Adjustment for net gain realized and included in other income, net	(21)	—	—
Total comprehensive loss	$ (65,725)	$ (51,074)	$ (41,101)
Net loss per share, basic and diluted	$ (1.99)	$ (2.14)	$ (23.39)
Shares used in computing net loss per share, basic and diluted	33,088,095	23,904,828	1,757,102

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	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balance—December 31, 2017	17,510,045	$ 137,469	1,627,032	$ 2	$ 2,470	$ (1)	$ (85,763)	$ (83,292)
Issuance of Series D convertible preferred stock, net of issuance costs of $80	1,090,608	14,920	—	—	—	—	—	—
Exercise of Series A-1 warrants	69,675	417	—	—	—	—	—	—
Issuance of common stock warrants	—	—	—	—	104	—	—	104
Exercise of stock options	—	—	197,820	—	326	—	—	326
Unrealized gain on available-for-sale securities	—	—	—	—	—	1	—	1
Vesting of early exercised options	—	—	—	—	78	—	—	78
Stock-based compensation	—	—	—	—	1,297	—	—	1,297
Net loss	—	—	—	—	—	—	(41,102)	(41,102)
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

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,		
	2020	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (65,699)	$ (51,109)	$ (41,102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,863	1,337	700
Stock-based compensation	10,350	3,646	1,297
Amortization of right-of-use assets	1,483	944	—
Accretion of discount on available-for-sale securities	300	(543)	—
Loss on write down of fixed assets	187	67	31
Change in fair value of warrant liability	—	609	52
Amortization of debt issuance costs	646	436	206
Changes in operating assets and liabilities:			
Accounts receivable	(4,312)	(4,527)	(2,211)
Inventory	(17,056)	(6,824)	(2,608)
Prepaid expenses and other current assets	(501)	(785)	(144)
Other assets	(306)	41	(917)
Accounts payable	(1,392)	1,272	360
Accrued and other current liabilities	4,017	8,339	2,773
Lease liabilities	(764)	(1,010)	—
Other liabilities	—	—	98
Net cash used in operating activities	(71,184)	(48,107)	(41,465)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of available-for-sale securities	(167,953)	(119,476)	—
Proceeds from maturities of available-for-sale securities	72,000	63,750	1,807
Purchase of property and equipment	(11,520)	(3,817)	(1,981)
Net cash used in investing activities	(107,473)	(59,543)	(174)
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 convertible preferred stock, net of issuance costs	—	—	14,920
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	(1,420)	—	—
Proceeds from term loans	3,265	—	14,988
Payment of deferred offering costs	(179)	—	(626)
Proceeds from stock option exercises	4,317	2,206	426
Proceeds from issuance of common stock under employee stock purchase plan	1,795	—	—
Proceeds from warrant exercises	—	110	101
Principal payment of term loan	(1,111)	(1,667)	—
Net cash provided by financing activities	90,035	208,052	29,809
Net increase (decrease) in cash, cash equivalents and restricted cash	(88,622)	100,402	(11,830)
Cash, cash equivalents and restricted cash at beginning of period	140,495	40,093	51,923
Cash, cash equivalents and restricted cash equivalents at end of period	$ 51,873	$ 140,495	$ 40,093
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 549	$ 534	$ 156
Income tax paid	$ 22	$ 120	$ 5
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Common stock issued on conversion of convertible preferred stock	$ —	$ 152,806	$ —
Issuance of Series A-1 convertible preferred stock on net exercise of warrants	$ —	$ —	$ 316
Deferred offering cost included in account payable and accrued liabilities	$ —	$ —	$ 893
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	$ 226	$ 6,948	$ —
Property and equipment purchases included in accounts payable and accrued liabilities	$ 2,448	$ 52	$ 55
Issuance of common stock warrants in connection with debt financing	$ —	$ —	$ 104
Transfer of fixed assets to inventory	$ 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 and Japan.

Initial Public Offering

On March 11, 2019, the Company completed an initial public offering ("IPO") of its common stock. As part of the IPO, the Company issued and sold 6,555,000 shares of its common stock, which included 855,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $17.00 per share. The Company received net proceeds of approximately $99.9 million from the IPO, after deducting underwriters' discounts and commissions. Prior to the completion of the IPO, all shares of Series A, A-1, B, C and D convertible preferred stock then outstanding were converted into 18,670,259 shares of common stock on a one-to-one basis.

In addition, on the completion of the IPO, all the Company's outstanding preferred stock warrants were converted into 54,903 common stock warrants, which resulted in the reclassification of the convertible preferred stock warrant liability to additional paid-in capital. Furthermore, 101,744 shares of common stock were issued upon net exercise of warrants at the time of the IPO.

Concurrently with the IPO, the Company issued 588,235 shares of its common stock in a private placement for net proceeds of $10.0 million.

Public Offerings

On November 15, 2019, the Company completed an underwritten public offering of 2,854,048 shares of its common stock, including 372,267 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price of $36.25 per share. The Company received net proceeds of $96.7 million from the follow-on offering after deducting underwriters' discounts and commissions. On June 19, 2020, the Company completed an underwritten offering of 1,955,000 shares of its common stock, including 255,000 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price of $45.75 per share. Upon completion of the June 2020 offering, the Company received net proceeds of $83.4 million, after deducting underwriting discounts and commissions and offering expenses.

Liquidity

As of December 31, 2020, the Company had cash, cash equivalents and short-term investments of $202.4 million, which are available to fund future operations. The Company believes that its cash, cash equivalents, and short-term investments as of December 31, 2020, 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 ("SEC").

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 ("U.S. GAAP") 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, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 50,423	$ 139,045
Restricted cash	1,450	1,450
Total cash, cash equivalents, and restricted cash	$ 51,873	$ 140,495

Restricted cash as of December 31, 2020 and 2019 relates to letters of credit established for real property leases entered into in May 2018 and December 2019 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.

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 the Company's investments have investment grade ratings when purchased. 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, 2020, 2019 and 2018 no customer accounted for 10% of the Company's revenue. There was one customer which accounted for 15% of the Company's accounts receivable as of December 31, 2020. There was one customer which accounted for 11% of the Company's accounts receivable as of December 31, 2019.

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 our 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 our assessment of expected credit losses for our 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,		
	2020	2019	2018
	(in thousands)		
Beginning balance	$ 194	$ 76	$ —
Amounts charged to costs and expenses	205	121	77
Write-offs	(19)	(3)	(1)
Ending balance	$ 380	$ 194	$ 76

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

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 significant portion of the Company's revenue is generated through a consignment model under which inventory is maintained at hospitals.

Under ASC 606, 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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company elected to exclude taxes assessed by a governmental authority on revenue-producing transactions from the transaction price.

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. For consignment inventory, control is transferred at the time the 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.

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

The Company adopted ASU No. 2016-02, *Leases* (Topic 842) using the modified retrospective approach with a cumulative-effect adjustment as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under Topic 842. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historical accounting under previous lease guidance, ASC 840: *Leases* (Topic 840).

For its long-term operating lease, 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.

Rent expense 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. This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax basis. The Company is authorized to make matching contributions. During 2020, the Company made matching contributions up to $3,000 of an employee's eligible deferred compensation. The Company recognized expense related to its contributions to the plan of $1.1 million for the year-ended December 31, 2020. The Company did not make such contributions for the year ended December 31, 2019 or 2018.

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 gains of $261,000 and $56,000 for the years ended December 31, 2020 and 2019, respectively. In December 31, 2018, there were net foreign currency transaction losses of $46,000.

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. The unvested portion of early exercised stock options are excluded from the computation of weighted-average shares as the continuing vesting of such shares is contingent on the holders' continued service to the Company. 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.

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 all held in the United States with the

exception of certain equipment on loan to customers held internationally, which was not material for the years-ended December 31, 2020 and 2019.

Recently Adopted Accounting Pronouncements

Effective January 1, 2020, the Company adopted ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for most financial assets and certain other instruments. Unrealized losses on available-for-sale debt securities that are attributed to credit risk are recorded through earnings rather than to other comprehensive income. Credit losses relating to available-for-sale debt securities are now recorded through an allowance for credit losses. The adoption of this guidance did not result in a cumulative effect adjustment as of the date of the adoption.

In addition, Topic 326 also provides new guidance related to the measurement of expected credit losses on the Company's allowance for bad debt for accounts receivable, which is estimated upon assessment of various factors including historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of the Company's customers. As of March 31, 2020, the Company considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and increased the overall reserve for credit losses by $0.2 million in response to an assessment of the evolving credit environment under the COVID-19 pandemic. The Company continued to monitor our customer collections and credit risk, however, no additional material changes to the allowance for doubtful accounts, subsequent to March 31, 2020, were recorded for the year-ended December 31, 2020. The Company will continue to update its estimate of credit losses from accounts receivable in future periods in response to the uncertainties caused by the COVID-19 pandemic.

Recent Accounting Pronouncements Not Yet Adopted

In November 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)*, which simplifies the accounting for income taxes, primarily by eliminating certain exceptions to the guidance in ASC 740. This ASU is effective for fiscal periods beginning after December 15, 2020. The Company is currently evaluating the effect of adopting this standard but does not expect the adoption of this standard to have a material impact on its consolidated financial statements. ASU No. 2019-12 became effective for the Company upon adoption on January 1, 2021.

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, 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

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
U.S. Treasury securities	$ 43,245	$ —	$ —	$ 43,245
Money market funds	29,386	—	—	29,386
Reverse repurchase agreements	—	10,000	—	$ 10,000
Commercial paper	—	6,958	—	$ 6,958
Corporate bonds	—	8,096	—	$ 8,096
Total assets	$ 72,631	$ 25,054	$ —	$ 97,685

4. Cash Equivalents and Short-Term Investments

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

	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

	December 31, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury securities	$ 43,219	$ 27	$ (1)	$ 43,245
Money market funds	29,386	—	—	29,386
Reverse repurchase agreements	10,000	—	—	10,000
Commercial paper	6,958	—	—	6,958
Corporate bonds	8,087	9	—	8,096
Total	$ 97,650	$ 36	$ (1)	$ 97,685
Reported as:				
Cash equivalents				$ 41,381
Short-term investments				56,304
Total				$ 97,685

At December 31, 2020, the remaining contractual maturities for available-for-sale securities were less than one year. For the year ended December 31, 2020, the Company recognized $21,000 in realized gains on cash equivalents and short-term investments. There were no material realized gains or losses on cash equivalents and short-term investments for the years ended December 31, 2019 and 2018.

5. Balance Sheet Components

Inventory

Inventory consists of the following:

	December 31,	
	2020	2019
	(in thousands)	
Raw material	$ 4,995	$ 2,501
Work in progress	6,051	1,364
Finished goods	16,952	6,642
Consigned inventory	1,861	1,567
Total inventory	$ 29,859	$ 12,074

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
	2020	2019
	(in thousands)	
Equipment	$ 3,794	$ 3,759
Equipment on loan to customers	1,756	1,495
Office furniture	157	76
Software	175	97
Leasehold improvements	5,808	1,329
Construction in progress	7,800	553
Property and equipment, gross	19,490	7,309
Less accumulated depreciation and amortization	(3,128)	(2,399)
Total property and equipment, net	$ 16,362	$ 4,910

Depreciation and amortization expense amounted to $1.9 million, $1.3 million and $0.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2020	2019
	(in thousands)	
Accrued employee compensation	$ 10,885	$ 8,139
Accrued research and development costs	3,057	3,090
Accrued asset purchases	2,527	—
Accrued professional services	1,325	804
Other	2,148	1,744
Total accrued liabilities	$ 19,942	$ 13,777

6. Commitments and Contingencies

Operating Leases

In May 2018, the Company entered into a lease agreement for office, laboratory, and manufacturing space located at 5403 Betsy Ross Drive in Santa Clara, California, which consists of approximately 35,000 square feet (the “5403 Lease”). The term of the 5403 Lease commenced in September 2018 and ends in August 2022. In connection with the 5403 Lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $0.5 million, which is secured by restricted cash recorded as other assets on the consolidated balance sheets. In connection with the 5403 Lease, the Company has an operating lease right-of-use asset of $1.3 million as of December 31, 2020 and an aggregate lease liability of $1.4 million on its consolidated balance sheet. The remaining lease term is one year and eight months.

In December 2019, the Company entered into a lease agreement (i) for additional office, laboratory and manufacturing space located at 5353 Betsy Ross Drive in Santa Clara, California, which consists of approximately 50,200 square feet (the “5353 Lease”); and (ii) to modify the terms of the 5403 Lease. The 5403 Lease will continue in its existing terms (and with no changes to its terms, including its base rent) until its expiration on August 31, 2022, at which point the leased space under the 5403 Lease will become subject to the terms of the 5353 Lease. The initial term of the 5353 Lease began in December 2019 and is for 96 months, with an option by the Company to extend for an additional five years on either or both of the 5403 and 5353 Betsy Ross buildings. The base rent of the first floor of the premises for the 5353 Betsy Ross building shall be abated for the first 19 months, and the base rent for the second floor of the 5353 Betsy Ross building shall be abated for the first four months. The landlord provided the Company with a tenant improvement allowance of up to $1.8 million for both 5403 and 5353 Betsy Ross buildings. In connection with the 5353 Lease, the Company provided an initial security

deposit of $1.0 million in the form of a letter of credit, which is secured by restricted cash recorded as other assets on the consolidated balance sheets. While this amount will increase to $1.5 million on September 1, 2022 when the office, laboratory and manufacturing space of the 5403 Lease is included under the terms of the 5353 Lease, the letter of credit will be reduced annually from and after September 1, 2022 until the expiration of the 5353 Lease. In connection with the lease of the 5353 Betsy Ross building, the Company has recorded an operating lease right-of-use asset of $6.1 million as of December 31, 2020 and an aggregate lease liability of $6.8 million on its consolidated balance sheet. The remaining lease term is six years and eleven months.

The Company also leases vehicles for use by employees. In connection with the vehicle leases, the Company has an operating lease right-of-use asset and an aggregate lease liability of $0.2 million as of December 31, 2020 on its consolidated balance sheet. The weighted average remaining lease term for these vehicle leases is two years and four months.

The weighted average incremental borrowing rate used to measure the operating lease liability is 6.98%. As of December 31, 2020, the Company has no finance leases.

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.

The following are minimum future rental payments owed under these agreements which have commenced as of December 31, 2020:

		(in thousands)
2021	$	1,946
2022		2,123
2023		1,529
2024		1,546
2025		1,594
Thereafter		3,232
Total minimum lease payments	$	11,970
Less: imputed interest		(3,609)
Total lease liability	$	8,361

The following are minimum future rental payments owed for the modified 5403 Betsy Ross Lease which has not yet commenced as of December 31, 2020:

		(in thousands)
2021	$	—
2022		345
2023		1,044
2024		1,078
2025		1,112
Thereafter		2,253
Total minimum lease payments	$	5,832

Operating lease cost for the years ended December 31, 2020 and 2019 was $2.2 million and $1.2 million, respectively. Rent expense for the year ended December 31, 2018 was $0.9 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 was available in two tranches, of which the first tranche of $10.0 million was funded in June 2018 and the second tranche of $5.0 million was funded in December 2018.

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 its 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, 2020.

The supplemental term loan matures on December 1, 2023. The Amended Credit Facility provides an interest-only payment period which will end on (a) June 30, 2021, if the Company's revenue for the trailing 12-month period ended June 30, 2021 is not at least 75% of the Company's projections; (b) December 31, 2021, if the Company achieves the financial performance target referred to in clause (a), but does not obtain premarket approval of the Company's C^2 catheters from the FDA by such date and/or the Company's trailing 12-month revenue for the period ending December 31, 2021 is not at least 75% of the Company's projections; or (c) June 30, 2022, if the Company achieves the milestones referred to in clauses (a) and (b).

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.

During the years ended December 31, 2020, 2019 and 2018 the Company recorded interest expense of $0.6 million, $0.5 million and $0.2 million, respectively. Debt discount amortized as interest expense was $0.6 million, $0.4 million and $0.2 million for the years ended December 31, 2020, 2019 and 2018, 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,	
	2020	2019
	(in thousands)	
Principal amount of term note	$ 16,500	$ 13,334
Net premium associated with accretion of final payment and other debt issuance costs	119	485
Term note, current and noncurrent	16,619	13,819
Less term note, current portion	(3,300)	(6,667)
Term note, noncurrent portion	$ 13,319	$ 7,152

Future minimum payments of principal and estimated payments of interest on the Company's outstanding variable rate borrowings as of December 31, 2020 are as follows:

Year ending December 31:	(in thousands)
2021	$ 3,861
2022	6,961
2023	8,294
Total future payments	19,116
Less amounts representing interest	(1,048)
Less final payment	(1,568)
Total principal amount of term note payments	$ 16,500

8. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO, 18,670,259 shares of outstanding convertible preferred stock converted into 18,670,259 shares of common stock.

Preferred Stock

The Company's amended and restated certificate of incorporation, which became effective upon the completion of the IPO, authorizes 5,000,000 shares of preferred stock, of which no shares were issued or outstanding as of December 31, 2020 and 2019.

Preferred Stock Warrants

Upon the closing of the IPO, all of the outstanding convertible preferred stock warrants were converted into 54,903 common stock warrants, which resulted in the reclassification of the convertible preferred stock warrant liability of $0.8 million to additional paid-in capital. In April 2019, all of these common stock warrants were net exercised into 49,321 shares of common stock. There were no preferred stock warrants outstanding of December 31, 2020 and 2019.

Common Stock Warrants

Upon the IPO, 91,446 common stock warrants held by related parties were net exercised based on the IPO price of $17.00 per share into 79,632 shares of common stock.

In February 2018, in connection with the execution of a Loan and Security Agreement with Silicon Valley Bank for a term loan and revolving line of credit, the Company issued warrants to purchase shares of the Company's common stock. In April 2019, all of these common stock warrants were net exercised into 29,887 shares of common stock. There were no common stock warrants outstanding of December 31, 2020 and 2019.

9. Stock-Based Compensation

Total stock-based compensation was as follows:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Cost of product revenue	$ 496	$ 268	$ 67
Research and development	2,464	943	235
Sales and marketing	3,478	972	294
General and administrative	3,912	1,463	701
Total stock-based compensation	$ 10,350	$ 3,646	$ 1,297

Stock-based compensation of $316,000 was capitalized into inventory for the year ended December 31, 2020. No material stock-based compensation was capitalized into inventory for the years ended December 31, 2019 and 2018. 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	2018
Expected term (in years)	6.08	6.08
Expected volatility	42.4%-42.9%	40.8%-41.9%
Risk-free interest rate	2.4%-2.6%	2.5%-3.1%
Expected dividend yield	0%	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 "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 Stock Option and Incentive Plan (the "2019 Plan"), which became effective in connection with the IPO. 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. 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 Company's board of directors.

The Board has the authority to determine to whom options will be granted, the number of shares, the term and the exercise price. If an individual owns stock representing 10% or more of the outstanding shares, the price of each share shall be at least 110% of the fair market value, as determined by the Board. Options granted under the Plan have a term of up to 10 years and generally vest over a 4 year period with a straight-line vesting and a 25% one year cliff. As of December 31, 2020, the Company had reserved 2,689,624 shares of common stock for issuance under the 2019 Plan.

Stock Options

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, 2017	426,370	3,108,604	$ 2.81	8.03	$ 3,647
Awards authorized	691,503	—			
Options granted	(1,015,963)	1,015,963	5.25		
Options exercised	—	(197,820)	2.20		
Options cancelled	290,389	(290,389)	3.42		
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
Vested and exercisable, December 31, 2020		1,360,650	$ 4.63	6.36	$ 134,825
Vested and expected to vest, December 31, 2020		2,087,202	$ 5.92	6.77	$ 204,137

There were no options granted during the year ended December 31, 2020. The weighted-average grant date fair value of options granted during the year ended December 31, 2019 and 2018 was $6.58 and $2.56 per share, respectively. The total grant date fair value of options vested was $2.3 million, $1.9 million and $1.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, total unrecognized stock-based compensation related to unvested stock options was $2.5 million, which the Company expects to recognize over a remaining weighted-average period of 1.3 years.

Restricted Stock Units

Restricted stock units ("RSUs") are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. The 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 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 the 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

The total grant date fair value of RSUs vested for the years ended December 31, 2020 and 2019 was $2.7 and $0.1 million, respectively. There were no RSUs granted prior to 2019. As of December 31, 2020, there was $35.3 million of unrecognized stock-based compensation expense related to RSUs to be recognized over a weighted-average period of 3.1 years.

Employee Share Purchase Plan (ESPP)

In February 2019, the Company adopted the 2019 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 $786,000 and $255,000 of stock-based compensation expense related to the ESPP for the years ended December 31, 2020 and 2019, respectively.

	Year Ended December 31, 2020	Year Ended December 31, 2019
Expected term (in years)	0.5	0.5
Expected volatility	44.31%-74.03%	76.93%
Risk-free interest rate	0.12%-0.3%	1.89%
Expected dividend yield	0%	0%

10. Income Taxes

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

	December 31,		
	2020	2019	2018
	(in thousands)		
Domestic	$ (65,957)	$ (51,179)	$ (41,145)
Foreign	338	132	81
Total loss before income taxes	$ (65,619)	$ (51,047)	$ (41,064)

Current income tax provision consists of the following:

	December 31,		
	2020	2019	2018
	(in thousands)		
Domestic	$ 3	$ —	$ 3
Foreign	77	62	35
Total current income tax provision	$ 80	$ 62	$ 38

The components of the deferred tax assets are as follows:

	December 31,	
	2020	2019
	(in thousands)	
Deferred tax assets:		
Net operating loss carryovers	$ 73,453	$ 49,862
Fixed and intangible assets	718	450
Accruals and reserves	2,245	1,619
Stock-based compensation	2,060	780
Research and development credits	3,379	2,336
Contributions	42	20
Lease liability	2,004	2,135
Total deferred tax assets	83,901	57,202
Less valuation allowance	(82,087)	(55,085)
Gross deferred tax assets	1,814	2,117
Deferred tax liabilities:		
Right-of-use-assets	(1,814)	(2,117)
Gross deferred tax liabilities	(1,814)	(2,117)
Total net deferred tax assets	$ —	$ —

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

	December 31,		
	2020	2019	2018
	(in thousands)		
Income tax benefit at federal statutory rate	$ (13,780)	$ (10,720)	$ (8,624)
State and local income taxes net of federal tax benefit	(9)	(9)	3
Foreign tax rate differential	6	35	11
Change in valuation allowance	27,990	14,470	8,497
Stock-based compensation	(13,425)	(3,403)	123
R&D tax credits	(611)	(354)	(313)
Other	(91)	43	341
Total current income tax provision	$ 80	$ 62	$ 38

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 and other deferred tax assets. The valuation allowance increased by $27.0 million, $22.8 million and $10.0 million during the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, the Company had net operating loss carryforwards available to reduce future federal, California and other state income of $301.9 million, $52.4 million and $123.7 million, respectively. The federal net operating loss carryforwards of $80.8 million and $221.1 million begin expiring in 2030 and never expire respectively, the California net operating loss carryforwards begin expiring in 2031 and other state net operating loss carryforwards begin expiring in various years, starting in 2029.

As of December 31, 2020, the Company had research and development credit carryforwards of $4.0 million for federal income tax purposes and $3.5 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 net operating loss carryforward may be subject to an annual limitation due to the ownership change provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization. The Company has not prepared a Section 382 study to date to determine if a greater than 50% ownership change has occurred and to determine the annual Section 382 limitation if applicable. Thus, the Company has not determined if there are any limitations on the Company's ability to utilize its net operating losses in the future and if any reduction in the net operating loss deferred tax assets is required until such study is performed. Upon completion of a 382 study, to the extent that our net operating losses are reduced due to ownership changes, the impact would result in a reduction of the net operating loss deferred tax assets offset by a reduction in the valuation allowance.

Uncertain Tax Positions

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

	December 31,		
	2020	2019	2018
	(in thousands)		
Beginning balance	$ 2,586	$ 1,896	$ 893
Additions (Reductions) based on tax positions related to prior years	(3)	—	394
Additions based on tax positions related to current years	1,163	690	609
Balance at end of year	$ 3,746	$ 2,586	$ 1,896

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.

It is the Company's policy to include penalties and interest expense related to income taxes as a component of the income tax provision as necessary. The Company determined that no accrual for interest and penalties was required as of December 31, 2020.

The Company is subject to taxation in the United States, Germany, and Japan. The Company's income tax returns since inception remain subject to examination by U.S. federal and most state tax authorities due to its net operating loss. The income tax returns of Shockwave Medical GmbH for the 2016 through 2020 tax years remain subject to examination by the German taxing authorities and the income tax returns of Shockwave Medical Japan KK for the 2020 tax year will be subject to examination by the Japanese taxing authorities once filed. The Company is not currently under audit with either the IRS, foreign, or any 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 net operating loss or credits.

11. Net Loss Per Share

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,		
	2020	**2019**	**2018**
		(in thousands)	
Convertible preferred stock on an as-converted basis	—	—	18,670,328
Common stock options issued and outstanding	2,087,202	3,315,001	3,636,358
Restricted stock units	859,577	280,904	—
Employee stock purchase plan	15,251	16,420	—
Early exercised options subject to future vesting	—	—	13,422
Convertible preferred stock warrants	—	—	54,903
Common stock warrants	—	—	176,218
Total	2,962,030	3,612,325	22,551,229

12. Revenue

Disaggregation of revenue

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Peripheral	$ 41,994	$ 26,325	$ 8,828
Coronary	24,586	15,621	3,210
Other	1,209	981	225
Product revenue	$ 67,789	$ 42,927	$ 12,263

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,		
	2020	2019	2018
	(in thousands)		
United States	$ 37,121	$ 22,699	$ 7,022
Germany	4,314	3,402	1,393
Rest of Europe	19,142	14,097	3,516
All other countries	7,212	2,729	332
Product revenue	$ 67,789	$ 42,927	$ 12,263

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, or 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 SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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, 2020 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, 2020. The effectiveness of our internal control over financial reporting as of December 31, 2020 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and our report dated February 26, 2021 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 26, 2021

Item 9B. Other Information.

None.

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 SEC in connection with our 2020 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2020 (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.

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. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

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 Restricted Stock Unit Agreement	10-Q	001-38829	10.1	August 6, 2019
10.6†	Employee Stock Purchase Plan	S-1/A	333-229590	10.5	February 25, 2019
10.7†	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
10.8†	Offer Letter with Douglas Godshall	S-1	333-229590	10.7	February 8, 2019
10.9†	Separation Pay Agreement with Douglas Godshall	10-Q	001-38829	10.1	November 8, 2019
10.10†	Offer Letter with Dan Puckett	S-1	333-229590	10.8	February 8, 2019
10.11†	Offer Letter with Isaac Zacharias	S-1	333-229590	10.9	February 8, 2019

10.12†	Form of Separation Pay Agreement for Executive Officers (other than CEO)	10-Q	001-38829	10.2	November 8, 2019
10.13†	Amended and Restated Non-Employee Director Compensation Policy	S-1/A	333-229590	10.11	February 25, 2019
10.14	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
10.15	First Amendment to Loan and Security Agreement	10-K	001-38829	10.15	March 12, 2020
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	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement.

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 Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Shockwave Medical, Inc.

Date: February 26, 2021

By: /s/ Douglas Godshall
Douglas Godshall
President, Chief Executive Officer & Director
(principal executive officer)

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 Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Douglas Godshall Douglas Godshall	President, Chief Executive Officer & Director (principal executive officer)	February 26, 2021
/s/ Dan Puckett Dan Puckett	Chief Financial Officer (principal financial and accounting officer)	February 26, 2021
/s/ C. Raymond Larkin, Jr. C. Raymond Larkin, Jr.	Chairman & Director	February 26, 2021
/s/ F.T. “Jay” Watkins F.T. Watkins	Director	February 26, 2021
/s/ Antoine Papiernik Antoine Papiernik	Director	February 26, 2021
/s/ Colin Cahill Colin Cahill	Director	February 26, 2021
/s/ Frederic Moll, M.D. Frederic Moll	Director	February 26, 2021
/s/ Maria Sainz Maria Sainz	Director	February 26, 2021
/s/ Laura Francis Laura Francis	Director	February 26, 2021

Exhibit 4.3

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our restated certificate of incorporation, amended and restated bylaws, the amended and restated investors' 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 investors' rights agreement, copies of which are 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, 2020, there were 34,684,337 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, 2020, 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. At present, we have no plans to issue any of the preferred stock following consummation of this offering.

Common Stock Options

As of December 31, 2020, we had outstanding options to purchase an aggregate of 2,087,202 shares of our common stock, with a weighted-average exercise price of $5.92 per share, under our 2009 Plan and 2019 Plan.

Restricted Stock Units

As of December 31, 2020, we had outstanding RSUs that may be settled for an aggregate of 859,577 shares of our common stock granted pursuant to our 2019 Plan.

Registration Rights

Certain holders of our common stock 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 Investors' 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.* The holders of approximately 1,459,807 shares of our common stock as of December 31, 2020 are entitled to certain 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 commissions) 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 the holders of approximately 1,459,807 shares of our common stock as of December 31, 2020 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, the holders of approximately 1,459,807 shares of our common stock as of December 31, 2020 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 Investors' 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. Class I, Class II and Class III directors will serve until our annual meetings of stockholders in 2020, 2021 and 2022, respectively. 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 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 not later than the close of business on the later of (1) the 120th day prior to the annual meeting and (2) 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 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 shall 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; o

- 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 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 21.1

SHOCKWAVE MEDICAL, INC.

The following is a list of subsidiaries of the Company as of December 31, 2020:

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

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, and
(3) Registration Statement on Form S-3 (No. 333-239202) of Shockwave Medical, Inc.

of our reports dated February 26, 2021, 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, 2020.

/s/ Ernst & Young LLP

San Jose, California
February 26, 2021

Exhibit 31.1

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

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

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

Date: February 26, 2021

By: /s/ Douglas Godshall
Douglas Godshall
President and Chief Executive Officer

Exhibit 31.2

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

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

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

Date: February 26, 2021

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer

Exhibit 32.1

CERTIFICATION 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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and

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

Date: February 26, 2021

By: /s/ Douglas Godshall
Douglas Godshall
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION 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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and

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

Date: February 26, 2021

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer